

September 6, 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-1770-P; Medicare and Medicaid Programs; CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts

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

Dear Administrator Brooks-LaSure,

Trinity Health appreciates the opportunity to comment on policies proposed in CMS-1770-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 115,000 colleagues and nearly 26,000 physicians and clinicians caring for diverse communities across 25 states. Nationally recognized for care and experience, the Trinity Health system includes 88 hospitals, 131 continuing care locations, the second largest PACE program in the country, 125 urgent care locations and many other health and well-being services. 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 \$20.2 billion with \$1.2 billion returned to its communities in the form of charity care and other community benefit programs.

Trinity Health has 17 Clinically Integrated Networks (CINs) that are accountable for approximately 2 million lives across the country through alternative payment models. Our health care system participates in 14 markets with Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs), which includes eleven markets partnering in one national MSSP Enhanced Track ACO, Trinity Health Integrated Care. Two of the 14 markets also participate in CPC+. In addition, we have had 33 hospitals participating in the Bundled Payments for Care Improvement Advanced (BPCIA) initiative, and three hospitals in the Comprehensive Care for Joint Replacement (CJR) program. Our work—and experience in value-based contracting—also extends beyond Medicare as illustrated by our participation in 123 non-CMS APM contracts.

Unwinding the Public Health Emergency (PHE)

The flexibility provided by CMS has been integral in our ability to respond to the COVID-19 pandemic and care for our patients. This flexibility was created through a complicated patchwork of waivers, regulations, enforcement discretion and other guidance. We appreciate CMS recognizing how significant the end of the PHE is and working to develop a framework for unwinding the various authorities provided. Hospitals and physician offices developed a significant amount of system programming and logic to respond to the PHE, we urge CMS to continue to be mindful of the need for plenty of time to undo this complex system programming hospitals and physician offices have put into place throughout the PHE. Examples include automation of modifiers (e.g. CS), of condition codes (e.g., DR, 90, 91) and of charging for facility component of telehealth visit based on documentation elements.

The Administration has stated a 60-day notice will be provided prior to ending the PHE and while this notice is important and appreciated, it may not allow enough time to return to normal practices and undo the build put in place to accommodate flexibilities under the PHE. We ask that a six-month grace period be provided to allow hospitals/physician offices time to reverse all of the programming and practices that have been established over the last 2 and ½ years.

Payment Updates

The proposed conversion factor for 2023 is \$33.08, a whopping 4.4% reduction from 2022. This cut would be in addition to the 2% sequester that was fully reinstated July 1, 2022 and a 4% PAYGO cut scheduled to take place in 2023. In total, the proposed decrease in the conversion factor, the sequester, and the pending PAYGO cuts would reduce Medicare reimbursement for Part B services by more than 10%. 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. 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 understands the conversation 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. We urge CMS to consider recent data sources and exercise the full extent of the Agency's flexibilities to avoid payment cuts.

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

Payment for Evaluation and Management (E/M) Visits

CMS proposes to adopt new CPT codes and descriptors for certain E/M services to align with revisions made by the CPT Editorial Panel. Trinity Health supports these changes, as they would allow providers to use one set of guidance and reduce administrative burden.

Split (Or Shared) E/M Visits

CMS proposes to delay until 2024 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. Trinity Health supports this delay and echoes concerns that this policy 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 urges CMS to maintain time and medical decision-making as key determinates of which physician or practitioner bills for an E/M visit.

<u>Telehealth</u>

The proposed rule codifies authority provided by the Consolidated Appropriations Act that allows for certain key telehealth flexibilities provided by Congress to continue 151 days beyond the end of the public health emergency (PHE), including: originating site and geographic area flexibility, allowing audio-only for certain services, and allowing physical and occupational therapists and speech language pathologists to furnish services via telehealth. In addition, CMS is proposing to add 53 services to the new telehealth Category 3 list, which would allow providers to continue furnishing these services using telehealth while CMS collects information on clinical benefits.

Beginning on the 152nd day following the end of the PHE, CMS is proposing to revert payment back to pre-PHE rules. This proposal would revert payment for these telehealth services at the lower facility rate. The staffing and resources needed to provide telehealth are not materially different than an in-office visit. Trinity Health urges CMS to continue to pay appropriately for telehealth services at the non-facility payment rate so as not to pay providers less for the same care.

In addition, CMS is proposing to discontinue the separate payment for audio-only E/M services at the end of the PHE. Trinity Health recommends CMS continue separate payment for these audio services, as many patients do not have access to the devices or the broadband services necessary to receive care through video-based technology.

We have seen firsthand how 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. At a minimum, we encourage CMS to extend the policies allowed during the COVID-19 PHE for a sufficient number of years to collect robust data on patient outcomes and satisfaction and access to care for Medicare beneficiaries, especially in rural areas and in communities with shortages of healthcare personnel.

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.
- Clarify the facility component of telehealth offered in a provider-based clinic is eligible for reimbursement.
- Reimburse providers for telehealth services in home health benefits.
- Include attribution to an ACO as evidence of an existing provider/patient relationship.
- Maintain flexibility for remote-patient monitoring and reimburse for this service, including when provided through home health.
- Allow clinicians to be reimbursed for telehealth when seeing new patients or a patient not previously seen at their practice.
- Remove limitations on frequency of services.
- Advance policies that ensure access to affordable broadband, technology resources, and telehealth services for communities of color and other underserved populations.
- Allow providers to practice across states lines and at the top of their license, including medication prescription and flexibility to allow physicians to treat their patients while in a state where they may be temporarily located.

Opioid Use Disorder Treatment Programs (OTPs)

CMS proposes a few updates to the pricing methodology used for certain aspects of the bundled payment for episodes of care for the treatment of opioid use disorder furnished by OTPs, including methadone pricing, individual therapy rates, telehealth, and clarifying coverage of mobile OTP units.

Trinity Health supports these policies, which will lead to increased access for OTPs.

Revising the Medicare Economic Index (MEI)

CMS is proposing to 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.

Trinity Health has 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 is planning to collect new data next year. Trinity Health urges CMS to wait for the revised AMA data rather than use the proposed Census and other data that would result in large redistributions. At minimum, CMS should postpone this policy by at least one year to allow for a more thorough evaluation of its impact.

Payment for Vaccine Administrative Services

If finalized, CMS would make a series of changes to payment for vaccine administration, including: annually updating the payment amount for the administration of Part B preventive vaccines based on the increase in the Medicare Economic Index; adjusting payment using the geographic adjustment factor (GAF); and

updating the \$40 payment amount for COVID-19 vaccine administration using the MEI as long as the Emergency Use Authorization (EUA) declaration is still in place.

Given the concerns raised on the proposed MEI policy notes above, Trinity Health recommends CMS not change payment for vaccine administration using the MEI at this time.

Requiring Hospital Outpatient Departments and Ambulatory Surgical Centers to Report Discarded Amounts of Certain Singe-Dose or Single-Use Package Drugs

The proposed rule would implement provisions of the Infrastructure Investment and Jobs Act that requires drug manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. CMS will require HOPDs and ASCs to report the JW modifier to identify discarded amounts of these drugs as well as a new modifier, JZ, in cases where no billing units of such drugs were discarded and for which the JW modifier would be required if there were discarded amounts.

Requiring reporting of the new JZ modifier will create additional administrative burden for providers. Trinity Health urges CMS to simply ensure that providers properly report the JW modifier as required and not impose additional administrative burden by finalizing the JZ modifier proposal. If onus is placed on hospitals, physician offices, and now ASCs to appropriately and completely report JW modifier as required, the JZ modifier is not necessary. It is also essential for CMS to determine mechanisms for decreasing provider burden associated with documentation. Should CMS finalize the JZ modifier, we recommend the agency provide a 12-month runway for implementation to give providers additional time to prepare to meet the reporting requirement. Extending the implementation timeframe would be consistent with prior policy on the JW modifier, as CMS provided about 8 months for implementation of the modifier.

The proposed policy is not just a simple modifier substitution-- this is different work because extra programming is required to first determine if JW is present and, if not, then apply the JZ. Depending on when the PHE expires, the 12-month extension would also provide a grace period for compliance as hospitals begin to unwind systems and other requirements that were put in place during the PHE.

Clinical Laboratory Fee Schedule (CLFS)

CMS proposes to codify and clarify various laboratory specimen collection fee policies, which are currently described only in the Medicare Claims Processing Manual.

Trinity Health supports the codification of these policies and urges CMS to continue paying for the collection of the nasal and throat specimens for COVID-19 and the flu after the expiration of the PHE.

"Incident To" Physician Services Regulation for Behavioral Health Services

CMS proposes to amend the direct supervision requirement under the "incident to" regulations to allow behavioral health services to be furnished under the general supervision of a physician or non-physician practitioners (NPP) when these services or supplies are provided by auxiliary personnel incident to the services of a physician or NPP.

Currently, there is no separate benefit category under the statute that recognizes the professional services of licensed professional counselors (LPCs) and licensed marriage and family therapists (LMFTs), so payment cannot be made under the PFS for services made by these professionals. Trinity Health is pleased to see these changes that will allow for the potential hiring of additional clinicians to increase access for patients.

New Coding and Payment for General Behavioral Health Integration (BHI) Billed by Clinical Psychologists (CPs) and Clinical Social Workers (CSWs)

Trinity Health supports CMS' efforts to expand the Psychiatric Collaborative Care Model. A number of Trinity Health sites in Michigan are successfully implementing this model and seeing improved health outcomes and patient and provider satisfaction.

CMS proposes to create a new G code, CBH11, describing General BHI performed by CPs or CSWs to account for monthly care integration where the mental health services furnished by a CP or CSW are serving as the focal point of care integration. There is an increasing need for BHI and having additional options for billing, coding and documentation will only make it easier to increase access for patients.

Trinity Health encourages CMS to consider policies that further BHI including:

- Support increased behavioral health training for primary care providers (PCPs).
- Align payment policies and quality incentives in clinically integrated networks and across payers to facilitate integrated care and reduce administrative burden.
- Encourage states and payers to eliminate restrictions on same-day billing for more than one service per day, a barrier to integrated care.
- Allow psychiatrists, psychologists, social workers, nurses, care coordinators, CHWs and peer support
 specialists to practice in collaborative, team-based environments according to their highest level of
 education, training and licensure.

Comment Solicitation on Payment for Behavioral Health Services Under the PFS

COVID-19 and the resulting physical and economic anxiety and social isolation have exacerbated what was already a major strain on the delivery of behavioral health services across the nation. Addressing this crisis requires breaking down barriers to care, such as workforce shortages and lack of reimbursement, ensuring that access to care across the continuum can be better supported. Trinity Health supports CMS' goal to improve access to and quality of behavioral health services.

CMS solicits comments on how it can best ensure beneficiary access to behavioral health services, including any potential adjustments to the PFS rate setting methodology. Inadequate and inconsistent reimbursement rates for behavioral health continue to be the top challenge identified by providers across Trinity Health and have forced our health system, in some cases, to transition away from providing services as it was not financially sustainable.

While Medicare does include treatment services for behavioral health, coverage and reimbursement can be limited. Medicare currently does not cover crisis services (crisis stabilization unit, behavioral health urgent care). Additionally, Medicare beneficiaries can have difficulty accessing detox services for alcohol use disorder. Trinity Health recommends CMS consider opportunities to expand coverage and access to these services.

Medicare Shared Savings Program

Advanced Investment Payments

Trinity Health supports the overall proposal of the Advanced Incentive Payment for new groups entering into ACOs. This policy will help groups lower their upfront investment to enter into these models and would encourage CMS to consider allowing those groups who have applied for a 2023 start an opportunity to submit supplemental AIP application and receive AIPs beginning in 2024 to prevent ACOs from delaying their start dates from 2023 to 2024 to receive AIPs. We also support the proposed use of payments as we believe these are the

categories of need for smaller ACOs. We urge CMS to consider lowering the 5000-beneficiary threshold to become an ACO so that more groups may join and take advantage of this proposal to invest in their communities. In order to address concerns about actuarial soundness with fewer lives, CMS could settle multiple years (2-3) together, rather than settle each year individually.

Transition to Performance-Based Risk

We support the extended glidepath to risk in order to attract smaller, inexperienced providers. However, the high/low revenue distinction can be arbitrary, and all ACOs need a greater share of the savings they create. Even within Trinity Health, with the same essential structures, we have markets which would be considered high revenue and others low revenue, simply based on whether they bill under a hospital TIN. We urge CMS to eliminate the high/low revenue distinction to ensure all vulnerable providers, such as rural and safety net providers, have a reasonable progression to risk. Evaluations show that ACOs with FQHCs, RHCs, and CAHs as participants will be qualified as high revenue and therefore would be permitted less time in upside-only models as currently proposed despite these providers having limited access to capital to invest in ACO activities. CMS has acknowledged the historic lack of access to health care in underserved communities [and these entities] still lack the significant resources and infrastructure necessary to meaningfully address patients' social drivers of health (SDOH) and overcome longstanding inequities in our health system. CMS should instead consider alternative approaches, such as evaluating the demographics of the population served by an ACO. The high/low revenue status is arbitrary and leaves out the very ACOs CMS is trying to attract to the program.

We would also like to see CMS go further and create a payment model for FQHCs and Critical Access/Rural hospitals that removes barriers to participation by providers in cost-based reimbursement models. Short of a different benchmarking approach for these entities, such providers participating today should be allowed the full on-ramp to risk proposed here for new entrants even through their next agreement period. Such a provision would allow these providers to continue to participate on their own for the fully proposed 7 years without having to move to two-sided risk or feel pressured to consolidate, reorganize or join a convener organization to avoid risk in a program that was designed for a different payment model.

We support CMS for proposing to make the Enhanced Track optional for all ACOs, allowing to continue to participate in the Basic Track Level E indefinitely. ACOs that choose this level of risk/reward are still contributing greatly to the Trust Fund and assuming substantial levels of risk. This policy change, if finalized, will contribute to the long-term goals of the model. We also support the proposal of allowing ACOs currently participating in Basic Track Level A or B the option to remain in upside-only Track for the duration of their agreement period.

Financial Methodology Changes

Trinity Health is pleased to see CMS take effort to create fairer, more accurate financial benchmarks. We would ask that CMS allow current ACOs to opt into certain policies beginning in 2024 without going through the onerous process of early renewing.

In addition to the financial policies proposed in this rule, Trinity would urge CMS to consider adding a full risk track within MSSP building off of the success of Next Gen. We would also like to see CMS incorporate learnings from the Next Gen model into the MSSP program such as the frequency and types of financial reporting. Specifically, Trinity requests that CMS consider adding the Quarterly Benchmark, Claims Lag, and Monthly Expenditure Reports to the reporting package of the MSSP program. These reports added transparency, predictability and supported our efforts to reduce the overall cost of care.

Reducing 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.

We also agree that the calculation of the regional adjustment under prospective assignment should mirror the time period that corresponds to the ACO's assignment window. However, we ask CMS to consider ways to mitigate the negative impact of the benchmark as nearly 40% of ACOs use prospective assignment, including Trinity ACOs, and may experience a lower benchmark due to this change.

Improving the Risk Adjustment Methodology to Better Account for Medically Complex, High-Cost Beneficiaries CMS proposed to account for changes in demographic risk scores for an ACO's assigned population between BY3 and the performance year before applying the 3% cap on positive HCC scores for agreement periods starting 2024. While we appreciate what CMS is doing to try to lessen the impact on coding intensity, we have concerns about the amount of complexity within the model. We also have concerns about modeling such an impact to predict performance in the models and are concerned the current policy would drive inequity. Disabled and dual eligible beneficiaries are more than twice as likely to hit the current 3% cap as those in the aged non-dual category. Trinity Health recommends CMS apply the risk score cap after accounting for demographic changes at the aggregate level rather than at the enrollment type. We also recommend CMS implement a floor on the risk score and to adjust for COVID, and apply a cap to the increase, if any, that is the same for all Medicare populations, creating a level playing field for all Medicare APMs.

Impact of the PHE for COVID-19 on ACO's Expenditures

CMS indicated in the proposed rule that using the combination of 2020 and 2021 years was reasonable to base future benchmarks since spending rebounded in 2021. We have ongoing concerns about using COVID-19 in benchmark calculations. While on a national level, there may not be a large impact, but COVID-19's impact was not uniform across the entire country and therefore impacted regions differently. Certain regions have been slower to recover from the pandemic's impact, making the combination of 2020 and 2021 still not enough to mitigate potential negative effects on their benchmarks. As noted below, we noticed a wide variation between markets when using a national trend compared to regional. As such, we urge CMS to allow ACOs the opportunity to elect pre-pandemic years for benchmarks.

Incorporating a Prospective, External Factor in Growth Rates Used to Update Historical Benchmark

CMS proposes to add an "Accountable Care Prospective Trend" (ACPT) to update historical benchmarks. This would count as one-third of the trend with the existing national-regional blended growth rate compromising the other two-thirds. We are supportive of CMS taking the first step in adding a prospective component to the trend. We'd like to see the math behind what CMS is doing to come up with the prospective trend, described as a "variant of the USPCC." In addition, we'd like to see how this is built and what adjustments are being made over the 5-year period.

We recommend CMS evaluate the impacts of continuing to use a two-factor benchmarking methodology but: (1) replace the current national trend factor with the ACPT trend factor, and (2) remove an ACOs beneficiaries from the regional trend calculation. Under this approach, CMS would continue to weight the regional trend factor by the ACOs market share and thus combine the benefits of a prospective national ACO-specific trend with a more accurate assessment of regional spending changes. This approach would also directly address the "rural glitch" issue on which HCTTF has previously commented whereby ACOs that represent a majority of their markets are

penalized for their efforts to control costs. Further, this approach would represent a reasonable transition state while CMS develops a fully Administrative benchmark methodology.

If CMS does finalize the proposed three-way trend update, Trinity strongly urges that significant guardrails are put in place to protect ACOs who would see lower benchmarks because of the ACPT.

Seeking Comment on Incorporating an Administrative Benchmarking Approach Into the MSSP

CMS seeks feedback on how it can implement a prospective, administratively set annual growth rate to update benchmarks. Trinity supports the concept of administrative benchmarks and ask that CMS engage us and other stakeholders throughout development. We believe there needs to be better accounting for regional variations in spending so that ACOs are not penalized based on their geography. If the agency does move forward with a prospectively set trend, we recommend CMS use a regional calculation, rather than a national as we have seen wide variability between regional and national trends as we look at our markets. According to our data for all of our markets, the 2017-2019 trend (pre-COVID-19) and 2019-2021 trend (through COVID-19) vary wildly when compared to the national trend. Essentially an 18% variance from one to the other. Please see table below for more information.

	2021		Variance to
	Membership	2019-2021 Trend	National
South Philadelphia	5,838	0.9008	-6.7%
Columbus, OH	10,891	0.9079	-6.0%
North Philadelphia	11,264	0.9454	-2.2%
South Bend	7,655	0.9565	-1.1%
National		0.9675	0.0%
New Jersey	19,039	0.9798	1.2%
Syracuse	19,110	0.9821	1.5%
Chicago	23,476	1.0000	3.3%
Albany	23,937	1.0011	3.4%
Wilmington, DE	12,889	1.0167	4.9%
Boise	7,802	1.0238	5.6%
West Michigan	13,637	1.0779	11.0%
	Range of Variance		17.7%

Health Equity Adjustment to Benchmark

CMS is thinking about looking at the Area Deprivation Index (ADI) at the national level and trying to use that to "rank" areas of highest need and modify benchmarking financial metrics based on the amount of beneficiaries an ACO serves at certain ADI levels.

Trinity Health has concerns using the ADI ranking for this adjacent because 1) it does not include race/ethnicity as a variable, and 2) it considers "increased healthcare usage" to be an indicator of socioeconomic disadvantage. Further, it does not take into account some of the very important socioeconomic reasons why health care usage may be *low* in a given area – examples include: services aren't nearby or are not easy to access with public transportation; many people are uninsured or have high-deductible plans and avoid seeking care; individuals cannot take time away from work so they don't seek care. Areas like this would not be

considered high on the ADI but may in fact be very vulnerable. In addition, we know that structural/systemic racism impacts health, so it is problematic to leave out this important variable.

Should CMS finalize this policy, we recommend they use the Social Vulnerability Index (SVI), as it's at the county level instead of the census tract level and includes race as a factor in addition to socioeconomic factors.

Quality

Trinity is pleased to see CMS taking steps to improve quality performance standard requirements for ACOs. However, Trinity Health still has significant concerns with the move to all-payer eCQM/MIPS CQM reporting to evaluate ACO quality. 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. Alternatively, we strongly propose that CMS consider continuing using a sample of the ACO's population in determining quality performance in the MSSP program. Further, CMS should work with ACOs and the electronic health record (EHR) vendor community to find solutions to data aggregation problems. Until these resources and solutions are widely available, eCQMs should not be mandated for ACOs. We urge for continued delay of eCQM or allow ACOs to continue to choose to report through either the eCQM or the web interface.

Trinity Health supports the re-implementation of a sliding scale approach to shared savings in regard to quality performance standard as well as the extension for the incentive in reporting via the eCQM mechanism. We still would appreciate more information on the Quality Performance Standard determination related to measurement for the MSSP ACO, as well as having a known target for measures in advance of performance years. Trinity Health would also like to see more transparency in performance data throughout the performance year to better target and implement specific interventions based upon the ACO specific data.

CMS proposes to establish a health equity adjustment that would award bonus points to the quality performance score for ACOs delivering high quality care to underserved populations. The bonus points would only be available to ACOs reporting eCQMs or MIPS CQMs. While Trinity supports this concept of a bonus opportunity, we believe that if an adjustment is implemented it should be implemented additionally for those ACOs reporting via the web interface until expiration. We also need more detail from CMS that utilizing the area deprivation index (ADI) is the appropriate measurement tool to differentiate by regional populations. We appreciate the approach of a positive impact only, but to achieve policy CMS needs to ensure that we are accurately identifying underserved populations without extrinsic factors influencing the measurement criteria.

Reducing Administrative Burden for ACOs

Trinity Health supports the removal of the requirement that ACOs submit marketing materials to CMS before use as this reduces the processing and approval time required by CMS. We also support the reduction of the frequency of the annual standardized written notices to beneficiaries to once per five-year agreement period. However, CMS is proposing 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. While these requirements were intended to reduce administrative burden, requiring two notices increases the burden in the first performance year of the agreement period, which is the most administratively intense. Trinity Health urges CMS to reconsider this requirement as we believe it will cause extra beneficiary confusion and frustration.

We have received direct feedback from our beneficiaries in focus groups that tell us the current standard 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 will be extremely burdensome to the 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. In addition, we urge CMS to allow flexibility for ACOs to tailor the language of the current written notice within standards defined by CMS regarding what the letter must and cannot say. This would enable us to use this opportunity to educate patients on the benefits of the ACO as we believe information would be more beneficial to patients.

Request for Information: Adding Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health Measures

CMS seeks comment on the future inclusion of two new measures in the MSSP quality measure set: screening for social drivers of health and screen positive rate for social drivers of health measures.

Trinity Health supports adding these new measures in the MSSP quality measure set. In addition, we support the potential future question for the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS survey outlined in the rule that would address health disparities and patient experience with discrimination. We strongly encourage CMS to include race/ethnicity and language skills as potential responses to this survey.

Quality Payment Program

Request for Information: QPP Incentives Beginning in PY 2023

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. As we continue to build upon our ACO and other AAPM model provider base, changing the bonus criteria to the proposed adjustment is a drastic reduction in payment for their participation. The APM bonus has been a strong component of providers (both primary care and specialty) considering participation in AAPM models. Trinity is concerned that providers may lose incentive to participate thus lowering the amount of Medicare beneficiaries that are managed under an AAPM arrangement. This goes against ours, and the CMS stated goals of continuing to grow Medicare FFS beneficiaries under AAPM models.

Trinity also has concerns that qualifying APM participant thresholds are scheduled to increase to 75% for payments and 50% for patient counts in 2023. This increase will put our ACO providers at risk of achieving the QP threshold and cause our ACO to remove providers like specialists who have lower thresholds.

Without an extension of the 5% incentive payment and adjustments to the QP thresholds, growth in AAPM models will slow. The lack of incentives for risk-based models will make it more difficult for CMS to achieve the goal of having all traditional Medicare beneficiaries in accountable care relationships with their providers by 2030. We encourage CMS leadership to work with congressional leaders to support an extension of the 5% AAPM incentive payments and use the agency's authority to lower the QP threshold through the patient count method.

Low-Volume Exceptions

To bring more providers in to value-based care and maintain momentum away from FFS, Trinity Health recommends CMS eliminate the low-volume exceptions to MIPS. This policy has the adverse impact of limiting rewards for high performers and allows a substantial portion of physicians to stay outside the value-based framework.

Request for Information: Potential transition to Individual QP Determinations Only

CMS is requesting public comment on transitioning away from an APM entity level QP determination and instead making QP determinations at the individual eligible clinician level for all eligible clinicians in AAPMs. Trinity Health supports keeping the QP determination criteria at the entity level and not moving to an individual provider QP determination. Today many specialists would never meet the threshold rates for payment or patient count without being subsidized from the PCP participation. If the criteria changes many of our specialists would no longer become QPs and their incentive to be AAPM participants would be removed. Specialists are critical for our ACO programs for care coordination and quality of our patients care.

In addition, changing the QP determination to the individual level would also increase administrative burdens on ACOs and providers who may additionally become confused on their eligibility for QP status. Instead of changing the QP determination, Trinity Health encourages CMS to pay future APM incentive payments directly to the APM entity to then distribute to providers. This would align with how CMS pays the ACO for shared savings.

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 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