



October 1, 2020

Seema Verma, Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1734-P- Medicare Program; CY 2021 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy

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

Dear Administrator Verma,

Trinity Health appreciates the opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS) proposed CY 2021 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy. Our comments and recommendations reflect a strong interest in public policies that support better health, better care and lower costs to ensure affordable, high quality, and people-centered care for all.

Trinity Health is one of the largest multi-institutional Catholic health care delivery systems in the nation, serving diverse communities that include more than 30 million people across 22 states. We are building a People-Centered Health System to put the people we serve at the center of every behavior, action and decision. This brings to life our commitment to be a compassionate, transforming and healing presence in our communities. Trinity Health includes 94 hospitals as well as 106 continuing care locations that include PACE, senior living facilities, and home care and hospice services. Our continuing care programs provide nearly 2.5 million visits annually. Committed to those

who are poor and underserved, Trinity Health returns \$1.2 billion to our communities annually in the form of charity care and other community benefit programs. We have 35 teaching hospitals with graduate medical education (GME) programs providing training for more than 2,000 residents and fellows in 184 specialty and subspecialty programs. We employ approximately 123,000 colleagues, including more than 6,800 employed physicians and clinicians, and have more than 15,000 physicians and advanced practice professionals committed to 16 Clinically Integrated Networks (CINs) that are accountable for approximately 1.5 million lives across the country through alternative payment models.

Trinity Health participates in 11 markets with Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs), which includes five markets partnering as an MSSP Track 3 ACO. We also have three markets partnering as a Next Generation ACO and 2 participating in CPC+. In addition, we have 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.

We welcome the opportunity to continue to partner with CMS and other stakeholders to implement policies that support delivery of high-quality, people-centered care.

I. Provisions of the Proposed Rule for the Physician Fee Schedule

Professional Scope of Practice

CMS proposes several policies that would reduce supervision requirements and make permanent flexibility provided during the COVID PHE, including allowing NPs, CNSs, PAs, and CNMs to supervise diagnostic tests consistent with state law and scope of practice requirements. **In general, Trinity Health is supportive of the increased flexibility and applaud CMS for reducing burden.**

Payment for Specimen Collection for COVID-19 Tests

Trinity Health supports CMS permanently extending payment for specimen collection for COVID tests after the PHE. We expect the COVID-19 virus to be with us well into CY2021 and it is appropriate for CMS to continue to pay for testing for as long as the virus is a threat.

Psychiatric Collaborative Care Model (CoCM) Services

We support CMS' proposal to establish new G-code GCOL1, as it integrates behavioral health into primary care and will allow for payment of care management.

Remote Physiologic Monitoring Services (RPMs)

In the proposed rule, CMS clarifies several CPT codes used for RPM and makes flexibility provided through the COVID PHE permanent. We support the proposed changes and see this as a positive step. With the expansion of telehealth, RPMs are more critical. **In addition, we urge CMS to develop additional RPM codes for services provided within a briefer time period to aid providers in monitoring and follow-up for patients at risk for hospital readmission.**

One Year Delay of Electronic Prescribing Requirements

Trinity Health strongly supports the one-year delay in implementation for the electronic prescribing requirements under the SUPPORT Act and appreciates CMS reducing burden for this requirement at this time. Trinity Health is committed to the use of Electronic Prescribing for both non-controlled and controlled medications. This is evidenced in that, as of today, Trinity has successfully deployed Electronic Prescribing for non-Controlled medications in all our Health Ministries within our hospitals and physician office practices. In addition, Trinity utilizes EPCS in most of our Health Ministries and was on track to successfully deploy to the remaining sites by July 2021. This would have been accomplished through our system wide Electronic Health Record standardization work as we are moving all our sites to EPIC. However, the COVID pandemic required us to reprioritize our work and resources – both human and financial - to properly support both our colleagues caring for and the patients and families impacted by this unfortunate event. Today, we are once again moving forward with our deployment of the EPIC Electronic Health Record across Trinity with a newly released timeline for implementation. Unfortunately, with the challenge of COVID, that timeline is further delayed even with our best intentions.

Telehealth and Other Remote Services

Trinity health's telehealth experience during COVID

Telehealth flexibilities from Congress and HHS in response to COVID relaxed long-standing barriers to providing care through telehealth. These valuable telehealth changes have offered several advantages, including keeping patients and providers safe from exposure, preserving personal protective equipment, and allowing patients access to their existing physicians, which has been critical for patients with chronic conditions. Further, these changes pushed health care in the direction it needed to go. Telehealth has created a new standard--and expectation—for how we deliver care.

The positive experience Trinity Health has had with the increased adoption and expansion of telehealth across our health system makes it clear telehealth is a critical component for how we provide high quality, patient-centered care moving forward. Recent patient surveys were overwhelmingly positive about their virtual interactions with care providers and this held true even when technological challenges arose (indicated for lower scores with technology-related items). In addition, patients reported our clinicians are successfully meeting their interpersonal communication needs through telehealth. During COVID, our "likelihood to recommend" responses have been consistently high (93%-94%) at a time in which patients have been more actively using telehealth. CBO has often scored telehealth expansions as a cost due to increased utilization; however, we have not experienced an increase in new patients or services we would not have otherwise provided (consistent with [findings](#) from multi stakeholder Task Force on Telehealth Policy).

Telehealth has enhanced the personalization of medicine. Providers are able to reach out into the home and see patients' surroundings, use tech that allows providers to continually monitor important information remotely—such as blood pressure and blood sugar levels. Staff are able to provide care at the right time and in the place that meets patient needs, more easily catching and tracking conditions *before* they develop into health issues that are more dangerous for the patient and harder to address. We anticipate more access to telehealth will save costs due to prevention and more

person-centered, efficient management of conditions. In addition, the population in the United States is ageing rapidly and we have not increased the supply of physicians or other health care providers. Telehealth is a critical tool to address our rapidly ageing population and health care workforce challenges.

Fraud

The expansion and increased adoption of telehealth have prompted concerns of fraud and abuse. However, telehealth has the same processes and checks and balances as in-office visits. Similar to in-office visits, there are documentation requirements and CMS can monitor visits for utilization, variances, and outliers. Further, telehealth visits have more stringent requirements for documented inputs such as consent and time. Trinity Health is conducting audits of telehealth visits to ensure compliance and appropriate education is given to providers and to date, we see the same adherence rate as we see for in-person visits across our health system.

Expansion of telehealth services

CMS proposes several changes related to telehealth services beyond the PHE, including extending flexibilities provided during the PHE on a permanent or temporary basis.

Trinity Health appreciates the telehealth flexibilities provided to-date during the COVID PHE. The positive experience Trinity Health has had with the increased adoption and expansion of telehealth across our health system makes it clear that telehealth is a critical component for how we provide high quality, patient-centered care moving forward. **Assuming that the end of the PHE coincides with the end of the COVID-19 pandemic**, Trinity Health is supportive of the three proposed telehealth categories. We are concerned however, that CMS proposes to define the duration of Category 3 services to the end of the calendar year in which the PHE expires. **Instead, we recommend CMS set a defined time period, such as the end of the 2023.** This would provide sufficient time for data collection and analysis to demonstrate clinical benefit, as well as provide time for stakeholders to submit requests to CMS for moving a Category 3 service permanently to the telehealth list.

Frequency for telehealth in nursing homes

Trinity Health supports revising the frequency limitations for telehealth nursing facility visits to once every three days compared to the existing policy of once every 30 days. Trinity Health also supports allowing physicians and NPPs to perform required nursing home resident visits using two-way, audio/video telecommunication when due to continued exposure risks, or other factors, the clinician determines an in-person visit is not necessary.

In addition, Trinity Health supports maintaining the ability for nursing home visits to be conducted via telehealth beyond the PHE, permanently allowing for two-way, audio/video telecommunications for required nursing home resident visits when, due to continued exposure risks, or other factors, the clinician determines an in-person visit is not necessary.

Audio-only telehealth

Trinity Health supports CMS permanently codifying payment on a permanent basis audio-only visits and developing coding and payment similar to a virtual check-in for a longer unit of

time. We understand some may have concerns this would drastically increase patient visits; however, to-date we are not seeing a high number of patients we have not seen before.

Critical care services and telehealth

There are instances for which telehealth in an ICU can be incredibly beneficial and reduce mortality. For example, if a patient has a problem with a ventilator, a provider can have a telehealth visit using a two-way camera, listen to lung sounds, and help identify the problem and prescribe a solution. **Trinity Health recommends CMS either better define or relax parameters to allow for audio and visual telehealth in an ICU. We recommend CMS consider utilizing or monitoring E-ICU with provider-based codes for provision of services, similar to what is done for neonatal intensive care units.**

Facility component of telehealth

Trinity Health recommends CMS continue to reimburse hospitals for a facility component after the end public health emergency (PHE). Hospitals will continue to have costs related to staffing and office space post PHE and while physicians may continue to have the same number of "visits", the facility will lose reimbursement for each telehealth visit after the PHE.

Medicare Shared Savings Program Quality Measures

CMS proposes a complete restructuring of the quality program through the APM Performance Pathway (APP), a new—and undefined—reporting process and an increase to the quality threshold for MSSP, while at the same time reducing burden for other types of ACOs. **Trinity Health does not support these significant changes and strongly urges CMS not to finalize these policies during the ongoing COVID pandemic. Rather, CMS should engage stakeholders to determine appropriate measures and implementation timeline. In addition, ACOs need CMS to address quality reporting for 2020. Trinity Health urges CMS to make 2020 a pay for reporting year due to COVID.**

Quality Measures

Trinity Health has long advocated for CMS to streamline and simplify the current 23 quality measures. Specifically, we have asked CMS to reduce the number of overall measures and merge eQMs and ACO measures. We applaud CMS attempt at burden reduction; however, Trinity Health is concerned with changes to the measures and reporting as proposed.

Proposed measures

The proposed six quality measures focus on the most expensive patients and those who would be most vulnerable for COVID and at risk for adverse outcomes. Two of the measures are specifically impacted by COVID as they focus on patients with chronic conditions; **Trinity Health has concerns from a quality standpoint how these will be an accurate measurement. Further, CMS needs to clarify whether the proposed utilization measures account for the impact of COVID-19 diagnosis that lead to hospitalization and rehospitalization.**

In addition, CMS proposes to remove all preventive health measures. This would shift the population health focus entirely to management of illness and cost. Trinity Health, like many other participants in APMs, has committed and invested in population health to assess and identify needs of the whole

person. **Trinity Health recommends CMS add vaccination and cancer screening measures that are foundational to preventive care and care coordination.**

Further, specification for the selected six measures do not allow ACOs to report results during telehealth visits. **CMS should ensure the telehealth expansion includes quality measures for services performed and data captured via a telehealth visit.**

Pay for reporting

CMS proposes to remove the pay for reporting year. **Trinity Health opposes this change, as pay for reporting is important for new quality measures introduced and recommends CMS maintain the pay for reporting year (especially if the Agency finalizes APP). We urge CMS to not finalize this approach and instead maintain the pay-for-reporting year provided to ACOs in their initial contract year, as well as new quality measures when they are introduced or significantly changed.** There are often issues with marginally tested measures or measures that have not been used for ACOs in the past. This change would remove the ability of CMS to provide a pay for reporting year when measures undergo significant changes, such as guideline and specification changes. Further, providing a newly introduced measure with a pay for reporting year ensures there are no unintended consequences or flaws in the measure specifications before holding an ACO accountable for performance on the measure. Seeing some of the backend of how measures get approved, having a real-world test for at least a year is important. In addition, new ACOs need a pay for reporting period as they set up infrastructure and analytics to support their improvement efforts.

Reporting

The proposed rule would eliminate the Web Interface as a reporting method and require ACOs to actively report on clinical quality measures using a registry or direct via electronic medical records (EMRs) using electronic clinical quality measure (eCQM) standards.

Trinity Health has concerns with using eCQMs, as they are not yet mature enough. While the measures have published standard specs, EMR vendors themselves do not necessarily follow those specs and/or interpret their meaning in different ways. Output from one EMR to another may not be standard and there remains too much variability in how different EMRs build the numerator. For example, a mammogram patient could say "I will get my mammogram in September" and this could be captured and counted as "completed" by some EMRs, whereas others would only look for a completed service. **More work needs to be done with vendors to truly make this reporting functional for purposes of quality measurement.**

Quality scoring methodology

CMS proposes to increase the minimum attainment standard to the 40th percentile and CMS would compare ACO total quality scores to *all other MIPS participants*. More specifically, CMS proposes that ACOs must meet the minimum attainment standard to be eligible to share in any savings earned. However, once the minimum standard is met an ACO would receive the maximum shared savings rate automatically regardless of the ACO's final quality score. If an ACO does not meet the minimum attainment standard, the ACO would not be eligible for shared savings. **Trinity Health is concerned with such a significant change during the COVID pandemic and urges CMS to maintain the**

existing policy for FY2021. Further, this all or nothing approach would reward ACOs for meeting the bare minimum, which is not aligned with the goal of value-based care models. If CMS finalizes this proposal in future years, we suggest CMS use percentile scores by measure with point assignment, as using domains makes less sense if the number of measures is going to be greatly reduced.

Alternative Proposal Allowing ACO Selection of Quality Measures

CMS also seeks comment on an alternative approach that ACOs could use in the event the three measures ACOs are required to actively report on are not applicable to their beneficiary population. **Trinity Health opposes this proposal.** The proposed rule lacks detail on how CMS would determine if the three measures were in fact not appropriate for the ACO and we have concerns this would be incredibly complex. This proposal could allow organizations to select measures for which they have the highest historical performance, not allowing for a true and fair assessment of quality improvement efforts across ACOs. Further, the lack of standardization would make program evaluation nearly impossible.

Extreme and Uncontrollable Circumstance Policy for 2021

For PY 2021 and subsequent years, CMS proposes to provide an ACO affected by an extreme and uncontrollable circumstance with the higher of its own quality score or a score equal to the 40th percentile MIPS Quality performance category score. **Trinity Health supports this approach.**

Extreme and Uncontrollable Circumstances Policy for 2020

Due to the negative impacts of COVID-19, CMS proposes to provide automatic full points for each of the CHAPs survey measures within the patient/caregiver experience domain for PY 2020. **Trinity Health supports this flexibility and encourages CMS to consider alternative policies for 2021 as the public health emergency continues.**

II. CY2021 Updates to the Quality Payment Program

Quality Payment Program (QPP)

MIPS

As noted in our detailed comments above, Trinity Health does not support CMS proposals to make significant changes to how ACO quality is assessed, how quality data is reported and how ACOs are evaluated on quality for MIPS at this time. Just as CMS has delayed moving forward with the MVP due to the significant changes it would require while clinicians continue to grapple with the affects and uncertainty caused by the COVID-19 PHE, CMS should not move forward with proposed structural changes to the way all APMs are scored in MIPS. Additionally, the proposed APP is a one size fits all approach that will not work well for every APM. **We urge CMS to maintain the current MIPS APM scoring standard and scoring rules.**

Telehealth

Trinity Health supports CMS' proposals to change the CAHPS survey for MIPS for CY2012 to recognize the increased use of teleleath during the COVID pandemic. **We also urge CMS to adjust quality measure specifications to allow for data collected during teleleath to be used to report quality.**

MIPS Quality Methodology

Due to COVID, CMS proposes to set benchmarks for the CY 2021 period using measure data from the performance year. **While Trinity Health supports this decision, we have concerns using performance year benchmarks in a brand-new program as proposed by CMS. If CMS moves forward with implementation of the APP, they should allow for a pay for reporting period.**

Advanced APMS

QPs and Partial QP Determinations

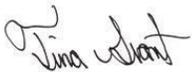
CMS proposes to exclude prospectively assigned beneficiaries from the denominators of other ACO/APM Entity QP calculations when that beneficiary is ineligible to be added to the ACO/APM Entity's list of assigned beneficiaries. Effectively, this decreases the QP denominator, thus increasing the overall QP score. **CMS should apply this flexibility for all ACOs—both prospectively and retrospectively assigned. In addition, we urge CMS to address QP thresholds by holding 2020 thresholds in place for 2021.**

Incentive Payments

We urge CMS to commit to pay the Advanced APM incentive payment no later than June 30th in future years. The extended gap between QPP performance and incentive payment continues to present a barrier to greater adoption of Advanced APMs. Timely payment of the Advanced APM incentive payment would reflect a supportive approach by CMS to the hard work that providers are doing and encourage additional movement toward advanced risk models. We also encourage CMS to implement an appeal process related to these payments.

We appreciate CMS' ongoing efforts to improve delivery and payment systems and to implement policies that further support delivery of value-based care. Thank you for the opportunity to respond to this proposed rule. If you have questions on our comments, please feel free to contact me at granttw@trinity-health.org or 734-343-1375.

Sincerely,



Tina Weatherwax Grant, JD
Vice President, Public Policy and Advocacy
Trinity Health