



September 27, 2019

Seema Verma, Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1715-P,
P.O. Box 8016,
Baltimore, MD 21244-8016

RE: CMS-1715-P- Medicare Program; CY 2020 Revisions to 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; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations

Dear Administrator Verma,

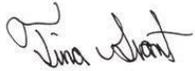
Trinity Health appreciates the opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS) proposed rule *Medicare Program; CY 2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations*. 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. Our People-Centered Health System puts 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 109 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 \$1.1 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 133,000 colleagues, including more than 7,800 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 (APMs) across all populations and product lines: Medicaid, Commercial, Medicare Advantage and Medicare ACOs. Trinity Health participates in the Medicare Shared Savings Program (MSSP)—Tracks 1 and 3, and the new Pathways to Success Enhanced—the Next Generation ACO, Comprehensive Primary Care Plus (CPC+), and the Bundle Payment for Care Improvement Advanced programs.

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

Trinity Health Comments on Updates to the Medicare Physician Fee Schedule, Quality Payment Program and Other Proposals

Trinity Health appreciates CMS' ongoing efforts to improve the Medicare program through the delivery of high-value care. We support many of the proposals in the rule and also offer recommendations for improving others to further reduce barriers to beneficiaries receiving necessary care, to simplify the program, and to reduce administrative burden. Our major recommendations are described below.

- **Payment for Opioid Use Disorder Treatment Services.** Trinity Health strongly supports CMS' efforts to expand Medicare coverage of and payment for opioid use disorders (OUD) services. However, we offer recommendations for how CMS can strengthen and simplify the two proposed bundle payments for OUD—one for services furnished at OTP and the other under the PFS—to maximize their impact.
- **Office/Outpatient E/M Coding.** We applaud CMS' decisions to maintain five levels of E/M visit in place of its proposal last year to create a blended rate for levels two through four. We also support the proposal to increase valuations for all E/M codes and the new prolonged services add-on code. We believe these proposed changes will further incentivize physicians to spend the appropriate amount of time and resources with patients based on their health and care needs.
- **MIPS Value Pathways.** We agree that there is a need to simplify the Merit-Based Incentive Payment System (MIPS) program. However, we strongly recommend that a MIPS Value Pathways (MVP) framework develop population health focused MVPs rather than specialty or condition focused MVPs as proposed. We offer recommendations for how a new MVP could support population health.

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

Payment for Medicare Telehealth Services under Section 1834(m) of the Act

Trinity Health supports the expansion of Medicare telehealth codes covered under the physician fee schedule (PFS) - especially for behavioral health services and other areas with workforce shortages or other barriers to accessing care. Trinity Health has always been a strong advocate for the expansion of telehealth services because they support access to providers and help drive value for patients.

Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs (OTPs)

Trinity Health appreciates CMS' efforts to establish a new Medicare Part B benefit for OUD provided at an Opioid Treatment Program (OTP) and to create a bundled payment for services furnished by an OTP during an episode of care as required under the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act). Expanding coverage and access to services to treat OUD and other behavioral health conditions is essential to providing people-centered care.

Trinity Health has long advocated for the alignment of the Health Insurance Portability and Accountability Act (HIPAA) and 42 CFR Part 2, as this is necessary to treat the whole patient. We appreciate CMS' efforts to accomplish this in the recent proposed rule, *Confidentiality of Substance Use Disorder Patient Records*.

Trinity Health recommends that CMS include case management and contingency management to the proposed list of OUD treatment services. We also believe that OTPs should be able to provide and bill for couples and family therapy given the effectiveness of a family systems approach.

Proposed Bundled Payments for OUD Treatment Services

We support the coverage of OUD services furnished by an OTP and appreciate CMS' effort to establish a bundled payment for OUD services. However, we believe the bundled payment as proposed is overly complex, which could impede its use.

Given that providers have limited experience with bundled payments under the fee schedule, we offer suggestions on the structure of the bundled payment and on simplifying the proposal. We recommend that CMS provide greater clarity on the beneficiaries these codes would apply to and which providers within OTPs would be permitted to bill these codes. We also recommend CMS provide more details on the treatment of drugs in the bundled payment. Based on Trinity Health's experience, many of the drugs included—Methadone (oral), Buprenorphine (oral, injection and implant), and Naltrexone (injection)—are limited to a pass through at a clinic or are self-administered.

We also recommend that therapeutic referrals to a psychologist be added to the bundled payment to address the needs of the patient and their family and to best utilize the system of care. Currently, referrals are often limited due to payment barriers for services provided by a psychologist. Finally, we recommend services from a Community Health Worker or Community Resource Coordinator be billable services provided by OTPs and be included in the bundle. These services are critical to addressing a patient's social and economic needs.

Finally, Trinity Health supports CMS' proposal to allow OTPs to provide counseling and therapy services furnished via two-way interactive audio-video communication technology under the bundle, as clinically appropriate. However, we request clarity on which patients this would apply to and which providers would be eligible to deliver these services. As noted above, we recommend that couples and family therapy be included under the bundle.

Further, with a growing number of alternative payment programs, we ask that the CMS clarify how the OUD bundle will align with the existing episode-based programs (e.g., the Bundled Payment for Care Improvement (BPCI) Advanced model, Comprehensive Care for Joint Replacement model, and the Oncology Care Model). For example, if a beneficiary triggers an inpatient BPCI Advanced episode for congestive heart failure and is referred to an OTP, the payments within each episode type should be mutually exclusive. We suggest that CMS ensure there is no payment adjustment to episodes where overlap occurs.

Bundled Payment Under the Physician Fee Schedule for Substance Use Disorder

Trinity Health supports the creation of a bundled payment for SUD services as this could expand payment for and access to services for OUD, which is an important step in addressing the national opioid crisis. We believe the three codes CMS proposes for inclusion in this bundle are sufficient and align with the approach used for chronic care management, which providers are already familiar with. However, our main concern with CMS' proposal is the utility of these codes—and thus the bundle—for two reasons. First, utilization is likely to be limited because the bundle is based on G codes instead of CPT codes. Second, based on our experience, sites would need to have a substance abuse license to bill therapy codes for substance use disorder as the primary diagnosis. This restriction may limit use of the proposed bundle, resulting in providers continuing to bill mental health codes. If CMS finalizes this proposal, we strongly recommend that barriers—such as licensure and challenges with temporary codes— be addressed to maximize utilization and impact of the bundle on the opioid crisis.

As noted above, we strongly recommend that CMS ensure that each episode-based payment program be mutually exclusive and that there is no payment adjustment to episodes where overlap occurs.

Physician Supervision for Physician Assistant (PA) Services

Trinity Health supports CMS' proposal to revise the regulations to allow for supervision requirements to be met if delivery of services by a physician assistant (PA) is in compliance with state law and state scope of practice rules in the state in which the services were furnished. CMS notes that where state laws do not exist, documentation in the medical record of the physician supervision required by Medicare and the PA's approach to working with a physician to administer the services would be required.

Review and Verification of Medical Record Documentation

Trinity Health appreciates CMS' continued efforts to reduce physician administrative burden. We support CMS' proposal to extend to PAs, and advanced practice registered nurses (APRNs) who furnish and bill for their professional services the ability to review and verify—rather than re-document— notes entered into a medical record by a physician, resident, nurse, student or other members of the medical team.

However, we recommend that this practice be limited to providers verifying and entering information that are of the same discipline. Similarly, in the case of information entered by students in a patient's medical record, Trinity Health only supports verification of the information by another physician if the physician reviewing and verifying the information is within the same discipline as the student.

Care Management Services

Transitional Care Management (TCM) Services

Trinity Health supports CMS' proposal to remove restrictions that prohibit the same provider from concurrently billing 14 HCPCS codes during the 30-day period covered by TCM services. The 14 HCPCS codes identified by CMS are distinct from services provided as part of TCM and that permitting concurrent billing of these codes with TCM services will allow physicians to more accurately capture services delivered.

Additionally, we believe that CPT code 99491 for chronic care management (CCM) should be separately payable from TCM when billed by the same practitioner during the same service period because these are distinct services. We also support CMS' proposal to adopt the RUC recommended payment amounts for TCM services. Together, these policies could increase utilization of TCM codes and enhance quality and comprehensiveness of care delivered to beneficiaries transitioning from inpatient to community settings.

Chronic Care Management (CCM) Services

Trinity Health agrees that current CCM codes are underutilized and should be revised to better support patient access to necessary services, to improve accuracy of payments, and to reduce administrative burden. However, we have concerns with the proposal and offers recommendations to strengthen CMS' approach below.

First, Trinity Health recommends that CMS wait for the CPT Editorial Panel to replace the existing non-complex and complex CCM CPT codes with new CPT codes—rather than adopting the four proposed temporary G codes. This would minimize transitions and administrative burden from existing codes, to G codes, to new CPT codes. Second, we believe the descriptor language for the proposed G codes is complex and would limit use of these codes—especially in regards to the requirements related to the complexity of the patient and designation that services be provided per calendar month (for non-complex CCM). Reporting these new G codes will be even more difficult because EHRs do not document time spent with patients that is not face-to-face during a calendar month.

However, we agree that CCM codes should be for shorter increments of time. We recommend that CMS use 15-minute increments—instead of the proposed 20 minutes—as this more accurately captures time spent by providers completing CCM.

Typical Care Plan

We support CMS' proposed definition of the typical care plan, which is comprehensive and aligned with general care plan requirements. We believe it will ensure the appropriate components are included in a patient's care plan and support long-term health.

Principal Care Management (PCM) Services

While Trinity Health appreciates CMS' efforts to support access to care for beneficiaries with only one chronic condition, we are uncertain of the need for the new PCM codes given the opportunity to improve existing CCM service codes. The proposed PCM services codes could lead to fragmented care, reduced coordination between specialists and primary care providers, and duplicate services if used by providers to treat a specific chronic condition rather than as part of a comprehensive approach to care. Trinity Health recommends that CMS not finalize the proposal to establish new PCM codes at this time.

Chronic Care Remote Physiological Monitoring

Trinity Health strongly supports CMS' proposal to allow Remote Physiological Monitoring services to be furnished under general supervision rather than direct supervision.

Consent for Communication Technology Based Services

Trinity Health agrees with CMS that it is burdensome to obtain advanced beneficiary consent for services provided via telecommunications technology in certain circumstances. To reduce burden while still maintaining the protection associated with obtaining patient consent, we recommend that CMS utilize a standard advanced beneficiary consent when a patient is receiving the same services via telecommunications technology over a set period of time (e.g. one year). This would allow for a patient's consent to apply to delivery and receipt of the same service over a defined period, while still requiring consent to receive any new type of service. We believe this approach will ensure patient protections and reduce burden for the patient and provider.

Therapy Services - Payment for Outpatient PT and OT Services Furnished by Therapy Assistants

Trinity Health has significant concerns with CMS' proposed approach for establishing a modifier to identifying outpatient physical and occupational therapy services furnished "in whole or in part" by a therapy assistant, which the Balanced Budget Act (BBA) of 2018 established must be paid at 85% of the PFS amount effective January 1, 2022. The modifier must be reported on relevant claims starting on January 1, 2020. In the CY 2019 final rule, CMS finalized that services would be

considered furnished “in whole or in part” by a therapy assistant when more than 10% of the services provided during a visit were furnished by a physical therapist assistant (PTA) or occupational therapy assistant (OTA). First, which we understand that the 85% payment rate for services furnished in whole or in part by a therapy assistant was established in the BBA of 2018, but we are concerned that this reduction in payment could limit access to care, especially in rural and underserved areas. If CMS finalizes this proposal, we recommend that providers in rural and underserved areas be exempt from the requirements.

In this rule, CMS proposes to calculate the 10% threshold based on the respective time spent by the therapist and the PTA or OTA. While Trinity Health recognizes that the BBA of 2018 requires CMS to establish a modifier, the proposed approach for calculating “in whole or in part” could impede access to quality care and diminishes the role of the therapist. Further, we recommend that only services furnished independently by the assistant—not in conjunction with the therapist or when the therapist is present—should count toward the 10% standard. We also believe that the proposed calculation is complex and would cause additional administrative burden to determine if the modifier should be included on the claim.

Last, Trinity Health recommends that CMS not finalize the proposed documentation requirements for therapy coding and billing that would require an explanation of the use or absence of the PTA or OTA modifier for each service furnished as these will be administratively burdensome and conflict with CMS’ “Patients Over Paperwork” initiative.

Payment for Evaluation and Management (E/M) Visits

Trinity Health supports CMS’ proposal to adopt the Joint American Medical Association (AMA) CPT Workgroup’s E/M proposal to maintain separate payments for five levels of E/M services for existing patients and to create four levels for new patients. Trinity Health had significant concerns with the proposal CMS finalized last year to collapse levels two through four for new and existing patients given the negative impact it would likely have had on beneficiary access and quality of care, especially for those with complex needs. CMS’ decision to keep the five-level E/M visit codes will support delivery of high-quality, patient-centered care as it will maintain incentives for physicians to spend the amount of time with patients appropriate for their health and care needs.

Office/Outpatient E/M Visit Coding and Documentation

Trinity Health also supports CMS’ proposal to adopt the CPT Workgroup’s office visits codes for 2021 as well as the prefatory language and the newly proposed ranges for total time expended by the physician (including face-to-face and non-face-to-face). Adoption of these codes will support standardization across Medicare and other payers, reduce burden, and allow providers to spend more time focused on delivering high-value, person-centered care.

Trinity Health also supports CMS’ proposal to allow physicians to use either medical decision-making (MDM) using the AMA’s MDM complexity grid or time using the new ranges included in the revised code descriptors to select the appropriate E/M visit level. Further, we support the inclusion of the AMA’s MDM complexity grid in the CPT manual for 2021, which will then be recognized across payers.

Office/Outpatient E/M Visit Revaluation

Trinity Health supports CMS’ proposal to adopt the AMA Relative Value Scale (RVS) Update Committees’ (RUC) recommended valuations for all E/M codes and the proposed prolonged services add-on code. We urge CMS to adopt these changes for calendar year 2020. CMS’ proposal to reverse the E/M code collapse it proposed last year, paired with the revaluation of E/M payment levels will better support physicians in spending the appropriate time and resources necessary to deliver high-value, person-centered care.

Simplification, Consolidation and Revaluation of HCPCS codes GCG0X and GPC1X

Trinity Health appreciates CMS' proposal to consolidate the add-on codes for complexity of primary care and complexity of nonprocedural specialist office visits that were introduced last year into one code. However, we do not believe this change will result in the codes being more broadly or appropriately used. We recommend that CMS work through the CPT Editorial Panel to develop codes as this will increase the likelihood that they will be properly used for patients that require complex care.

Valuation of CPT code 99xxx (Prolonged Office/Outpatient E/M)

Trinity Health strongly supports CMS' proposal to eliminate the add-on code that was finalized last year and replace it with a new CPT add-on code for prolonged office/outpatient E/M visits. Using 15-minute increments will allow providers to more accurately capture and report time spent with patients. Based on our experience, providers spending 30 additional minutes with patients was uncommon and therefore the previously finalized add-on code did not support typical, additional care provided to patients.

Medicaid Promoting Interoperability

Trinity Health supports CMS' proposal to maintain its policy from CY 2019 and require Medicaid Eligible Professionals (EPs) to choose six measures from the eCQM list used under MIPS to streamline reporting of measures for providers participating in both programs.

Further, Trinity Health recommends CMS maintain that the eCQM reporting period be any continuous 90-day period for all EPs—regardless of whether they are demonstrating meaningful use for the first time—as this aligns with the eCQM reporting periods under MIPS and will allow for streamlined reporting for providers participating in both programs.

Medicare Shared Savings Program Quality Measures

Trinity Health generally supports the use of an adult composite immunization measure to promote recommended preventive care. However, the inclusion of the proposed *ACO-47, Adult Immunization Status*, in the MSSP ACO quality measure set for 2020 would be operationally difficult to implement due to the variation in measure population inclusion, timeframe, exceptions, exclusions, and reporting requirements. Additionally, we are concerned that only certain immunizations included in the measure are covered under Part B, while others are covered under Part D, which creates access barriers and challenges for beneficiaries.

We also strongly urge CMS' to maintain pay for reporting for *ACO-17, Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention* in 2019.

Advisory Opinions on the Application of the Physician Self-Referral Law

Trinity Health supports several of CMS' proposed changes to the physician self-referral advisory opinion process through which CMS provides opinions, when requested, on whether referrals would violate the Stark law. Specifically, we support CMS' proposal to shorten the timeframe for when it must respond to a request for an advisory opinion from 90 days to 60 days as this will expedite the process. Last, we support CMS' proposal to allow any party to an arrangement that receives a favorable advisory opinion to rely upon that opinion.

II. CY 2020 Updates to the Quality Payment Program

MIPS Value Pathways (MVPs)

Trinity Health appreciates CMS' aim to reduce complexity and administrative burden and provide meaningful information across providers and patients under the proposed MIPS Value Pathways

(MVP) proposal. We also commend CMS' interest in stakeholder feedback as it refines the MIPS program and offer recommendations to strengthen the proposal to accomplish these objectives.

Structure of MVPs

CMS proposes to develop MVPs that will streamline activities and measures from the existing 4 MIPS performance categories and align them to a specialty, medical condition, or other issues (e.g. population). Trinity Health urges CMS to establish population health focused MVPs—such as preventive health, chronic care management, opioid use, care coordination, or palliative care—rather than specialty or condition-focused MVPs to better manage the health and costs for a population.

We support CMS' aim to include consistent, population health measures across all MVPs – and efforts to continue to align quality measures in MIPS with the MSSP ACO program. To this end, we recommend that CMS align ACO and MIPS quality reporting to include the same domains currently included in the MSSP measure set and streamline the number of measures across all measure domains.

Assignment/Selection

Providers currently participating in MIPS have the option to select quality measures and improvement activities relevant to their practices. We believe it is essential that CMS maintain this choice under the MVP framework. Specifically, we recommend that CMS allow providers the opportunity to select the MVP that includes measures and activities relevant to their practices and the beneficiaries they serve. This is especially important for certain providers (e.g. primary care physicians) for whom a specific set of quality measures does not exist and whose care may impact a range of measures. For example, in *TABLE 34: Examples of Possible MIPS Value Pathways* in the proposed rule, CMS' example of a Major Surgery MVP includes quality measures relevant to primary care physicians or other providers even though the pathway was likely designed for physicians within a surgical specialty.

Implementation

The proposed changes to transition from the current MIPS program to MVPs will require administrative, health information technology, and operational changes. If CMS maintains its proposed implementation date of 2021, we recommend that 2021 be a reporting year, followed by a performance year - similar to the approach taken with the ACO program.

MIPS Performance Category Measures and Activities

Quality Measures

As discussed earlier, Trinity Health urges CMS to continue to align the quality measure set available for providers under MIPS with the set included in the MSSP ACO program and to align the quality measure reporting domains currently used in MSSP across both programs. We do not support changes to the MSSP quality measures or scoring methodology to align with MIPS as this could impede the evolution of meaningful quality measurement in the ACO program. We strongly recommend CMS maintain the current quality measures and scoring methodology for ACOs.

Improvement Activities

Trinity Health supports CMS' proposal to require that at least 50% of a group's NPIs perform an IA activity for the same continuous 90-day performance period, rather than requiring that only one clinician from the group complete an activity to encourage performance improvement across more providers.

Advanced APMs

Trinity Health strongly believes that alternative payment models (APMs) and value-based payment arrangements are essential to driving system transformation that improves quality and care for beneficiaries and reduces health care costs. We look forward to the continued opportunity to

develop and participate in Advanced APMs across our footprint to meet the unique needs of the communities that we serve.

Marginal Risk Standard for Other Payer Advanced APMs

Trinity Health supports CMS' proposal to use an alternative approach to assessing marginal risk rate in certain cases where payment arrangements that would otherwise meet other payer APM criteria do not meet the marginal risk standard.

However, we continue to recommend that CMS include business investments (e.g. care management and patient education, redesigning care delivery and associated staff training, development of patient management and engagement tools, etc.) necessary to improve care in the definition of more than nominal risk.

Partial QP

Trinity Health supports CMS' proposal to apply partial QP status only to the TIN/NPI combination(s) through which a provider gains QP status starting in 2020.