

September 9, 2025

Dr. Mehmet Oz, Administrator Centers for Medicare and Medicaid Services Department of Health and Human Services 7500 Security Boulevard Baltimore, MD 21244-1850

Re: CMS-1832-P; Medicare and Medicaid Programs; CY 2026 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program

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

Dear Administrator Oz,

Trinity Health appreciates the opportunity to comment on policies set forth in CMS-1832-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. In addition, the comments below are recommendations on modifications to the Medicare fee-for-service payment system. Many of these issues would be lessened, or in some cases eliminated, if CMS gave non-profit health systems, such as Trinity Health, more accountability in total cost of care payment and delivery arrangements.

Trinity Health is one of the largest not-for-profit, Catholic health care systems in the nation. It is a family of 127,000 colleagues and more than 29,000 physicians and clinicians caring for diverse communities across 26 states. Nationally recognized for care and experience, the Trinity Health system includes 93 hospitals, 107 continuing care locations, the second largest PACE program in the country (a total cost of care program), 142 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 \$23.9 billion with \$1.3 billion returned to its communities in the form of charity care and other community benefit programs.

Trinity Health has 12 Clinically Integrated Networks (CINs) that are accountable for 2 million lives across the country through alternative payment models. Our health care system participates in 12 markets with Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs), which includes 10 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 12 markets also participate in the Comprehensive Primary Care Plus Model. 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.

In addition, Trinity Health owns a non-profit, mission-focused Medicare Advantage plan—MediGold—that plays a vital role in our integrated delivery network and provides care coordination for patients while using fair practices. Serving 56,000 beneficiaries across 6 states, MediGold is a highly-effective best practice plan model. In order to place a better emphasis on care and outcomes rather than profit, MediGold has a lower profit margin and lower administrative costs compared to commercial for-profit plans because they say "yes" more to providers and beneficiaries. In addition, MediGold utilizes standard and transparent guidelines for decisions on precertification and other authorization approval processes, removing ambiguity of guidelines for providers.

In our detailed comments below, Trinity Health offers the following recommendations:

- Trinity Health has significant concerns with the proposed efficiency adjustment and changes to practice
 expense RVUs, both of which would redistribute payments and would inappropriately disadvantage
 certain providers, including physicians who are largely hospital-based. We urge CMS to not finalize
 these proposals.
- Telehealth:
 - CMS should permanently extend the waiver previously granted to providers that would allow a
 distant site practitioner to use their currently enrolled practice location instead of their home
 address when providing telehealth services from their home for the privacy and safety of
 practitioners.
 - We also urge CMS to work with Congress to permanently extend the waivers of geographic and originating site requirements, as this is a critical flexibility necessary to continue to care for our communities.
- For Skin substitutes, we encourage CMS to analyze cost data, WAC, and ASP and update OPPS
 reimbursement rates for APCs 6001, 6002, and 6003 quarterly throughout CY2026 to reflect differences
 in costs in a timely fashion and to mitigate clinical practice shifts due to inadequate reimbursement.
- Medicare Diabetes Prevention Program (MDPP):
 - We recommend clarification on the collection of weight measurements that may be self-reported and recommend CMS ensure that providers receive at minimum the existing maximum payment of \$755/beneficiary for the program.
 - We offer additional recommendations to improve the MDPP.
- Feedback on the Medicare Shared Savings Program and Quality Payment Program.
- Ambulatory Specialty Model (ASM):
 - CMMI should exempt providers in existing advanced alternative payment models, including ACOs, from the model.
 - Should CMMI finalize the ASM as proposed, Trinity Health urges CMMI to design and implement robust monitoring procedures to ensure that beneficiary access is not negatively impacted by the model test.
 - There should be no model overlap between the ASM and other value models. If CMMI finalizes this policy, additional, granular detail is needed on the methodology for financial reconciliation for providers participating in both models.
 - o CMMI should raise the low volume threshold to a minimum of 50 episodes, allow specialists the opportunity to pool with others in their practice, and risk adjust the quality measures.
 - We urge CMMI to continue to support incentives for ACOs and create a more level playing field across ACO participants in lieu of creating new specialty models.
- Responses to value-based care and chronic disease prevention requests for information.

Conversion Factor

Beginning in CY 2026, CMS proposes implementing two separate conversion factors: one for physicians and practitioners who participate in advanced alternative payment models (payment increase of +3.83%) and one for physicians and practitioners who don't participate in these arrangements (payment increase of 3.62%). In addition, the rule also includes a statutory update of 2.5% as required by the One Big Beautiful Bill Act.

Trinity Health is pleased that CMS is proposing a positive payment update for physicians, as this will be the first positive and significant payment adjustment under the PFS in years (see chart below). However, we have significant concerns with the proposed efficiency adjustment and changes to practice expense RVUs, both of which would redistribute payments and would inappropriately disadvantage certain providers, including physicians who are largely hospital-based.

Medicare Physician Conversion Factor				
(2017–2026)				
Year	CF for QPs	CF for non-QPs	Actual Updat e QPs (%)	Actual Update non- QPs (%)
Jan 1, 2017	35.8887	35.8887	0.24	0.24
Jan 1, 2018	35.9996	35.9996	0.31	0.31
Jan 1, 2019	36.0391	36.0391	0.11	0.11
Jan 1, 2020	36.0896	36.0896	0.14	0.14
Jan 1, 2021	34.8931	34.8931	-3.32	-3.32
Jan 1, 2022	34.6062	34.6062	-0.82	-0.82
Jan 1, 2023	33.8872	33.8872	-2.08	-2.08
Jan 1, 2024	33.2875	33.2875	-1.77	-1.77
Jan 1, 2025	32.3465	32.3465	-2.83	-2.83
Jan 1, 2026	33.5875	33.4209	3.84	3.32

Efficiency Adjustment

CMS assumes a provider's time directly providing the service to a patient as well as their work intensity would decrease as they develop expertise in performing the service and as such, the proposed rule includes an efficiency adjustment.

To calculate the efficiency adjustment, CMS proposes using the Medicare Economic Index (MEI) productivity adjustment and for CY 2026, CMS would apply the efficiency adjustment using a look-back period of five years. This methodology yields a proposed efficiency adjustment of -2.5%. As a result of this policy, specialties that bill more often for timed codes (such as family practice, clinical psychologists, clinical social workers, geriatrics and psychiatry) would see an increase in RVUs, while specialties that bill more often for procedures, diagnostic imaging and radiology services (such as radiation oncology, radiology, and some surgical specialties) would see a decrease in RVUs.

The net impact of the conversion factor increase would be reduced by the proposed efficiency adjustment. If finalized, CMS would walk back what should have been an opportunity to correct for the fact that the conversion factor is roughly 30% behind where it needs to be to account for the past 25 years of inflation. We urge CMS not to finalize the proposed efficiency adjustment. For long-term sustainability, CMS should update the conversion factor annually by an amount equal to the annual percentage increase in the MEI.

Practice Expense (PE) Methodology

The proposed rule would reduce the portion of facility indirect PE relative value units (RVUs) based on work RVUs. The rule notes that since the initial implementation of the PE methodology, physician practice ownership trends have shifted and the majority of physicians work in hospital-owned practices or are employed directly by the hospital. To address this shift to facility-based work, for each service valued in the facility setting under the PFS, CMS proposes to reduce the portion of the facility PE RVUs allocated based on work RVUs to half the amount allocated to non-facility indirect PE RVUs beginning in 2026.

This proposal reflects a significant payment cut to physicians for facility-based services with a reduction in payment of -7% across provider-based practices. Similar to the efficiency adjustment, this proposal would negate the positive conversion factor update being proposed for providers. We urge CMS to not finalize this provision and perform additional data analysis before making such a significant payment change. MedPAC notes in its June 2025 report that there is currently insufficient data on the relationship between indirect PE payments and continued access to services for Medicare beneficiaries. In addition, we believe the proposed policy could have an outsized impact on providers in rural areas that already struggle to provide specialized care to vulnerable Medicare populations.

Telehealth

CMS proposes several changes to telehealth policy, including:

- Changing its review process for the Medicare Telehealth Services List by removing the distinction between provisional and permanent services.
- Permanently removing frequency limitations for subsequent inpatient visits, nursing facility visits and critical care consultations.
- Permanently adopting a definition of direct supervision to include virtual presence via audio/video realtime communications technology.
- Extending the ability for federally qualified health centers and rural health clinics to bill telehealth services through Dec. 31, 2026.

Trinity Health is broadly supportive of CMS' proposals to streamline and increase access to telehealth services. We believe these changes will increase patients' access to high-quality care while reducing administrative burden for providers. However, we urge CMS to permanently extend the waiver previously granted to providers that would allow a distant site practitioner to use their currently enrolled practice location instead of their home address when providing telehealth services from their home for the privacy and safety of practitioners. Requiring that providers disclose their home address can increase safety risks, especially for behavioral health professionals. We also urge CMS to work with Congress to permanently extend the waivers of geographic and originating site requirements, as this is a critical flexibility necessary to continue to care for our communities.

Modification of Payment Structure for Skin Substitute Products

CMS proposes to pay separately for certain groups of skin substitute products as supplies when they are used during a covered application procedure paid under the Physician Fee Schedule in the non-facility setting or under the OPPS. This proposal includes grouping skin substitutes that are not drugs or biologicals using three Food and Drug Administration (FDA) regulatory categories (PMAs, 510(k)s, and 361 HCT/Ps) to set payment rates. To accomplish this categorization and incorporation into OPPS payment policy, CMS proposes to create three new APCs for HCPCS codes describing skin substitute products organized by clinical and resource similarity and by

their FDA regulatory pathway. The proposed APCs include APC 6000 (PMA Skin Substitute Products), APC 6001 (510(k) Skin Substitute Products), and APC 6002 (361 HCT/P Skin Substitute Products) with an initial payment rate of \$125.38 for each of the new proposed APCs.

Trinity Health is concerned that the flat rate reimbursement proposal may negatively impact provider choices away from high-cost, innovative and clinically effective products to less costly, less clinically effective products. We encourage CMS to analyze cost data, WAC and ASP and update OPPS reimbursement rates for APCs 6001, 6002, and 6003 quarterly throughout CY2026 to reflect differences in costs in a timely fashion and to mitigate clinical practice shifts due to inadequate reimbursement for high-cost, highly effective products.

We also note that suspicious billing practices could cause significantly inaccurate and inequitable payment and repayment obligations in the Medicare Shared Savings Program if not addressed in expenditure and revenue calculations. We encourage CMS to continue to work with ACOs to improve the process for reporting suspected fraud, waste and abuse and to explore new opportunities to deepen its partnership in promoting high-quality and efficient patient care.

Social Determinants of Health Risk Assessment/Community Health Integration

The rule proposes that marriage and family therapists and mental health counselors can bill Medicare directly for Community Health Integration and Principal Illness Navigation services. In addition, CMS proposes creating addon codes for Advanced Primary Care Management services that complement previously established Behavioral Health Integration or psychiatric Collaborative Care Model services. Lastly, CMS proposes deleting the HCPCS code finalized in the CY 2024 PFS final rule that describes social determinants of health risk assessment and altering language throughout the regulations to refer to "upstream drivers" of health rather than "social determinants."

Trinity Health supports these changes, including the removal of the health risk assessment. While health risk assessments remain an important tool for ensuring the health of the communities we serve, the specific code and did not fit into hospital workflows. Billing codes for population-level screening (i.e. high-level screening of all patients for initial social need identification) would be more useful.

Medicare Diabetes Prevention Program

CMS' Medicare Diabetes Prevention Program Expanded Model (MDPP) is an evidence-based behavioral intervention that aims to prevent or delay the onset of type 2 diabetes for eligible Medicare beneficiaries diagnosed with prediabetes. To increase uptake of the program, CMS proposes several changes:

- Adding the following definitions: Live Coach interaction, Online delivery period, and Online session and modifying the definition of "Online".
- Making changes to the expanded model to address operational questions and barriers related to weight collection requirements.
- Continuing to extend flexibilities allowed during the Covid-19 Public Health Emergency through 2029.
- Testing the inclusion of asynchronous delivery modality by which will allow MDPP suppliers to deliver online services through 2029 and introduce payment for online sessions.

Trinity Health has leveraged resources to build a sustainable national MDPP system-wide, partnering with hospitals, community-based organizations, payers, pharmacies, technology, public health and professional associations to accelerate diabetes prevention. **We applied CMS for modifying the MDPP to increase take**

up and prevent/delay the onset of type 2 diabetes and we are generally supportive of the proposed changes.

The rule proposes the beneficiaries using the online delivery modality submit their weight requirement on the date of which the online session is completed. **Trinity Health recommends clarification on the collection of weight measurements that may be self-reported.** We have observed barriers throughout the year when collecting self-reported weights (i.e.: coach observation, time-stamped photos, video submission) and we note that several beneficiaries do not have access to a Bluetooth scale or a digital scale. These members are using an analog scale; however, safely taking a picture or video of themselves as they are standing on a scale has presented a safety concern.

Trinity Health recommends the following changes to the policy:

- Clarification on self-reported weight measurement submission requirements.
- Increased safety measures and/or alternative options for beneficiaries reporting on analog scales.
- Guidelines on duration for keeping and securely storing video or pictures of participants who self-report their weight.

In addition, we note that the current maximum payment for this year's payment with inclusion of the risk reduction is \$755/beneficiary and not the \$619 outlined in the proposed rule. **CMS should ensure that providers receive at minimum the existing maximum payment of \$755/beneficiary for the program.**

For overall program improvement of the MDDP program, Trinity Health recommends that CMS:

- Allow flexibility in the program design--given that MDPP is currently a once-per-lifetime benefit, CMS should explore ways to waive or extend flexibilities to take into consideration unexpected circumstances that may cause a member to disenroll from the program for an extended period of time.
- Increase provider engagement and member enrollment by distributing more provider and member directed materials that detail the MDPP program, its benefits, and coverage.
- CMS should provide increased access to CDC recognized Asynchronous (Virtual) platforms for program delivery.
- To increase take up, CMS must incentivize payers and providers to increase participation, such as
 introducing a quality measure that is specifically for pre-diabetic care to enhance STAR ratings. An
 alternative strategy is to align PMPM incentives with growth in MDPP enrollment under Value-Based
 Agreements or Advanced Payment Models (APMs), reinforcing value-driven care adoption.

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 increase participation in accountable care models.

ACO Eligibility Requirements

Eligibility Expansions

Trinity Health supports policies that will encourage and grow participation in ACO models, which is in alignment with CMS's desire to have more Medicare patients in an accountable care relationship. By providing ACOs with the flexibility to have fewer than 5,000 assigned beneficiaries in BY1 and/or BY2, it would make joining the Shared Savings Program more accessible for new entrants, as well as help avoid unnecessary

terminations of ACOs due to temporary dips in enrollment. **Trinity Health applauds CMS for this proposal and encourages CMS to finalize as proposed.**

Change in Ownership Reporting

Trinity Health supports the proposed change that would require ACOs to amend participant lists and SNF Affiliate lists when a change in ownership results in a TIN that is newly enrolled in PECOS with no prior Medicare billing claims history during the performance year or outside of the annual change request cycle. We are supportive of this change as it allows ACOs to retain attribution, as well as SNF 3-Day Waiver approved facilities when mid-year TIN changes occur.

Quality

APP Plus Quality Measure Set

Trinity Health acknowledges and appreciates CMS's efforts to align quality measure sets across programs and is in favor of the proposed changes to the APP Plus Measure Set, including the removal of the Screening for Social Drivers of Health measure. However, we'd like to reiterate the financial and operational challenges ACOs face with reporting eCQMs, and the growing measure set as a result. ACOs must make significant financial and people investments and implement workflow changes to adopt new measures using the new reporting types. Our national ACO has to aggregate, ingest, and de-duplicate over 6 million QRDA 1 files for all payers and patients to produce the required QRDA 3 file for Performance Year 2025 quality reporting. The number of files and associated burden will continue to increase dramatically with every eCQM measure that is added to the required measure set.

To help alleviate some of the burden ACOs are facing, when adding additional measures, CMS should allow for one full performance year after the new measure is finalized in the ruling to allow for adequate time for EHR vendors to build the measure and for providers to update their workflows. Additionally, Trinity Health urges CMS not to hold ACOs accountable for Certified EHR vendors who cannot produce the required QRDA measure files in the required timeframe. As an example, several EHR vendors do not support the 2025 Breast Cancer Screening eCQM metric and subsequent QRDA 1 file reporting due to a lack of awareness or understanding of the APP Plus Measure Set and how that differs from Traditional MIPS reporting. To maintain CEHRT status, CMS should require EHR vendors to build the required measures and produce the necessary files annually and provide QRDA 1 files at no cost to practices. Currently, many EHR vendors are charging upwards of \$3,500 per provider annually to produce QRDA 1 files. We urge CMS to communicate the requirement and mandate vendors to support these eCQMs, and in the interim, suppress the breast cancer screening measure so that ACOs are not in jeopardy of losing shared savings due to not being able to meet the 75 percent data completeness requirement for the BCS measure.

CAHPS for MIPS Survey

Trinity Health values the feedback of our Medicare beneficiaries and therefore is in favor of the proposal to require administration of the CAHPS for MIPS survey via web-mail-phone protocol increasing accessibility for our Medicare beneficiaries. However, we urge CMS to ensure that survey vendors do not charge practices unreasonable fees for the addition of the web-based option. Administrative burdens and program requirements are increasingly placing financial strain on practices and ACOs without adding meaningful value to their participation in the programs.

EUC Policy

Trinity Health applauds the Administration's acknowledgement for the need to expand the application of the Extreme and Uncontrollable Circumstances policies to ACOs that are affected by a cyberattack. Cyberattacks pose a serious threat to health systems, and these attacks interfere with ACOs' abilities to comply with program requirements such as quality reporting. Trinity Health appreciates CMS' efforts to safeguard ACOs and encourages CMS to finalize as proposed.

Health Equity Adjustment

Trinity was discouraged to see the proposal to remove the Health Equity Adjustment applied to ACOs quality scores starting in PY25 as this would disproportionately harm ACOs who primarily serve highrisk, dual eligible and/or underserved populations. We understand the desire to not provide duplicative adjustments; however, the incentives were not designed to serve the same purpose. The Health Equity Adjustment provides incentives for the challenges faced while serving high-risk, vulnerable populations, which tend to have lower quality scores – not due to lower quality of care, but due to the application of a measure set that was designed for the average, traditional Medicare population. The Complex Organization Adjustment was intended to provide incentives for the financial and technological difficulties ACOs face as they transition to all payer/all patient reporting via eCQMs and achieve data completeness thresholds. 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. Trinity Health strongly urges CMS to retain both the Complex Organizational Adjustment and the Health Equity Adjustment on a permanent basis.

Benchmarking Methodology

Accountable Care Prospective Trend (ACPT)

While CMS did not reference the ACPT in this proposed rule, we would like to reiterate our prior concerns over this benchmarking methodology. CMS introduced the ACPT to address benchmark ratchet challenges by allowing benchmarks to increase beyond actual spending growth rates as ACOs slow overall spending growth, and to serve as an initial step towards administratively set benchmarks. While the methodology was well-intended, the ACPT is likely to continue to arbitrarily reduce ACO benchmarks making it more difficult for ACOs to achieve shared savings. We urge CMS to remove the ACPT for 2025 and beyond and identify other ways to address the ratchet effect experienced by ACOs who lower expenditures during an agreement period.

Significant, Anomalous and Highly Suspected Billing Policy (SAHS)

In the CY2025 Physician Fee Schedule, CMS finalized a policy to exclude all payments from ACOs' performance year financial calculations, as well as historical benchmarks if the billings were identified by CMS as significant, anomalous, and highly suspect. Trinity still strongly supports this policy; however, we'd like to reiterate our prior concerns that the policy does not address all instances of fraud, waste and abuse that ACOs are experiencing outside of their control. We ask that CMS address all SAHS billings and provide additional details to support longer term strategies to address anomalous spending, as well as not hold ACOs financially accountable for any fraudulent billing that is identified and reported.

Quality Payment Program

Advanced APMs

QP Determination

Trinity Health supports CMS's proposal to make Qualifying APM Participant (QP) status determinations at both the individual and APM entity level. By doing so, it creates more opportunities for clinicians to qualify as QPs. However, we have concerns that using all covered professional services rather than E/M codes alone for

QP determinations could make it more difficult for certain ACOs with a higher mix of specialists to meet the increased qualifying thresholds. **Trinity Health encourages CMS to maintain the current QP attribution approach using only E/M codes for QP determinations.**

APM Incentive/Conversion Factor

While not explicitly addressed in the proposed rule, **Trinity Health remains concerned that the APM Incentive Payment is no longer available for Qualifying Participants, and increasingly, the incentives to participate in ACOs are becoming less clear.** Historically, providers, who participated in an Advanced APM that achieved QP status, were rewarded with a five percent APM Incentive Payment. For performance year 2025 and beyond, QP providers will receive a 0.75 percent conversion factor applied to payments for Medicare covered professional services. Whereas the MIPS program allows for a positive payment adjustment of up to nine percent with most positive adjustments typically around two percent. With the addition of new requirements such as reporting Promoting Interoperability, reporting quality via eCQMs, and the expiration of the APM Incentive Payment, it is becoming less meaningful for providers to participate in Advanced APM models.

Additionally, we are also concerned that the higher differential conversion factor for QPs will make it more difficult for ACOs to reduce spending below benchmark over time as opposed to the former APM Incentive Payment which was not included in FFS payment and therefore did not penalize ACOs. We encourage CMS to work with ACOs and stakeholders to determine an incentive solution that appropriately rewards QP providers for participation in Advanced APM models and ensures higher payments do not negatively impact providers' financial performance in models.

Promoting Interoperability

Trinity Health appreciates CMS's acknowledgement of the need to adopt a measure suppression policy, as well as the proposal to suppress electronic case reporting for PY25 due to the CDC pause of onboarding new healthcare organizations. Trinity Health supports the Promoting Interoperability proposals for both MIPS Promoting Interoperability Performance Category and the Medicare ACO Promoting Interoperability Program. However, we would like to reiterate our prior concerns about the mandatory Promoting Interoperability requirement regardless of QP status. This is a step backwards in being rewarded for participating in an advanced APM and introduces additional financial and administrative burden for model participation, which has providers questioning the value of participation in MSSP ACOs and investments they are making.

New Mandatory Ambulatory Specialty Model

CMS proposes a mandatory Ambulatory Specialty Model (ASM) under CMMI. As proposed, ASM would be a mandatory alternative payment model with five performance years, beginning January 1, 2027, and ending December 31, 2031, with model payment adjustments in 2033. The model would test whether adjusting Medicare part B payments for specialists based on their performance on quality, cost, care coordination and meaningful use of certified electronic health record technology (CEHRT) measures results in improved quality of care and reduced costs, specifically through more effective chronic care management. The model would be focused on the care provided by select specialists at the individual clinician level to Medicare beneficiaries with the chronic conditions of heart failure and low back pain. CMS selected these chronic conditions because they have previously established episode-based cost measures (EBCMs) used for the MIPS cost performance category and are conditions with a large share of Medicare spending, high number of responsible clinicians, and opportunities for care improvement.

Trinity Health firmly believes the solution to addressing high health care costs in the U.S. while improving patient health outcomes is value-based payment, including holding providers accountable for the total cost of care, rather than reimbursing based on volume. We appreciate CMS' continued focus on specialist integration in value-based care, as it is critical to the goal of improving access to high-quality care at lower costs. However, we are concerned that the ASM would compete with and limit specialists' participation in ACOs.

Participation

It remains unclear how potentially duplicative or conflicting attributions and financial methodologies will be reconciled in the ASM. Many ACOs are actively managing populations that include the very same conditions that would be targeted in the model. Requiring specialists in an ACO to participate will exponentially increase administrative burden, create duplicative reporting requirements, and more importantly, unintentionally discourage specialists from remaining in and joining advanced APM arrangements. At a minimum, providers that have QP/Partial QP status should be excluded from the model or allowed to voluntarily opt-in to ASM. Congress created incentives for clinicians to adopt risk arrangements by excluding QPs/Partial QPs from MIPS, including programs like ASM that are built on the MIPS Value Pathways. We believe ASM's mandatory approach does not uphold this statutory intent under MACRA.

Exempting specialists that participate in a total cost of care APM better focuses their resources on how to best integrate specialty care into the work that the total cost of care APM entity is already doing and invested in. Making this change would also encourage more specialists to participate in advanced APM arrangements without undue costs and burdens in creating separate workflows and investing in completely new infrastructure rather than leveraging their existing reporting processes and building from resources already allocated to specialist engagement.

Model overlap

CMS indicates that the ASM payment methodology allows for overlap with other Innovation Center models by avoiding shared savings payments to participants in more than one shared savings model. However, it is unclear how CMMI will implement payment reconciliations to account for financial overlap between models. **Trinity Health recommends CMMI not allow for model overlap between the ASM and other value models.** If CMMI finalizes this policy, additional, granular detail is needed on the methodology for financial reconciliation for providers participating in both models.

Account for statistical variation driven by small numbers

Because ASM proposes to assess individual specialists' performance within a single calendar year, many clinicians will see a very small number of patients that trigger an episode. This creates significant statistical variation, where specialists may appear to have excellent or terrible performance based solely on statistical chance, rather than actual performance. The primary options to address this variation are to (1) increase the low volume threshold (currently proposed at 20 episodes), (2) aggregate performance across multiple years or multiple people (e.g., by allowing clinicians in a practice to pool their results), and (3) risk adjusting the quality measures based on patient's clinical complexity. Trinity Health recommends that CMMI raise the low volume threshold to a minimum of 50 episodes, allow specialists the opportunity to pool with others in their practice, and risk adjust the quality measures.

Policies to support ACOs

ACOs already have the needed infrastructure, experience, and success in managing the health of their populations. We urge CMMI to continue to support incentives for ACOs and create a more level playing field across ACO participants in lieu of creating new specialty models. Trinity Health strongly agrees that specialist integration in value-based care is critical to the goal of improving access to high-quality care and we are supportive of reducing utilization and improving care for patients with low back pain and heart failure, but we urge CMMI to do so more in a more cohesive ACO structure. We are concerned that as more models are developed, they will lead to mismatched incentives that pull providers from ACOs, especially if AAPM bonuses are not extended.

Requests for Information: Value-Based Care

Query of Prescription Drug Monitoring Program (PDMP) Measure

In general, Trinity Health is concerned about a threshold requirement for this measure if moving from an attestation-based measure to a performance-based measure. Our recommendation would be to keep PDMP as an attestation-based measure, however, if the measure is going to move to a performance-based metric, our recommendation is that participants should be credited 10 points for having "1" in the numerator. This credit should be applied until participants can understand performance on this measure and provide additional feedback at that time.

Transition Toward Digital Quality Measurement in CMS Quality Program

Trinity Health welcomes the opportunity to partner with CMS on the transition from our current method of ACO quality reporting via eCQMs to dQMs via FHIR. Initial conversations with our system EHR vendor partner suggest it would be beneficial for this work to include representatives from our internal technical and quality teams, as well as Epic and CMS teams, to ensure a comprehensive conversion strategy is developed and tested that meets the intent and requirements of ACO quality reporting.

Specifically, Trinity Health would like to make two recommendations to support successful electronic ACO quality reporting. First, it would be helpful for QPP and/or ONC to develop EHR requirements for ACO participation that align with the technical requirements for supporting dQMs. CEHRT guidelines do not provide EHR vendors with adequate direction for preparing their platforms for annual CMS reporting, which is an issue we encountered at Trinity Health for the 2025 eCQM reporting transition. We would like CMS to provide guidance that includes a multi-year roadmap of what measures EHR vendors MUST support for annual reporting, and what tech functions (e.g., FHIR, QRDA1 creation) EHRs in an ACO must have enabled to be able to functionally report measures. Second, it would be helpful for the QPP to recommend roles and skills needed at the practices/ACOs to support dQM reporting. Many ACOs and associated practices do not have technically sophisticated staff because such staff were not required in previous years to be successful with quality reporting. Now, with eCQMs and dQMs, ACOs need guidance not only on what their EHRs need to be able to do, but on what kind of technical skills (e.g., DBA) their staff need to be successful with their annual quality reporting.

Requests for Information: Prevention and Management of Chronic Disease

1. How could we better support prevention and management, including self-management, of chronic disease?

CMS could better support prevention and management by continuing to acknowledge and appreciate the proven roles that social drivers of health and health-related social needs play in risk behavior mitigation. Behavioral choices are necessary, but not sufficient, for preventing and

managing chronic disease, and they cannot be divorced from the circumstances within which they are made. For instance, low income populations are at greatest risk for developing chronic diseases. When daily life involves a struggle to meet basic needs like food, housing, and transportation, little energy is available for the mental and emotional processes of learning and health behavior change, and few resources are available to support making healthy choices such as paying for transportation to the nearest grocery store selling fresh produce, which for the 53.6 million Americans is outside of their local community.

While the 2026 proposed rules would eliminate much of the focus on patients' health-related social needs that grew in recent years, health care providers cannot afford to ignore their impact on a patient's ability to understand and adhere to a treatment plan that includes making healthy behavioral choices. As a payor whose decisions impact almost all health care providers in the U.S., we urge CMS to keep health-related social needs in the conversation and work to create conditions that make the healthy behavioral choice realistic for all Americans to make.

2. Are there certain services that address the root causes of disease, chronic disease management, or prevention, where the time and resources to perform the services are not adequately captured by the current physician fee schedule code set? If so, please provide specific examples.

Reimbursement is needed for the systematic, population-level identification and mitigation of health-related social needs. Healthcare providers cannot afford to forgo visibility into patients' health-related social needs, given what is known about the strong influence they have on accessing care and adherence to treatment plans – including the adoption of healthy habits like a nutritious diet and regular physical activity.

As the American Association of Family Practice says, "if you don't ask, you don't know", so routine screening of all patients will continue to be essential for need identification regardless of regulatory requirements. This is in contrast to the service covered by The SDOH Risk Assessment code (G0136) for which CMS recommends removal from the Physician Fee Schedule. G0136 was not applicable for this type of population-level screening nor would the required evidence-based screening tools be feasible for use with every patient. Providing reimbursement for health-related social needs screening using existing codes such as G9919 (screening performed and positive and provision of recommendations) and G9920 (screening performed and negative), as some payors already have, would support systematic identification and mitigation of social factors impeding healthy choices and treatment plan adherence.

3. Are there current services being performed that improve physical activity, where the time and resources to perform the services are not adequately captured by the current physician fee schedule code set? How should CMS consider provider assessment of physical activity, exercise prescription, supervised exercise programs, and referral, given the accelerating use of wearable devices and advances in remote monitoring technology?

Evidence-based group physical activity programs led by trained and certified lay people, like Enhance®Fitness for older adults with arthritis and LIVESTRONG at the YMCA for cancer survivors, have been shown to cost-effectively improve health outcomes, including reducing social isolation for older adults. As with the Medicare Diabetes Prevention Program, referral mechanisms can be set up

between health care providers and the community-based organizations licensed to deliver these programs or Community Care Hubs in which those organizations participate.

Providing reimbursement for such evidence-based programs and permitting community-based organizations to bill for them would promote sustainability and scalability of the services and deepen relationships between health care providers and the communities in which their patients live. Further, covering the cost of medically necessary wearable devices for Medicare patients would reduce barriers to tracking and remote monitoring of patients' physical activity. Wearable devices can facilitate a provider's visibility into the reality of a patient's physical activity and other health behaviors, but not all patients can afford such devices and providers have compliance restrictions around providing items of value to patients.

4. Should CMS consider creating separate coding and payment for medically-tailored meals, as an incident-to service performed under general supervision of a billing practitioner?

CMS should create separate coding and payment for medically tailored meals (MTMs), but consider a model for direct reimbursement to qualified suppliers rather than "incident-to" billing. MTMs are a great example of removing barriers to healthy choices for vulnerable patients. Much like medication, adhering to dietary recommendations can significantly improve the management of conditions that drive costs and utilization, like diabetes and heart failure, but some patients have difficulty understanding recommendations and/or do not have the capacity to purchase or prepare food as recommended. MTMs, which remove these barriers, have been shown to improve malnutrition, blood pressure, BMI, and self-reported health status among the highest-risk patients and reduce health care utilization among patients with diet-sensitive chronic diseases.

These meals are typically provided by non-profit community-based organizations who fund the services through grants and donations. Claims billing opportunities can significantly contribute to both quality and sustainability of the services. An "incident-to" model would be preferable to no reimbursement, but there is administrative burden associated with this billing mechanism. Unlike incident-to services such as Care Management, health care provider practices/systems do not typically provide MTMs themselves; CBOs are incurring the cost of providing the services, but the revenue is being sent to the initiating provider's practice. This increases accounts receivable days for community-based nonprofits that are often operating with limited cash reserves. In addition, incident-to billing requires development of many individual initiating/billing provider relationships, which is administratively more burdensome to scale.

As with the Medicare Diabetes Prevention Program provided by CDC-recognized organizations qualified as Medicare Suppliers, direct billing opportunity for qualified MTM suppliers (such as those accredited through the Food is Medicine Coalition) would empower CBOs to simplify workflows with referring providers, receive revenue more timely, and hold more ownership over their business model. Provider referral is already a leading mechanism for connecting patients to MTMs, so requiring a provider referral is a realistic way to ensure that appropriate patients are being served when it is medically necessary.

5. If so, what would be the appropriate description of such a service, and under what patient circumstances (that is, after discharge from a hospital)?

Because MTMs help to avoid hospitalizations, it would be preferable to identify the need for this service in the ambulatory setting, before conditions progress to the point of hospitalization. Patients with diet-sensitive chronic conditions who self-report food insecurity via social needs screening would be a logical priority population for this service.

- 6. Do community-based organizations providing medically tailored meals currently employ a physician, nurse practitioner, physician assistant, or other practitioner who could both bill Medicare and supervise a medically-tailored meal service?
 - No, it is not typical nor realistic for many community-based social service organizations to employ physicians or advanced practice providers due to the cost of such staff.
- 7. Should CMS consider allowing billing providers to refer to community-based organizations to deliver and ensure quality of medically-tailored meals while under general supervision (please see § 410.26(a)(3) for further information about general supervision) of the referring billing provider?
 - Yes, if the benefit is designed with an "incident-to" model. It would be neither realistic nor appropriate for meals to be prepared or provided with the billing provider on-site.
- 8. If CMS were to create separate coding and payment for medically-tailored meals, how should CMS ensure integrity of the service being delivered?
 - Designate an accrediting body to develop and ensure compliance with service delivery standards. For MTMs, the Food is Medicine Coalition already serves this function¹⁷.

Conclusion

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

Sincerely,

/s/

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