September 10, 2018

Seema Verma, Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1693-P,
P.O. Box 8016,
Baltimore, MD 21244-8016

RE: CMS-1693-P - Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program

Dear Administrator Verma,

Trinity Health appreciates the opportunity to respond to the Centers for Medicare & Medicaid Services’ (CMS) proposed rule Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program. 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 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 23 Clinically Integrated Networks (CINs) that are accountable for approximately 1.4 million lives across the country through alternative payment models (APMs).

We appreciate CMS' ongoing efforts to improve payment systems across the delivery system and to continue 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
I. Provisions of the Proposed Rule for the Physician Fee Schedule

**Modernizing Medicare Physician Payment by Recognizing Communication Technology-Based Services**
Trinity Health supports CMS’ proposal to establish new codes to pay physicians separately for certain non-face-to-face physicians’ services furnished using communication technology-based services. Trinity Health also supports CMS’ proposals to expand the list of Medicare telehealth codes covered under the physician fee schedule. Trinity Health has always been a strong advocate for the expansion of telehealth services in the Medicare program and we are pleased that CMS is proposing policies that support this expansion. We believe that telehealth services can significantly support access to providers and help drive value for patients—especially for behavioral health services and other specialties where there may be workforce shortages or other barriers to access.

**Evaluation & Management (E/M) Visits**

**Payment Rates for E/M Visits**
Trinity Health has significant concerns with CMS’ proposal to collapse the current five-level E/M visit codes into two levels and the impact it will have on beneficiaries. Based on our experience and assessment, we believe that CMS’ proposed changes to documentation, coding, and billing could negatively impact quality of care, coordination across providers, as well as physician payment that can support the delivery of patient-centered care. For instance, the proposed changes could create unintended incentives for providers to spend less time with patients to compensate for payment adjustments—potentially resulting in lower-quality care and impeding delivery of coordinated care. It could also make it difficult for patient’s to schedule longer visits with providers.

Collapsing level 2-5 visits does not take into account the knowledge, time, and resources that providers need to care for complex patients. Trinity Health has significant concern that the add on codes do not sufficiently make up the difference for treating the sickest patients, but rather add another layer of complexity to the coding process. Trinity Health has concerns that the proposal would not reward providers who provide more resource-intensive care and would only result in lower payment amounts for this type of care.

Trinity Health strongly supports and believes that APMs are the key to driving system transformation that improves quality and care for beneficiaries and reduces health care costs—not simply payment changes to the current fee-for-service system.

In addition, a likely decrease in physician payment levels resulting from CMS’ proposal would require practices and systems supporting them to revisit and adjust physician compensation plans based on work relative value units (wRVUs) or patient visit volume to ensure that the changes in coding do not incentivize physicians to spend less time with patients. This could have the unintended effect of causing volume, rather than value, to be the main driver of care delivery. Additionally, the proposed changes would necessitate significant updates to workflow and processes, electronic medical records, and billing systems, which would require additional time and resources to implement—and actually increase administrative burden.

Finally, Trinity Health is concerned with CMS’ proposed timeline for these changes to E/M payment rates, which it proposes would be effective January 1, 2019. Based on our experience, implementing Meaningful Use took several years of preparation and then several years to become a stable program. We believe that the proposed collapsing of E/M codes poses a greater potential impact on care—and costs—than Meaningful Use. Based on this experience, and the system and process changes that would need to accompany the changes CMS is proposing, we do not think it is realistic for these changes to be effective January 1, 2019.
Eliminating the Prohibition on Billing Same-day Visits by Providers of the Same Group and Specialty

Trinity Health appreciates CMS’ consideration of eliminating the existing prohibition on payment for two E/M services provided by and billed by a physician on the same day. Trinity Health strongly supports CMS’ proposal to eliminate this prohibition, and does not believe that it should be tied to condensing the E/M codes. Coordination of care is improved and a beneficiary can be cared for more holistically when providers are able to see them for multiple issues of the same day – e.g. a primary care and behavioral health visit. It is our experience that each department or provider will still bare the cost for providing that service, and thus these services should be billed as separate E/Ms at cost. However, if CMS plans to continue this policy, we support CMS’ proposal to reduce payment on the least expensive global procedure.

Streamlining E/M Visit Documentation

We appreciate CMS’ intention to simplify documentation and believe the goal of documenting care and health status in a patient’s chart is to accurately communicate a patient’s condition to them and their caregivers. Trinity Health is concerned that the E/M documentation changes paired with the E/M payment changes could undermine these goals. In addition, we are concerned that medical decision-making requires documentation – and the proposed changes could increase auditing burden and related work.

However, we believe that some of CMS’ proposals can be implemented irrespective of the E/M payment changes. Trinity Health supports CMS’ proposal to only require physicians to document changes in the patient’s chart since the last visit. We agree that this will help streamline documentation, however it is important to note that streamlining documentation requirements does not relieve the physician of the required attention and thought process necessary to ensure charts are up to date and accurately reflect a patient’s status.

Additionally, Trinity Health supports CMS’ proposal to no longer require physicians to re-enter certain information in a patient’s medical record that has been entered by an ancillary staff member or the patient, but rather confirm they have reviewed the information. We agree that this approach to documentation may ease physician burden while maintaining documentation of a patient’s health status and history.

And, Trinity Health supports eliminating the requirement to document the justification for providing a home visit instead of an office visit.

Bundled SUD Payment Rate

CMS is requesting feedback on the creation of a new Medicare bundled payment for the care and management of substance use disorders (SUDs) to aid efforts addressing the opioid crisis. Trinity Health commends CMS for its efforts to increase access to Substance Use Disorders services. However, we believe the proposal falls short of achieving this objective. For example, some outpatient facilities that provide SUDs cannot accept Medicare beneficiaries with traditional coverage, Military or VA clients as the operations at these facilities do not meet the criteria set by federal regulations. Additionally, Medicare beneficiaries do not receive benefits for Intensive Outpatient Services (IOS) or Outpatient Rehab services.

Providers at facilities certified by the Office of Alcoholism and Substance Abuse Services (OASAS) will still have to follow documentation requirements set by OASAS; therefore the proposed documentation changes will not put patients over paperwork relief to providers at OASAS facilities.

Appropriate Use Criteria for Advanced Diagnostic Imaging Services

Trinity Health supports the use of AUC for advanced diagnostic imaging. AUC can provide highly patient-centered and specific guidance to providers, which in turn can facilitate evidence-
based decision-making and reduce unnecessary utilization. However, Trinity Health has a number of concerns with CMS’ proposals for the AUC program, which are detailed below.

CMS is proposing that AUC reporting requirements include the following: 1) ordering professionals would consult with a clinical decision support mechanism (CDSM) and (2) “furnishing professional” would then include information about the ordering professional’s consultation on their Medicare claim. In the CY2018 MPFS Proposed Rule, for the first time, CMS was very clear that the “furnishing professional” claim and the hospital claim would both need to include information to show that the ordering professional consulted AUC through the implementation of various G codes and modifiers. In the CY2018 MPFS Final Rule, CMS acknowledged that the G codes and modifiers were too operationally burdensome and stated that a unique consultation identifier would be created. However, in the CY2019 MPFS Proposed Rule, CMS indicates they worked with stakeholders on the unique consultation identifier; however, Trinity Health is not aware of any Open Door Forum, transmittals or other communications soliciting stakeholder involvement or feedback on this topic. In this proposed rule, CMS notes that a unique consultation identifier cannot be created in time to implement in 2020; and is proposing to revert to the G codes and modifiers which they had previously recognized as too burdensome.

PAMA specifically states a furnishing professional must report on the ordering professional’s AUC consultation. We are concerned that CMS’ efforts to clarify the requirement that the furnishing facility and the furnishing professional must report the AUC consultation may go beyond the intentions of PAMA, will cause extreme operational burden on the performing facility, and will likely result in inconsistent data being reported for the same radiology procedure between the two reporting parties. In addition, CMS notes they may still pursue a unique identifier in the future. We are concerned that CMS is not allowing time to develop mechanisms or policies that result in the most accurate information and least long-term burden to the providers. We urge CMS to solicit additional feedback from stakeholders before finalizing their approach.

In particular, Trinity Health believes that the requirement to report AUC information on every order will be extremely burdensome on all parties and counteract CMS’ stated goal of reducing regulatory burden. As proposed, the AUC requirements will constitute additional work that is not currently being done, which will generate additional cost for providers. **Trinity Health has significant concerns about the potential impact of the proposed requirements on the furnishing professional and the performing facility and offers the following comments, suggestions and requests for clear guidance on any implemented requirements.**

**Trinity Health strongly recommends that the requirement to attest that AUCs were consulted be on the ordering professional.** CMS should implement the requirement such that the ordering professional reports the proposed G codes and modifiers. If CMS wants to track by the test being ordered, the ordering professional could be required to include the HCPCS code for the test on their claim. To support this, CMS could develop a non-payment modifier to indicate the code is being reported for data collection. **This would maintain the responsibility for the AUC with the responsible party and not penalize the furnishing professional and the performing facility with additional, burdensome work and potential payment reductions.** The cost estimates that CMS has provided only seem to focus on the burden to the ordering professional and do not include the on-going costs that will be incurred by the furnishing professional and performing facility to meet this requirement. Based on our experience, compliance with what is proposed will require an extremely burdensome, manual, on-going process to get this information onto the claims. We understand that PAMA specifically states that the furnishing professional must report the AUC consultation, but do not think Congress intended to create the additional complexity or burden associated with these policies.

Under CMS’ proposal, all of the billing burden and risk of payment denial will fall to the furnishing professional and the entity providing the service, not on the ordering professional. We strongly believe that the burden of proof that the ordering professional followed regulation and consulted the CDSM should not be placed on performing facilities. **If CMS does not choose to have the ordering**
professional report the G codes and modifiers, we urge CMS to develop a verification mechanism—for example, a yearly attestation—that would be required of the ordering professional to indicate they consulted the AUC for each advanced diagnostic imaging service that they ordered.

If CMS chooses to move forward with the proposed policies, Trinity Health would strongly recommend the following:

- **Allow sufficient time for CDSM to be incorporated into electronic health systems and ordering pathways.** These systems would need to determine the appropriate G code and modifier and be programmed to include this information on an electronic order. Without information systems automatically generating the G code and modifier and placing it automatically on the order, it is extremely unlikely that the ordering professional will provide this information manually. It is still unclear whether electronic health systems and ordering pathways can be updated to generate the G code and modifier even with the one-year notice included in the proposal.

- **CMS indicates that the AUC do not need to be consulted for emergency medical conditions but has provided no further details.** We ask for clarity on whether this means the AUC would not need to be consulted for all ED visits. If this is not the case, it will be operationally impossible for ED physicians to determine when AUC should be consulted versus when it does not need to be consulted. While in the process of treating emergency room patients, the physician does not always have sufficient time to assess if a case is one in which the AUC needs to be consulted.

- **If all advanced imaging services provided in the ED setting are truly exempt, do not require the G codes/modifiers be reported for ED visits.** The presence of revenue code 450 would demonstrate that the service was provided to an ED patient. The requirement for a G code and modifier to indicate the service was provided in an ED would necessitate hospital EHRs to also include which CSDM are used within the EHR and again require manual work to report something that is only reflecting that the service is exempt from the requirement. If hospital EHRs are not generally used to generate orders for future outpatient radiology services, this is yet another vendor that would need to be programmed to generate a G code and modifier that serves no real purpose other than to indicate the service was exempt.

- **CMS should clarify what recourse the furnishing professional and performing facility have when the necessary information is not included on the order.** Specific questions that may need to be addressed include:
  - Should an ABN be collected and the patient be held responsible?
  - Should the patient be inconvenienced and the service not be provided until the information can be tracked down?
  - Should hospitals assume the AUC was not consulted and report as such?
  - **We would recommend there be a G code that indicates AUC consultation information was not provided on the order.**

- **What will CMS do with data if the furnishing professional reported G code and modifier does not match that of the performing facility for the same patient?** Requiring two sources of data for the same patient will likely lead to inaccurate and conflicting information.

Trinity Health recommends that CMS re-examine its proposed approach and develop guidelines that will put the responsibility for reporting that the physician consulted AUC solely on the ordering physician. It is our belief that the ordering physician would want to be responsible for data that reflect their ordering practices to ensure accuracy. We believe CMS’ proposed approach will not achieve this and instead would burden performing facilities with this responsibility, while putting at risk the accuracy of the AUC practices of the ordering professional.

**Proposed Functional Reporting Modifications**

Trinity Health supports the elimination of the therapy functional reporting requirements. We appreciate that CMS recognizes the burden of this requirement and we ask that CMS recognize the operational burden of similar requirement for the AUC consultation.
II. Other Provisions of the Proposed Rule

Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs)
In general, Trinity Health is concerned that the proposed changes to the Medicaid Promoting Interoperability (PI) program (original Stage 3 measures as proposed in 2015) would require additional investment from providers—including CEHRT capabilities or work flow—and create unnecessary and excessive burden given that the program is due to end in 2021. We recommend not to move forward with Stage 3 measures but to align the Medicaid PI program with the MIPS PI measures (similar to the hospital program). Additionally, we are concerned that the proposed changes to scoring for the MIPS PI category will have a negative impact on high-performers in MIPS as the program requirements for Medicaid PI and MIPS PI are diverging. Below we offer recommendations for CMS to align Medicaid PI program changes with MIPS requirements to support the goals of interoperability while minimizing provider burden.

Proposed Revisions to the EHR Reporting Period and eCQM Reporting Period in 2021 for Eligible Professionals (EPs) Participating in the Medicaid Promoting Interoperability Program
Trinity Health supports CMS’ proposal to allow for a shorter reporting period of a minimum of 90 continuous days for CY 2021 and recommends that CMS allow for this shorter reporting period starting in 2019 to align with the MIPS Promoting Interoperability performance category. Shortening the reporting period to 90-days will also allow providers time to comply with the changes to the measures that CMS proposes.

Revisions to Stage 3 Meaningful Use Measures for Medicaid EPs
Trinity Health strongly encourages CMS to allow for a 90-day reporting period if it finalizes its proposed changes to select Stage 3 Meaningful Use Measures (e.g. Objective 6). Updates to measures require changes in workflow, which may not be fully in place by 2019. As a result, we strongly recommend that CMS institute a 90-day reporting period for these changed measures.

Electronic Clinical Quality Measures (eCQMs) for EPs under the Medicaid Promoting Interoperability Program
Trinity Health strongly supports CMS’ proposal to align the eCQMs for the Medicaid PI program with those available for MIPS-eligible clinicians for the CY 2019 performance period. We agree that this will allow for streamlined reporting of measures for providers participating in both programs.

eCQM Reporting Period for EPs under the Medicaid Promoting Interoperability Program
Trinity Health supports CMS’ proposal to align eCQM reporting periods for EPs under the Medicaid PI program and MIPS quality performance category reporting and this should be 90 days vs a full year. We agree that this will allow for streamlined reporting of measures for providers participating in both programs.

Medicare Shared Savings Program Quality Measures
In the proposed rule, CMS proposes to retire 10 of the measures currently included in the MSSP quality measure set in advance of 2019. Trinity Health does not object to removing most of the proposed measures from the MSSP 2019 set. However, we recommend CMS maintain ACO-16, BMI Screening and Follow-Up. We think this measure is important in ensuring appropriate care and follow-up is delivered by providers. We also strongly support CMS’ proposal to include ACO-47 Falls: Screening, Risk Assessment and Plan of Care to the 2019 measure set.

Finally, CMS requests comment on potentially expanding the core set of Web Interface measures to include specialty measures, but we do not feel we can comment until CMS provides more detail on what measures may be included. We look forward to providing further insights based on our experience.
Physician Self-Referral Law

Trinity Health supports CMS’ efforts to align Stark regulations with revisions to physician self-referral law codified in the Bipartisan Budget Act of 2018. Further, Trinity Health shares CMS’ commitment to transforming the health care delivery system into one that pays for value. We share the belief that care coordination is a key aspect of systems that deliver value, but we also believe additional changes to CMS programs, policies and regulations are essential to transforming the nation’s health care system. Trinity Health is committed to working with CMS to achieve these goals and appreciates the Department of Health and Human Services’ (HHS) commitment to helping accelerate this transformation and removing barriers, including those related to the Stark law. For further information, please see Trinity Health’s recent response to CMS’ request for information on Physician Self-Referral Law.

CY 2019 Updates to the Quality Payment Program

Definition of a MIPS Eligible Clinician

Trinity Health generally supports CMS’ intention to expand the list of clinicians eligible to participate in MIPS as it can support greater accountability and value across all providers in the health care system. However, CMS must consider if clinicians are able to meet MIPS reporting requirements across all performance categories before expanding the list of MIPS-eligible providers. For instance, CMS would need to ensure there are sufficient quality measures available to clinicians. If CMS expands the list of eligible clinicians, we urge the Agency to make participation optional to ensure these new provider types and health systems have sufficient time to prepare for successful participation in MIPS.

MIPS Low-volume Threshold

Trinity Health appreciates CMS’ concern that participating in the MIPS program can create some challenges for providers, however we believe that the existing - and proposed expansion of - the low-volume threshold criteria will result in too many Eligible Clinicians (ECs) being excluded from the program. We believe the program already includes reasonable hardship exemptions for small practices. For those that require additional assistance, there are also supports such as targeted funding to support small and rural providers as well as bonus performance points for small practices.

Further, based on our estimates, the impact of the low-volume threshold on participation results in a payment adjustment—2.02% for the highest performers in CY 2017—that does not adequately cover the investment required to be successful in the program. As a health system we have made significant investments to support MIPS-eligible clinicians comply with program requirements and we are concerned that excluding more providers from the program will limit the benefits for those performing well within the program. Specifically, we are making substantial investments in the following four areas:

1) Staffing models that support team-based care to achieve high performance in clinical quality;
2) Certified Electronic Health Record Technology;
3) Informatics and optimization to provide providers with panel performance improvement data; and,
4) Patient portals and Application Programming Interface (API) functionality so that patients can access to their health information and their provider.

We strongly believe that high performing MIPS providers should be rewarded for their investment in delivering the highest quality care and changes to the low-volume threshold criteria should not negatively impact the payment adjustment available to participating providers. While, Trinity Health supports the proposed option for providers to opt-in to MIPS, we are concerned that the incentives to participate in MIPS are reduced if positive payment adjustments are insufficient to help offset the investments practices and health systems must make to succeed under MIPS.
If CMS moves forward with this proposed expansion of the low-volume threshold criteria, we recommend CMS outline a plan for how it will include currently excluded providers in the MIPS program in the future.

MIPS Quality Category Weight
Trinity Health believes that all four of the performance categories—quality, cost, improvement activities, and promoting interoperability—represent important improvements in clinical care, quality, and value. To this end, our providers do not prioritize one MIPS category over another and do not view a quality measure as more important than the use of a patient portal in their clinical practice.

Trinity Health and its providers are committed to improving the entire continuum and process of care delivery—as this is essential to delivering people-centered care. We understand that the categories have historically been weighted to encourage participation and ease the transition to value, however, we recommend CMS consider allocating the performance category weights equally.

MIPS Cost / Resource Use Category
Trinity Health supports the addition of the eight episode-based cost measures to the list of MIPS cost measures. However, Trinity Health is concerned that the measures are largely inpatient and specialist focused. We believe that this list should include additional outpatient or acute care episode-based measures. Inclusion of these measures will better position providers to move into APMs and advanced APMs—especially ACOs—and prepare for increased accountability for total cost of care. Finally, CMS proposes that for providers to be scored on these episode-based measures that they have a case minimum of 10 or 20 cases, depending on the episode, and we question whether these numbers are sufficient.

MIPS Promoting Interoperability Category- Certified EHR Requirements
Trinity Health supports greater use of CEHRT and believes this is essential to interoperability, coordinated care, and the delivery of value-based care. However, Trinity Health has concerns with CMS’ proposal to require MIPS-eligible clinicians to use the 2015 Edition CEHRT starting in CY 2019. Providers’ ability to meet these CEHRT requirements are dependent on vendor capabilities. Providers not using the 2015 Edition CEHRT will either need to revise their contracts with current vendors and make an additional investment in updates to CEHRT or find a new vendor that can support use of the 2015 Edition CEHRT. Additionally, for providers that are currently not using the 2015 Edition CEHRT, meeting this new requirement will take time—and financial investment—and it is unlikely that all providers will be ready in CY 2019. We recommend that CMS allow for a 90 day reporting period both for the MIPS PI program as well as the Medicaid PI program to give providers time during CY2019 to gain familiarity and efficiency with the 2015 Edition CEHRT. Also, the incentives offered through the MIPS program need to be substantial enough to offset the costs incurred as new providers adopt 2015 Edition CEHRT.

Promoting Interoperability Performance Category Reporting Period.
Trinity Health supports CMS’ proposal to allow for a reporting period of a minimum of a continuous 90 days instead of a full calendar year effective 2019. We recommend CMS align reporting periods across the MIPS Promoting Interoperability (PI) category and the Medicaid PI program.

MIPS Promoting Interoperability Category- Promoting Interoperability Objectives and Measures for CY 2019 and CY 2020
We have specific concerns with the individual objectives and measures. Specifically, for the Patient Electronic Access objective, CMS proposes one measure—the Provide Patients Electronic Access to Their Health Information measure. This measure requires that the patient is able to access their health information in a timely manner and that the MIPS eligible clinician ensures the patient may access this information using an application of their choice configured to be compatible with the API in the CEHRT used by the MIPS-eligible clinician. It is our understanding that providers must provide patients with detailed instructions on how to authenticate their access through the API and provide the patient with supplemental information on available applications that leverage the API. While we encourage timely patient-provider communication, we recommend that CMS maintain the
current requirements of 4-business days for both the MIPS PI program as well as for proposed Stage 3 measures under the Medicaid PI. A change to this timeline will require changes to workflow and, time and investment.

In response to the national opioid epidemic, the proposed rule calls for two new opioid-related bonus measures related to electronic prescribing in the Promoting Interoperability performance category. Trinity Health generally supports these two new bonus measures but asks CMS for clarification with respect to when the use of the newest version of the electronic prescribing standard is permitted. Prescriptions sent electronically use the SCRIPT standard, which is developed in a consensus-building process through a standards development organization, the National Council of Prescription Drug Programs (NCPDP). The version currently in use and embedded in 2015 Certified EHR Technology (CEHRT) is version 10.6; the newest version – not yet in use – is version 2017071. Version 2017071 has significant new functionalities, including the ability to electronically prescribe additional specialty and compound drugs and the ability to share substance use and allergy history.

The first proposed new opioid measure would determine how many times the MIPS-eligible clinician checked a state prescription drug monitoring program (PDMP) for prescription drug history before prescribing opioids. After acknowledging that the current technological limitations of PDMPs could potentially pose hurdles to providers, CMS notes that it believes the new version of the SCRIPT standard (v. 2017071) could make it easier for EHRs to integrate with PDMPs. The second proposed new opioid measure assesses the ability of the MIPS-eligible clinician to identify the existence of a signed opioid treatment agreement and incorporate that agreement into the patient’s EHR when prescribing a Schedule II opioid for a patient whose total duration of opioid use is at least 30 cumulative days during a 6-month look-back period. CMS proposes that the 6-month look-back period would utilize at a minimum the NCPDP SCRIPT v10.6 medication history request and response transactions to determine the opioid use history. CMS also states in the proposed rule that providers could use a more advanced version of the SCRIPT standard (v. 2017071) to achieve the medication history transaction, and that ONC would permit CEHRT to incorporate and use a more advanced version of the SCRIPT standard (in place of the NCPDP SCRIPT v. 10.6 standard required for certification).

Trinity Health agrees with CMS that the new functionalities in v. 2017071 of the SCRIPT standard could be very helpful to patients, prescribers, the entire pharmacy services sector, and the nation. However, CMS encouragement of the use of the new SCRIPT standard, version 2017071, in 2019 in the proposed QPP rule is in direct conflict with the hard cut-off in the April 2018 Medicare Advantage (MA) Part D final rule, which says no one can test or move to the new SCRIPT standard until January 1, 2020, when all users must jump at once. See: https://www.gpo.gov/fdsys/pkg/FR-2018-04-16/pdf/2018-07179.pdf (pages 16636-38 and 16743).

Indeed, the MA/Part D final rule’s hard cut-off of NCPDP SCRIPT version 10.6 at midnight on January 1, 2020 would require prescribers, pharmacies, Part D plans, and others to move from version 10.6 to version 2017071 of the SCRIPT standard without any transition period or opportunity to test the new standard. This approach could jeopardize patient safety, as certified health IT vendors and the e-prescribing network could be overwhelmed trying to address issues related to the implementation of an update of this magnitude occurring overnight. In previous transitions to new versions of SCRIPT, CMS has regularly allowed for a lengthy transition period.

Accordingly, Trinity Health asks CMS to affirm that voluntary movement to the new version of the SCRIPT standard in 2019 is permissible. This clarification could also alleviate problems associated with the hard cut-over called for in the MA/Part D final rule.

Trinity Health also urges that CMS work with all interested parties to develop a more efficient method of transitioning to new versions of the SCRIPT standard. This is important to advancing interoperability because, for example, as noted above, the newest version of the SCRIPT standard includes functionalities that would allow prescribers to use standardized data fields to communicate
allergy and substance use history to pharmacies. This new functionality would likely be a useful tool in combating the opioid epidemic. We understand this new functionality was completed by NCPDP in July 2015 but is not yet available for use. Another new functionality in the new version of the SCRIPT standard is the ability to communicate instructions for specialty and compound pharmacy drugs in a standardized fashion so that these drugs can be prescribed electronically instead of communicated by fax or through written or oral prescriptions.

**Medicare Advantage Qualifying Payment Arrangement Incentive Demonstration**
Trinity Health supports efforts to continue to reward providers for participating in Advanced APMs or similar models. As a result, we support the goal of CMS’ proposed Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) demonstration, as it aims to support clinicians participating in certain Medicare Advantage payment arrangements that are similar to Advanced APMs.

**Advanced APMs - Use of Certified EHR Technology**
Trinity Health supports encouraging and incentivizing providers to adopt and use CEHRT as this can support delivery of coordinated, people-centered care. We believe it is important that providers in APMs use CEHRT and support CMS’ broader goal to encourage more providers to use CEHRT—in both the MIPS and Advanced APM tracks. However, we recommend that CMS finalize a more gradual increase in the percentage of eligible clinicians in an Advanced APM required to use CEHRT. Specifically, we recommend that the percentage be increased from 50% to 75% in increments of 5-10% per year and should not exceed 75%.

**Advanced APMs - Generally Applicable Financial Risk Standard**
Trinity Health believes that the amount of risk an entity bears must take into account the significant investment of capital and other resources necessary to redesign care delivery to improve beneficiary health. To this end, we strongly recommend that CMS revise the definition of more than nominal risk to consider business investments (e.g. care management and patient education, redesigning care delivery and associated staff training, development of patient management and engagement tool, etc.) necessary to improve care. For example in the proposed rule on MSSP, the models C & D include downside risk, but do not meet the risk standard and are not qualified to be AAPMs. We believe models C & D should be recognized as AAPMs.