



September 11, 2022

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

Re: CMS-1784-P; Medicare and Medicaid Programs; CY 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program

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

Dear Administrator Brooks-LaSure,

Trinity Health appreciates the opportunity to comment on policies proposed in CMS-1784-P. Our comments and recommendations to the Centers for Medicare and Medicaid Services (CMS) reflect a strong interest in public policies that support better health, better care and lower costs to ensure affordable, high quality, and people-centered care for all.

Trinity Health is one of the largest not-for-profit, Catholic health care systems in the nation. It is a family of 123,000 colleagues and more than 26,000 physicians and clinicians caring for diverse communities across 26 states. Nationally recognized for care and experience, the Trinity Health system includes 88 hospitals, 135 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 1,324 primary care providers and 4,193 specialty care providers. Based in Livonia, Michigan, its annual operating revenue is \$21.5 billion with \$1.4 billion returned to its communities in the form of charity care and other community benefit programs. Trinity Health is committed to serving as a critical provider in our communities and coordinating care across settings and the care continuum, with 41% of our revenue coming from Medicare and 18% from Medicaid and uninsured patients.

Trinity Health is a strong proponent of value-based care delivery. We have 17 Clinically Integrated Networks (CINs) that are accountable for approximately 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 11 markets partnering in one national MSSP Enhanced Track ACO, Trinity Health Integrated Care. All of these markets participate 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 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 3.4% reduction in the conversion factor will disproportionately impact small, independent, and rural physician practices, as well as those treating low-income or other marginalized patient communities. In addition, the payment cut further exacerbates the gap between inflation and physician payment. Trinity Health urges CMS to work with Congress to identify a permanent solution that would increase physician payment annually via an inflation-based payment update based on the full Medicare Economic Index (MEI).

We also urge CMS to slow down to obtain and work through stakeholder feedback prior to implementing policies that require significant time and resources for hospitals to implement. One example is what has occurred with Appropriate Use Criteria (AUC). Billions of dollars were spent by vendors and hospitals to implement AUC and these requirements are now being rescinded. These funds could have been used to implement other critical requirements.

There are many proposed policies that Trinity Health supports, including: delaying implementation of the revised MEI; paying for caregiving and social needs services, and expanding behavioral health access. In addition, many of the proposed policies for the Medicare Shared Savings Program align with our goals.

Below are detailed comments on the proposed rule.

Payment Updates

The proposed conversion factor for 2024 is \$32.75, a whopping 3.4% reduction from 2023. 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. These cuts are on top of a 2% payment reduction for CY2023 and further exacerbate the gap between inflation and physician payment.

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 conversion factor cuts are a statutory requirement of the Physician Fee Schedule. However, it is important that CMS explain to Congress the ramifications that the cut in the will have on the ability of healthcare providers to offer meaningful access to care for their Medicare beneficiaries and serve their communities.

The cuts outlined above would not occur in isolation and would 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.

Implementation of New add on Code for Complexity

CMS proposes implementation of a new add-on code (G2211) to account for intensity and clinical complexity. The add-on code was originally scheduled for implementation as part of the CY 2021 Physician Fee Schedule, but Congress delayed implementation. CMS proposes to implement January 1, 2024.

Trinity Health has concerns with implementation of the complexity add-code as it would further squeeze medical groups by increasing compensation to providers (who are predominantly on a per RVU compensation model across the country) without providing a corresponding revenue increase to the organizations themselves due to the proposed conversion factor reduction. If finalized, we recommend CMS delay implementation of this policy until Congress passes legislation to permanently fix how physician payments are updated each year, as outlined above.

Split (Or Shared) E/M Visits

CMS proposes the continued delay of a policy that was finalized in the CY22 PFS rulemaking that would define who performs the substantive portion of E/M visit—and therefore, bills for them—as the physician or practitioner who spent more than half of the total time performing the visit. In prior comments to CMS, Trinity Health urged delay of this policy as it would create significant administrative burden on care teams and may discourage team-based care. In addition, this policy would result in a significant reduction in physician revenue on top of the other sizeable cuts proposed in this rule. Trinity Health supports the proposed delay and urges CMS to maintain time and medical decision-making as key determinates of which physician or practitioner bills for an E/M visit.

Revising the Medicare Economic Index (MEI)

Last year CMS finalized a policy that would rebase and revise the MEI based on a methodology that uses publicly available data sources for input costs that represent all types of physician practice ownership, rather than just data representing only self-employed physicians. CMS proposed to delay this policy and will review additional data before implementation.

Trinity Health has noted concerns with this policy as it will cause significant and negative fluctuations in payment by specialty. We understand CMS is proposing to move away from AMA data for calculating the MEI since they haven't been updated in a long time; however, the AMA collected new data this year. Trinity Health appreciates CMS waiting for the revised AMA data, as we recommended last year, rather than use the proposed Census and other data that would result in large redistributions. Per our comments last year, we support the delay that will allow CMS to more thoroughly evaluate the policy's impact.

Telehealth

The proposed rule includes several provisions on telehealth.

The rule would add health and well-being coaches services to the Medicare telehealth services list on a temporary basis and social determinants of health risk assessments on a permanent basis. CMS would also replace category 1-3 status with a permanent or provisional status for any services assigned to the telehealth list.

CMS is proposing to Pay claims billed with POS 10 at the non-facility rate and claims billed POS 2 will continue to be paid at the PFS facility rate. In addition, CMS will continue to allow real time audio and visual communications to satisfy direct supervision requirements for presence and immediate availability of the supervising practitioner.

CMS will not issue proposals to limit or modify telehealth originating sites in 2023 or 2024 and audio only services will remain covered through 2024.

The telehealth flexibilities provided during the COVID-19 pandemic greatly benefit 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 and Congress work together to permanently achieve the following:

- 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 state 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.

Payment for Caregiver Training Services

CMS proposes to allow payment for behavioral management, modification training for guardians/caregivers of patients with mental or physical health diagnosis, and caregiver training in strategies and techniques to facilitate patients' functional performance based on an established plan.

Trinity Health supports this policy and applauds CMS for paying for these services.

Advancing Access for Behavioral Health Services

The 2023 Consolidated Appropriations Act included several provisions to advance access to behavioral health services, including establishing new benefit categories under Medicare Part B. In this rule, CMS proposes policies to implement those provisions as well as additional updates to improve payments for providers who deliver behavioral health services, including coverage of mobile crisis units.

Trinity Health strongly supports policies that will increase access to behavioral health services and recommends CMS finalize these provisions. In addition, we support CMS providing separate coding and payment for

interventions initiated or furnished in the ED or other crisis setting for patients with suicidality risk or at risk of suicide.

Addressing Health Related Social Needs

If finalized, the rule would reimburse for services that would address social needs, including:

- Community Health Integration (CHI) - services performed by certified/trained personnel, which can include a community health worker (CHW), incident to professional health services and under the general supervision of a billing practitioner.
- Social determinants of health (SDOH) risk assessment - proposes a HCPCs code for work for administering evidence-based SDOH risk assessment when medically necessary in relation to an E/M visit to inform diagnosis and treatment plan.
- Principal Illness Navigation (PIN) - services parallel to the proposed CHI services focused on patients with a serious, high-risk illness who may not have SDOH needs. CMS would also reimburse for patient referrals to supportive services.

Improving the health of individuals and communities is at the core of Trinity Health's mission. This includes leveraging resources and partnerships, focusing on those who are poor and vulnerable, and addressing social determinants of health. We fully support reimbursing for CHI, SDOH, and PIN.

We are supportive of these services being part of an annual wellness visit, but strongly urge CMS not to limit them to annual wellness visits as not all who are eligible receive them at this point in time.

In addition, CMS must clarify how to avoid double billing for Medicaid care coordination under the Medicaid health home which screens for social determinants and connects to community based resources almost identically to what is being proposed (these proposals would impact the duals in that model).

CMS asks targeted question on these proposed services.

Community Health Integration (CHI)

CMS requested comments on the following aspects of CHI:

Are proposed descriptor times appropriate and typical for services provided?

We agree that the 60-minute billing increment for the GXXX1 code is reasonable for initial CHI intake-type visits provided that the GXXX2 add-on code can also be billed within the same calendar month. To account for situations where the patient may not be available to complete a full hour visit, CMS could consider 20 or 30-minute increments for GXXX1 that could be billed individually, or as multiple units during the same encounter, with a maximum per calendar month of no less than 60 minutes total.

CHI visits can be especially enlightening when they take place in a patient's home. We encourage CMS to consider including a separate CHI home visit code, similar to those in the 99500-99600 "Home Visit Services" family of CPT codes, to be usable at least once after the initiating CHI provider visit. As with any service delivered in the home, the work and expense involved in CHI home visits differs from that of in-office or telephone visits and their effectiveness bears a billing structure that incentivizes them.

Once social care is established, it is important to follow up frequently with both patients and the community-based resources to which they are referred until the patients' needs have been met. Frequency of contact can sometimes be even more important than length of that contact. In light of this, we recommend a 15-minute billing

What is the typical duration of CHI services?

Especially given that billing for CHI services will be connected to the diagnosis and treatment of specific medical problems, duration of CHI services is likely to be 3-6 months after an initiating visit to 1) provide best practice health education and behavior change support, which requires time for patients to embed new habits and practice new skills, and 2) to fully manage referral to community-based resources, many of which have wait lists or no vacancies, necessitating outreach to additional resource providers.

Is the frequency limit relevant for the GXXX2 “add-on” code?

Trinity Health strongly advises against frequency limits for these follow-up CHI services. Studies have shown that frequency of contact is a key element of CHW value, and Trinity Health’s best practice is weekly patient contact from community health workers. That said, community social resource identification and engagement can be unpredictable and time sensitive; circumstances often necessitate contact that is unevenly distributed across the total period of work with a patient as CHI service providers are often creatively navigating around multiple barriers to get patients what they need. It is of the utmost importance that CHI billing structures allow for nimbleness and flexibility in the timing of services.

What is the typical amount of time practitioners spend per month furnishing CHI services to address social needs that pose a barrier to diagnoses or treatment of a problem addressed in an E/M visit?

In Trinity Health’s experience, CHI services typically require a sum total of 2 hours/patient in the first month (a 1 hour intake session, preferably in the patient’s home but sometimes split across multiple encounters, and approximately 3 follow-up sessions lasting 20 minutes each) and 1 hour per month thereafter (allowing for 4 follow-up sessions lasting 15-min each).

Is it appropriate to specify a minimum number of training hours for auxiliary personnel?

Yes, this will help with quality and consistency across the workforce and state-administered certification programs.

Is it appropriate to specify training content?

Yes, specifying training content will help with quality and consistency across the workforce. There is already an accepted set of competencies in the industry with which this could easily align. We agree with the content listed in the proposed rules.

Is it appropriate to specify who can provide training?

There should be some qualification or accreditation required to be a provider of this training, but the criteria and process for compliance should be kept simple and inexpensive for training vendors. Otherwise, potentially insurmountable barriers would be placed on the small, community-based (often BIPOC-led) organizations that may have years of experience giving high-quality training but cannot afford to comply with complex/expensive accreditation criteria. We should not set standards that, in effect, categorically exclude such vendors.

CMS believes most CHI services involve direct contact; a substantial portion would be in-person, and a portion may be via 2-way audio. Is this how CHI services are typically provided?

Yes. Two-way audio may be a greater proportion for the many patients who have transportation barriers.

Should patient consent be required?

Patient consent should be required only if verbal consent is acceptable, and then only if there are co-insurance or copay charges for which the patient may be responsible. By their nature, CHI services start with a conversation directly with the patient and/or their family to better understand their needs and capacities and what kinds of resources may be available to them. It would not be best practice for CHWs/auxiliary personnel to start working “behind the scenes” on behalf of a patient without having met with the patient first. However, “behind the scenes” work will occur throughout the care episode, and unexpected out of pocket expenses for patients should be avoided at all costs.

If there is no possibility for unexpected out of pocket charges for the patient, requiring patient consent above and beyond their willingness to meet with the auxiliary personnel would add an unnecessary administrative burden, especially if written consent is required.

Do states typically cover similar CHI services under their Medicaid programs? Would such coverage be duplicative?

In our experience, most state Medicaid programs do not directly cover CHI services at this time. It is more common for Medicaid managed care organizations to have their own staff of care managers and community health workers, but these are not well-integrated into clinical care teams nor the communities where patients live. It would be preferable to have health care provider entities or their contracted CHI vendors deliver and bill for such services as part of comprehensive, local patient care.

Are there other service elements not included in proposed CHI codes that should be included, or are important in addressing social needs that affect the diagnosis and treatment of problems?

CHI services are well and comprehensively described in the proposed rule.

*Social Determinants of Health (Social Needs) Risk Assessment***Should a condition of assessment payment be that the billing practitioner also have capacity to provide CHI, PIN, other CM services, or have related partnerships with community-based organizations?**

Yes.

Where and how are social needs assessments typically provided?

At Trinity Health, systematic, comprehensive social needs screening is occurring 1) via patient portals in conjunction with specific primary care visits, or 2) via paper screenings administered by clinical staff, but not providers, at the point of care – often primary care visits. It is not necessary for a staff member or provider to ask the questions to get high quality information, and it is much less scalable. Scale is essential now that authoritative bodies like the Joint Commission, CMS, and NCQA are requiring such screening for all patients. It is also notable that some patients are more likely to share accurate information on their social needs when they can complete the screening privately.

Additional/more in-depth information is always collected by community health workers but may only be collected by practitioners in the course of a provider visit or care management encounter if it comes up in conversation. The traditional clinical “social history” is more focused on behaviors like smoking, drugs, and alcohol consumption than basic needs like food and housing.

Comments on additional aspects of assessment proposal

The Joint Commission, CMS Inpatient Quality Reporting System, and NCQA (in clinical programs and HEDIS measures) are all incorporating requirements for social needs screening. At the scale required by these accrediting bodies (culminating in universal screening for all patients in both inpatient and ambulatory settings), it would not be realistic for all social needs assessments to take place during a 5-15 minute practitioner encounter, nor do we feel that is necessary. Rather than making a practitioner's real-time, verbal collection of social needs information billable, we recommend making time spent reviewing screening results and making plans for follow-up on identified social needs billable.

Principal Illness Navigation

Are there any gaps in covered services?

No, as long as there is no restriction on PIN personnel addressing social needs as thoroughly for serious illness patients with unmet social needs as they do for other patients.

Should there be any allowable pre-requisite for initiating PIN, other than an E/M visit?

It should be possible to initiate PIN after any type of visit when a need is appropriately identified, including Annual Wellness Visits.

Payment for Vaccine Administrative Services

CMS proposes to maintain the additional payment for the administration of a COVID-19 vaccine in the home and proposes to extend this in-home additional payment to the administration of the other three preventive vaccines in the Part B vaccine benefit: influenza, pneumococcal and HBV.

Trinity Health supports this policy.

Clinical Laboratory Fee Schedule (CLFS)

CMS has delayed the CLFS reporting period for 4 years and still plans on using 2019 data to determine payment in the future. Given the delay in reporting, CMS should use updated data more recent than 2019. In addition, should CMS determine it will delay reporting again, we urge CMS to let hospitals know as soon as possible. We have entered into a pattern in which we use sparse resources to prepare for reporting only to have it delayed again—the time and resources used to collect data can be redirected to other critical activities.

Diabetes Prevention Program Expanded Model

CMS proposes extension of flexibilities to allow virtual weight measurement via digital scales or self-reported data from digital scales and to eliminate limits on virtual sessions. In addition, CMS also proposes to move from fee-for-service to a hybrid model, where attendance would be paid for on a fee-for-service basis and weight loss paid on an outcomes basis.

Trinity Health fully supports these changes, as they would simplify the program.

Appropriate Use Criteria

The rule would rescind regulations governing the program and still encourages the use of CDSMs where these mechanisms fit within the clinical workflow and meet the needs of the end user.

Trinity Health supports rescinding regulations for the AUC. We urge CMS to slow down and obtain stakeholder feedback prior to implementing policies that require significant time and resources for hospitals to implement.

Billions of dollars have been spent by vendors and hospitals to implement this requirement that could have been used to implement other critical requirements.

Promoting Interoperability

For the CY 2024 reporting period, CMS is proposing several changes to the Promoting Interoperability performance category. These changes mirror some of the same changes that CMS proposed for the hospital Promoting Interoperability program in the FY 2024 IPPS rule.

Performance Period

The rule would increase performance period to any 180 continuous days in the calendar year.

CMS should consider impact of this on MIPS eligible clinicians that, for example, transition EHRs during the calendar year OR MIPS eligible clinicians that transition EHRs within 6 months of the start of the reporting period (as testing and validation of the new system would be active during this time). In addition, we request that CMS provide clarification on the use of hardship exception in these situations – particularly when the EHR transition occurs within 6 months of the start of the reporting period since this may or may not be within the same calendar year. We also ask CMS's consideration of this suggestion as a MIPS eligible clinician's ability to meet PI Program requirements during a reporting period often requires additional investments into EHR systems.

Query of Prescription Drug Monitoring Program Measure

Modifications to make the exception available to those clinicians that do not electronically prescribe any Schedule II opioids or Schedule III or IV drugs during the performance period.

Trinity Health supports this change and thanks CMS for the proposal.

Anti-Coagulation Management in Hospital Outpatient Department

Anti-coagulation is a high-risk therapy involving complex dosing/monitoring and ensuring patient adherence to outpatient therapy plans of care. Increasingly, hospital outpatient departments are providing anti-coagulation monitoring to assist physicians. These services may be performed by nurses or pharmacist based on physician order and dosing protocols. CMS has not provided concrete guidance on appropriate CPT/HCPCS coding for these services provided by hospital outpatient departments. Over the past several years, some MACs have provided guidance generally recommending use of CPT 99211 which does not apply under OPSS. Currently most hospitals are reporting this service using G0463 (Hospital outpatient clinic visit for assessment and management of a patient).

CPT guidance is to use the most specific code available that appropriately represents the service provided. CPT code 93793 (Anticoagulant management for a patient taking warfarin, must include review and interpretation of a new home, office, or lab international normalized ratio (INR) test result, patient instructions, dosage adjustment (as needed), and scheduling of additional test(s), when performed) was created in 2018. This code accurately describes the anti-coagulation management services performed in hospital outpatient departments. OPSS status indicator B is assigned to this code.

We are requesting that CMS update the status indicator for CPT 93793 to a covered status indicator such as SI=A, S or V. The service could be paid through the physician fee schedule or under OPSS.

Medicare Shared Savings Program

Trinity Health is pleased that CMS continues to work to improve and enhance MSSP. Many of the proposed policies align with Trinity Health's goals of having all Medicare beneficiaries in an accountable care relationship by 2030, providing care to patients with complex needs through team-based care and addressing social barriers to care. As the only permanent total cost of care model, CMS must ensure that current MSSP participants remain in the model and that the model can attract new clinicians and other providers. CMS should do the following to accomplish this goal:

- Address the benchmark ratchet effect. In 2025, we will be starting a new agreement period and will have our benchmark rebased and lowered due to achieving savings during the current contract cycle. This will be true for majority of ACOs over the next two years. While CMS has adopted some policies to reduce the impact of the ratchet (ACPT) these policies do not go far enough and many ACOs, like us, will face deep reductions to their benchmarks. It is critical that ACOs have fair and accurate benchmarks. The savings achieved in these models directly impact patient care by expanding care teams, providing additional beneficiary services that are not billed to Medicare, ensuring provider retention which enhanced provider payment, and investing in technology or other services that enable care coordination and population health management. Lowering benchmarks because of the ratchet effect reduces our ability to improve care and reduces the ACOs opportunity to achieve success and reinvest shared savings into beneficiary care.
- Remove burden from the program. Beyond payment incentives, reduction of the fee-for-service (FFS) burden is a key recruitment tool to bring clinicians into the ACO model. We are concerned that certain policies (e.g., eCQM reporting, PI reporting for QPs, beneficiary notification) are increasing burden within the program. Entering a population health program requires significant effort to redesign care processes. Clinicians in an ACO model should be rewarded with burden reduction. CMS should examine all policies and ensure that the ACO program is not introducing new regulatory burdens.
- Support inclusion of all providers within the model. ACOs are a unique opportunity to coordinate care across the continuum. While providers across the continuum participate in ACOs, more can be done to bring additional providers into the model. We encourage CMS to offer primary care population based payments to increase primary care participation, encourage specialist engagement in ACOs, and provide additional technical support for provider participants that are not paid under the PFS (e.g., FQHC, RHC, CAH).
- Strengthen nonfinancial incentives within the model. Despite the Innovation Center's testing of several waivers in ACO demonstrations, waivers available to MSSP ACOs have been limited. CMS must rapidly expand MSSP waivers and should create a process to accept public nominations for waivers in MSSP, similar to the process by which the public could annually request additions to the Medicare telehealth services list. Creating a transparent process for adding new waivers to MSSP would increase ACOs' flexibility to meet the needs of their populations and support CMS's goal to advance accountable care.

Quality

Trinity Health is pleased to see CMS proposals to introduce an additional reporting option, Medicare CQMs. This will potentially ease the transition to required electronic clinical quality measures (eCQMs). However, Trinity Health still has significant concerns with the move to all-payer all-patient eCQM/MIPS CQM reporting to evaluate ACO quality and would ask that CMS instead focus on future digital quality measurement (dQM) goals.

While we applaud the commitment to social risk factors across Medicare populations in the proposed rule, the all-payer reporting requirement will factor in differences in clinical complexities and social factors across all populations and regions, and we have not seen how these would be accounted for in the measurement model. We do not want to see this scenario punish ACOs serving those sicker more vulnerable populations which are emphasized throughout this rule. In addition, this policy has the potential to eliminate small independent practices from participating in ACOs.

During our eCQM transition discovery work, we have been told that many EHRs are charging \$200-500 per provider per instance of report that needs to be produced. Our national ACO has over 100 different instances of EHRs and approximately 40,000 patients attributed to over 2,000 independent providers which could end up costing our ACO over \$600k each year. This is expense with no additional shared savings benefit to offset. While CMS and others often assume that electronic health record (EHR) vendors with 2015 Certified HER Technology (CEHRT) would automatically include the capability to easily report the most recent version of an eCQM for MIPS with minimal manual effort, this is not the case.

This Medicare CQM policy does not advance digital quality measurement as it leaves the all-payer eCQM reporting option unchanged. CMS should work with ACOs and the electronic health record (EHR) vendor community to find solutions to data aggregation problems and cost. Until these resources and solutions are widely available, all-payer eCQMs should not be mandated for ACOs and instead the Medicare CQM option should be a permanent option for MSSPs.

Medicare CQMs

As stated above, Trinity Health is pleased to see CMS provide a new reporting option for MSSP ACOs, Medicare CQMs. We believe this approach eliminates the concerns above with the all-payer option regarding equity. Additionally, further limiting the definition of a beneficiary eligible for Medicare CQMs to those meeting ACO assignment criteria mitigates concerns with specialists reporting on primary care focused measures. We would like to see CMS clarify the reporting population of Medicare CQMs and limit it to only the ACO patient list provided by CMS at the start and end of the ACO reporting period.

Data Completeness

Trinity Health urges CMS to clarify what the data completeness requirement for Medicare CQMs is, as the regulation discusses a 75 percent data completeness requirement and also notes CMS expects ACOs to report on all patients meeting Medicare CQM eligibility criteria that also meet the measure criteria. It is not practical for CMS to expect ACOs to have 100 percent complete data when aggregating data across many practices, EHRs, and instances of EHRs for both employed and independent clinicians. We urge CMS to adopt exclusions and/or a lower data completeness requirement for ACOs to account for these very real obstacles that we are working to overcome when reporting data for eCQMs, MIPS, CQMs and Medicare CQMs.

Quality Benchmarks

For the first year that Medicare CQMs are made available (PY2024), we urge CMS to consider using Web Interface benchmarks. Not having enough data to know what benchmarks will look like prior to the start of the performance year will discourage ACOs from using the option. It is important for us to know our quality targets going into the performance year and when selecting a reporting option.

ACO Quality Measure Changes

Trinity Health supports CMS's efforts to align quality measures across its programs by using the new Universal Foundation measure set. We would like to see CMS first test measures before making them required and scored measures for ACOs. We also would not like to see any more changes to PY 2025 as this is the year the web interface is currently scheduled to sunset as a reporting option for ACOs and we will now have to consider a new reporting option (Medicare CQMs).

CMS should not require reporting on substance use disorder (SUD) treatment, until they are able to share SUD data with ACOs. Regarding the screening for SDOH measure, we caution this measure must be tested before making this a required measure. Trinity Health supports CMS efforts to improve health inequities and incentivize screening for SDOH. However, CMS must recognize the current state of this work and first start with efforts around data standardization before any such measure is required. If any implementation, this should first be pay-for-reporting which will allow ACOs to continue to learn and mature in this space. We believe that screening is an important tool in a larger plan to address health inequities and provide high value care to underserved communities, but we would like to see flexibility in how this data is collected and, therefore, would ask CMS to first test this measure with a broad definition of screening.

CEHRT Requirements for Shared Savings Program ACOs with MIPS

Trinity Health strongly opposes CMS proposals to align CEHRT requirements for MSSP ACOs with MIPS and we urge CMS to reconsider this policy. This policy creates a disincentive for ACOs to participate in the Advanced APM track and achieve QP status. CMS suggested this policy is intended to alleviate burden for ACOs, however, the result will be opposite. This will create a new reporting obligation for ACOs who participate in an Advanced APM. Achieving QP status excluded providers from the MIPS program and this proposal would now subject QPs to MIPS Promoting Interoperability.

Further, we would not be able to comply with this proposal in the timeline suggested. The final rule will not be published until November, and ACOs must report to CMS those participants they wish to eliminate from MSSP participation list in September. This would not give us enough time to remove participants who are not on CEHRT the start of the performance year 2024. We have been able to help transition practices not on CEHRT to meet the requirements as participants in the ACO. This process takes time and resources which will not be possible in the timeframe proposed. We urge CMS to keep the current 75% attestation approach as this new policy will stifle growth in the ACO program and create barriers to CMS reach its 2030 goals.

Beneficiary Assignment

Modifications to Assignment Methodology and Identification of Assignable Beneficiary Population

Trinity Health appreciates CMS's efforts to eliminate barriers for beneficiaries to be assigned to ACOs. CMS proposes several changes to the assignment methodology, including revising the physician pre-step, implementing an expanded window for assignment, adding a third step to the claims-based assignment methodology, and revising the definition of assignable beneficiary.

Use of Expanded Window for Assignment

Trinity Health supports the proposal to define "expanded window for assignment" as the 24-month period that includes the applicable 12-month assignment window and the preceding 12 months. We also support the efforts to better account for beneficiaries who primarily receive primary care services from non-physician practitioners (NPPs) during the assignment window. However, we have concerns that the lack of specialty designation for NPPs will lead to more specialty-driven assignment from these provider types. We would like to see updates made to the *Provider Enrollment, Chain, and Ownership System (PECOS)* to include specialty designations of

NPPs. Another solution to this challenge would be to allow MSSP participation at the TIN-NPI level as opposed to full TIN participation. We believe NPPs who deliver primary care should be part of an ACO and will increase attribution, however, in the absence of the solutions above, we would ask CMS to allow ACOs to remove specialty focused NPPs from assignment.

Revision of the Definition of Assignable Beneficiary

Trinity Health strongly urges CMS to conduct further analyses using additional years of data prior to revising the definition of an assignable beneficiary to align with the proposed expanded window for assignment. We are concerned that this change will have varying effects on ACO's financial performance based on its effect on the national and regional assignable populations which are used in calculations to adjust ACO's benchmark. We would urge CMS to expand the simulation and provide additional analyses to assess:

- Impacts to individual ACO benchmarks to ensure the policies do not harm performance and create artificial winners and losers,
- Potential changes to regional factors calculated with the new regional assignable population to ensure there are not unintended consequences for rural ACOs and ACOs in underserved communities,
- Changes to PBPY expenditures and average risk scores under the new assignable definition, and
- Differential impacts based on geography, ACO size and composition, and between retrospective ACOs and prospective ACOs.

Revisions to the Definition of Primary Care Services Used in Assignment

CMS proposes to add several codes to the definition of primary care services used to determine beneficiary assignment. Trinity Health supports the addition of the following codes:

- Smoking and Tobacco-use Cessation Counseling Services (CPT codes 99406, 99407)
- Cervical or Vaginal Cancer Screening (HCPCS code G0101)
- Complex E/M Services Add-on (HCPCS code G2211)
- Community Health Integration Services (HCPCS codes GXXX1, GXXX2)
- Principal Illness Navigation Services (HCPCS codes GXXX3, GXXX4)
- SDOH Risk Assessment (HCPCS code GXXX5)
- Caregiver Behavior Management Training (CPT codes 96202, 96203)
- Caregiver Training Services (CPT codes 9X015, 9X016, 9X017)

We believe these services support the delivery of comprehensive, coordinated, whole-person primary care and aligns with our efforts to integrate community health into primary care.

CMS also proposes to add Remote Physiologic Monitoring Treatment Management Services to determine beneficiary assignment. We would ask that before CMS implements this change, they collect experience from ACOs. This has the potential to pull attribution away from ACO providers and could attribute more patients to specialists due to the amounts and quantity of billing done for specific chronic conditions.

Finally, CMS proposes to add Office-Based Opioid Use Disorder (OUD) Services (HCPCS codes G2086, G2087, G2088). CMS notes in its proposal that it excludes these codes from CCLFs provided to ACOs and ACOs would not be able see these claims or identify why certain beneficiaries were assigned to their ACO related to these codes. Trinity Health opposes the addition of these codes to the definition of primary care services used in assignment until CMS provides this information to ACOs.

Financial and Benchmarking Methodology Changes

Trinity Health is pleased to see CMS take effort to create fairer, more accurate financial benchmarks. However, we do not believe that CMS has proposed anything in this rule that will solve the rebasing or ratchet effect, where ACO benchmarks will continue to be lower over time as they reduce spending in their populations and future benchmarks are rebased on lower historic spending. Since we have joined the MSSP program, Trinity Health has saved 2-4 percent every year. Without an alternative benchmarking strategy, the current methodology is unsustainable. We urge CMS to consider future changes to mitigate this rebasing problem, which we believe threatens future participation for ACOs working to create a higher quality, more efficient and more cost-effective health system. More dramatic benchmarking policies are needed to both attract new participants while keeping existing ACOs in the model.

Capping Regional Risk Score Growth

CMS proposes to cap an ACO region's growth in risk scores at 3 percent, similar to how it caps the ACO's own risk score growth. CMS proposes to apply the cap on the region independently, meaning the region could be subject to a cap in its risk scores even if the ACO isn't. ACOs in regions with risk score growth below the cap would not be affected. The cap for both the ACO and region is applied separately for each enrollment type. If finalized, the change would apply to new agreements starting in 2024. Trinity Health thanks CMS for addressing this concern and strongly supports this change. We ask that it be applied to all ACOs not just new agreements so that all ACOs can benefit.

Eliminating the Impact of the Negative Regional Adjustment

We support CMS in reducing the impact of a negative regional adjustment. We believe this change would reduce the barrier to entry for future ACOs who have spending higher than their region. This includes ACOs who serve high-cost and medically complex populations. While there is no proposed change for ACOs, like Trinity, with a history of positive regional adjustments, we would ask that CMS provides additional help to ACOs who have already lowered their costs in their communities and continue to do so. There is a cap on ACO's savings under these current policies, which should be addressed if CMS wants to keep successful ACOs in the program. We would like to see CMS eliminate the cap on savings in order to help ACOs continue to earn savings as they progress in their value-based care journey.

Introduction of New Risk Adjustment Model Version

For new agreements beginning in 2024, CMS proposes to use the same hierarchical condition code (HCC) risk adjustment model for a performance year and the relevant benchmark years. This means that as CMS introduces new risk models, including the forthcoming V28, risk scores would be calculated using a consistent model and any impacts a shift in the model version could create should be balanced. Importantly, these changes are proposed to only apply for agreement periods beginning in 2024. ACOs not starting new agreements in 2024 will have risk scores for their benchmark years calculated using different HCC model versions. Trinity Health strongly urges CMS to apply a consistent risk model for ALL ACOs starting in PY2024, not just those starting new agreement periods.

Future Developments for Shared Savings Program

Incorporating a Higher Risk Track than Enhanced

Trinity Health is pleased to see CMS request feedback on a full risk track within MSSP. We have been advocating for a model that builds off of the success of Next Gen and could provide a bridge or alternative to ACO REACH. Here are some recommendations for CMS to consider as the model is built:

- CMS should give ACOs a choice between full-risk with a discount and 85-90 percent shared savings rate. This would 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 percent.
- CMS should consider non-financial incentives in a full-risk model to entice participants to move towards higher levels of risk. Examples of these could be NPI level participation, option for population-based payments, 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. 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 Health 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.

Expanding the ACPT Over Time and Addressing Overall Market-wide Ratchet Effects

CMS is seeking feedback on future refinements to its new Accountable Care Prospective Trend (ACPT), including replacing the national trend in the current two-way blended update with ACPT, along with scaling the weight of the ACPT to account for ACO's market share in its region. We ask that CMS keep the current two-way trend that uses a blend of national and regional spending but recommended two changes: CMS (1) use the ACPT as the national component of the trend adjustment, rather than observed national FFS spending and (2) remove ACO-assigned beneficiaries from the regional comparison group, negating the effect of ACOs' savings on the regional trend. This would still allow CMS to move toward its goal of an administratively set benchmark while minimizing the unintended consequences of harming nearly a third of ACOs. Replacing the national trend in the current two-way blend with the ACPT is a step in the right direction. It creates a benchmark that is based less on national spending and more on regional spending.

In addition, Trinity Health would like to see guardrails put in place to protect ACOs who would see lower benchmarks because of the ACPT, these include:

- Setting ACOs' historic benchmark at the higher of the proposed three-way trend adjustment or the current two-way trend adjustment.
- Basing the ACPT on regional spending, rather than national. Because there is significant variation in regional spending growth, the use of a national trend will benefit ACOs in regions with slower spending growth and reduce benchmarks for ACOs in regions with higher spending growth.

Using a 3-year projection of the ACPT, which is the current projection used in the USPPC. It would be difficult to project five years out, and reserving the right to make mid-agreement period adjustments simply introduces uncertainty.

Promoting ACO and CBO Collaboration

CMS seeks feedback on general approaches for encouraging or incentivizing increased collaboration between ACOs and CBOs.

Reducing Administrative Burden for ACOs – Beneficiary Notification Requirements

CMS did not propose any changes to the current beneficiary notification requirements in this rule. Trinity Health would like to reiterate concerns with the requirements as currently written and highlight our challenges in implementing and complying with these requirements. It was CMS's intent to remove burden from ACO when it proposed these changes in the 2023 proposed rule, however, these changes *increased* the burden on ACOs.

Last year, CMS added a new requirement that a follow-up written, or verbal communication must occur no later than the beneficiary's next primary care service visit or 180 days after the first standardized written notice was provided. ACOs would be required to track and document how the follow-up communication is implemented and make this documentation available to CMS upon request. Trinity Health strongly opposed this policy due to concerns of beneficiary confusion and operational complexity. Even after multiple attempts, CMS still has failed to provide sufficient guidance as to how ACOs are supposed to meet this requirement and have provided conflicting information when asked. Trinity Health has attempted multiple ways to comply with this requirement including letters, verbal and electronic communication. We have received direct feedback from our beneficiaries in focus groups that tell us the additional communication is confusing and does not improve comprehension of the ACO objectives. In addition, tracking this process with 11 chapters, over 200 participant TINs, and 7,400 providers has been nearly impossible because the follow-up happens at different times and in different ways. This is extremely burdensome to our small ACO staff and not contribute to ACO goals and objectives. Today, we make meaningful connections with our beneficiaries and provide them opportunities to give feedback and connect with us organically through their relationships with our providers.

Trinity Health urges CMS to reconsider the follow-up requirement as we believe it is causing undue beneficiary confusion and frustration and

Quality Payment Program

Merit Based Incentive Payment System

MIPS Value Pathways (MVP) Reporting for Specialists in Shared Savings Program ACOs

Trinity Health is supportive of policy to further engage specialists that participate in the ACO program. However, we oppose policy that would require specialists' participants to report MVP measures in addition to quality reported through the APP, as we feel this would damage engagement rather than support it. To identify methods of supporting engagement by specialist participants, we would request more detailed data on specialists related to cost and quality to be able to establish policy that both engages specialists and lowers total cost of care and increases quality for assigned beneficiaries.

Request for Information on MIPS Incentives to Advance Alternative Payment Models

Trinity Health shares the agency's concerns that the QPP's incentive structure beginning in PY2023 does not create adequate incentives for providers to move from fee-for-service to Advanced Alternative Payment Models (AAPMs). Trinity Health strongly supports extending the 5% part B APM bonus for AAPM participants that meet the QP status thresholds. If the 5 percent advanced APM incentive payments expire this year and qualifying thresholds increase to unattainable levels, there will be a significant reduction in participants in risk-based models. The APM bonus has been a strong component of providers (both primary care and specialty) considering participation in AAPM models.

CMS should work with Congress to provide an initial short-term extension of MACRA's incentives and consider more sustainable longer-term incentive payments systems that helps clinicians move away from standard FFS.

This includes redesigning physician payment incentives to promote value by developing a three-tier system that provides increased flexibility and financial incentives for the adoption of value. The participation tracks should be:

- Fee-for-service (MIPS)—Clinicians that are not participating in any APM. MIPS should be revised so that the program does not incent remaining in FFS. Specifically, Congress should structure MIPS to have

adequate payment adjustments for physicians but no additional incentives unless clinicians are taking steps to move to value.

- APMs—Clinicians participating in ACOs or other APMs that hold them accountable for cost and quality. Clinicians in this track should be exempt from MIPS quality reporting and only held to the quality and payment parameters of their model. Financial incentives should recognize the up front and ongoing investments needed to be successful in APMs.
- Advanced APMs—Clinicians participating in risk-based models. This track should have the strongest financial incentives and flexibility.
- New approaches should focus on simplifying the incentive structure, account for providers serving rural and underserved populations.

QP Determinations

CMS proposed in this rule that the QP determination be made at the individual level rather than the entity level as it is today. Trinity Health strongly urges CMS to reconsider this policy and encourages the agency to finalize a policy where QP determinations can be made at both the APM entity and the individual level. Making determinations at only the individual level will discourage specialist participation in the ACO as many specialists partner with ACO on population health activities because they are able to be part of an Advanced APM and achieve QP status. This policy also creates extra burden on practices within the ACO because some of their providers will qualify as QPs and some may not. This requires the practice to support some of their clinicians in MIPS while others are reporting as an APM. In addition, we request that CMS provide the data used to develop the QP thresholds so that the ACO can better support clinicians in their MIPS or APM paths as we lack the necessary information to simulate the QP threshold for each provider in our ACO.

Conclusion

We appreciate CMS' ongoing efforts to improve delivery and payment systems and to implement policies that further support delivery of value-based care. If you have any questions on our comments, please contact Jen Nading at jennifer.nading@trinity-health.org.

Sincerely,

/s/

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