June 27, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-5517-P
200 Independence Avenue, SW
Washington, DC 20201

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

Re: Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models [CMS-5517-P]

Dear Acting Administrator Slavitt,

Trinity Health appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services’ (CMS) Proposed Rule, Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models (CMS-5517-P). Our comments and recommendations to CMS reflect a strong interest in public policies that support better health, better care and lower costs to ensure affordable, high quality, and people-centered care for all.

Trinity Health is one of the largest 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 92 hospitals, 120 continuing care programs — including PACE, senior living facilities and home care and hospice services that provide nearly 2.5 million visits annually. Committed to those who are poor and underserved, Trinity Health returns almost $1 billion to our communities annually in the form of charity care and other community benefit programs. We have 31 teaching hospitals with Graduate Medical Education (GME) programs providing training for 1,951 residents and fellows in 184 specialty and subspecialty programs. We employ approximately 97,000 full-time employees, including more than 5,300 employed physicians,
and have 13,800 physicians and advanced practice professionals committed to 19 Clinically Integrated Networks across the country.

Trinity Health is an organization that is committed to rapid, measureable movement toward value in the delivery of and payment for healthcare. We support the agency’s efforts to develop accurate, equitable and forward-thinking payment methodologies. Our commitment to transformation goes much farther than principles and theoretical support. Trinity Health is currently participating in 14 Shared Savings Plan (SSP) ACOs and has five markets partnering as a Next Generation ACO. We are participating in 98 non-CMS APM contracts. In addition, we have 43 hospitals participating in the Model 2 Bundled Payments for Care Improvement (BPCI) program, 13 Skilled Nursing Facilities (SNFs) in Model 3 BPCI, and 2 hospitals in the Comprehensive Care for Joint Replacement (CJR) program. We are firmly committed to transforming our delivery system into a People-Centered Health System focused on delivering the triple aim in our communities.

Our comments reflect our best suggestions for improvements that we believe will facilitate the transformation of the American health care system towards better health, better care and lower costs to ensure affordable, high quality, and people-centered care for all. We believe that these interests are best served by encouraging as many practitioners as possible to become part of Advanced APMs. Furthermore, as we have pointed out in prior letters, we believe that all ACO tracks should be considered Advanced APMs. As described further in this letter, Trinity Health recommends a number of changes to CMS' MACRA NPRM, including recommendations that CMS:

- Change the first MIPS and Advanced APM Payment Year of 2019 to 2020 and delay the start date of the Performance Year to January 1, 2018.
- Implement a definition of more than nominal risk that recognizes the investments as business risk, and thus allows MSSP Track 1 ACOs to qualify as an Advanced APM.
- Adjust the rules so that ACOs may voluntarily move into a two-sided risk model at the start of any performance year rather than having to wait until the start of their next agreement period.
- Develop and implement a new MSSP Track 1.5, which moderates the level of risk that providers would need to accept, while at the same time includes accountability for downside risk.
- Provide an opportunity in final rulemaking for BPCI (through contract adjustment that includes CEHRT quality) and for CJR (through assumption of CEHRT obligations) programs to help qualify as Advanced APMs.

If you have any questions on our comments, please contact me at wellstk@trinity-health.org or 734-343-0824.

Sincerely,

Tonya K. Wells
Vice President, Public Policy & Federal Advocacy
Trinity Health
I. Overarching Concerns about the Implementation of MACRA

Trinity Health supports the objective of MACRA and this Proposed Rule: to accelerate transition away from payment based solely on volume and towards value-based purchasing. While we generally support CMS' efforts, we do have serious concerns related to the implementation timeline and the overall complexity of the program.

As we have spoken with physicians across our 22 state system, we have repeatedly heard concerns about their ability to process the necessary steps to participate in either Merit-Based Incentive Payment System (MIPS) or Alternative Payment Models (APMs). The types of fundamental changes that are necessary for physician practices to adapt to these new rules of the road are significant and enough time has not been built into the framework. Providers are experiencing innovation overload in the marketplace, and therefore need more time to adjust and align efforts.

Based upon what we are hearing across the country, we also have real concerns about a two-tiered system arising as those practices in more affluent, resource rich communities will be able to take advantage of the 5 percent bonus in the APM program or achieve the higher updates in MIPS, while safety net providers get left behind without the contracting opportunities to participate in APMs nor the resources needed to succeed in MIPS. Additionally, we have significant concerns about the implications this could have on the adequacy of primary care being provided in the most poor and vulnerable communities. Lastly, in addition to the safety net concerns, we have access concerns for all Medicare beneficiaries as physicians are likely to find MIPS and APMs so complex that they may exit the Medicare program altogether.

Implementation Timeline

CMS Proposal: CMS is proposing that for 2019, the first year of the payment adjustments under MIPS, the Performance Period will be CY 2017. CMS is proposing that it will assess clinicians participation in APMs in 2017 for the 2019 incentive payment.

Trinity Health believes that the current timeline does not provide sufficient time for clinicians and facilities to prepare for this change. Trinity Health recommends that CMS change the first Payment Year of 2019 to 2020 and delay the start date of the Performance Year to January 1, 2018.

Clinicians need adequate time to prepare to participate in these very complex programs that will directly and substantially affect payment. If CMS publishes a MACRA Final Rule in the fall of 2016, as expected, affected clinicians would have only two to four months to digest the regulations, make choices, prepare internal systems, hire vendors and train staff before beginning the Performance Year if the date remains at January 1, 2017.

In recent public comments, CMS officials have indicated that while the Performance Year starts on January 1, 2017, for most submission options for MIPS, measures and other data will not have to be submitted until the beginning of 2018. While we appreciate CMS' attempt to provide more flexibility and time, in reality, the various performance categories are based on services provided and activities...
performed in 2017. When providers will have to submit data is relevant; but, in the meantime, providers must focus on and meet the criteria described in these measures within and throughout the Performance Period. This all takes time, preparation and planning, and 60 to 120 days is just not an adequate amount of time.

**Timing Constraints Specific to APMs**
The MACRA Proposed Rule was released just days before registration information was due for participation in the Next Generation ACOs, which has been proposed as an Advanced APM for 2019. In addition, the deadline for participation in Tracks 2 and 3 of the MSSP program is July 29, 2016, which is only a month away and will come before the MACRA Final Rule is released.

This timing is forcing providers to scramble to consider if they should transition to more Advanced APM options without knowing what the final MACRA policies will be. Providers of all types need more time to consider, develop and pursue strategies to succeed in MACRA. As stated earlier, we recommend a one-year delay in the Payment and Performance Years, but also want to ensure these timing issues related to MACRA’s relationship with other programs is made clear and considered as further basis for the delay in implementation.

As an important point related to this timing, Trinity Health urges CMS to consider the relationship between MACRA-related timelines and current deadlines for related Medicare Innovation programs. Trinity Health recommends:

- CMS allow MSSP ACOs and Next Generation ACOs to begin on July 1, 2017. There is precedence for a truncated inclusion of a partial year – in 2012, MSSP ACOs were allowed to start year one of their three-year contracts on April or July 1 with the first “year” in effect lasting either 21 or 18 months, respectively. Or, if current requirements will not allow for a mid-year state date, then CMS should delay the overall timeline and allow MSSP ACOs and Next Generation ACOs to begin January 1, 2018 as we previously recommended.

- CMS allow providers’ ACOs participants to sign up to participate in ACOs two months prior to the beginning of the program year instead of four months. This would allow providers more time, when deciding whether to participate in an Advanced APM or MIPS, to assess the impact on their practices of the final Medicare payment policies for the coming year. With the proposed deadline four months in advance, these providers would need to make critical business decisions on the basis of proposed regulations and uncertain assumptions.

**Overall Complexity of MIPS**
Trinity Health urges CMS to consider as much flexibility as possible in the initial years of the MIPS program in order to attract clinicians to MIPS who may otherwise be overwhelmed by its complexity.

The goals of the MIPS program are ambitious. While CMS has made a significant effort to simplify implementation, the breadth and scope of the program makes it inherently complex. It is no wonder that the Proposed Rule is more than 400 pages. In order to meet the various reporting requirements, clinicians, medical groups and health systems will need to invest heavily in reporting and tracking. We fear that implementation will require significant resources and that some providers may be sufficiently
overwhelmed and overcome by the complexity, and choose to not pursue the reforms CMS seeks, which would be bad for patients, people-centered care, and the program.

II. Merit-Based Incentive Program (MIPS)

MIPS Performance Categories

Quality
The Quality performance category replaces the current Physician Quality Reporting System (PQRS) program. Quality accounts for 50 percent of the total MIPS score.

CMS Proposal: Clinicians are required to report on six measures with at least one cross-cutting measure and an outcome measure, if available. If no outcome measure is available, the clinician will be required to report one other high priority measure. This represents a reduction in the required number of measures from the PQRS program. Quality measures can be reported either individually or from a specialty-specific measure set.

Trinity Health supports CMS' proposal to reduce the number of measures and align measures with other national payers. We also support CMS' proposal to no longer require that a certain number of measures must span multiple domains, and that a provider has the flexibility to select the measures that best pertain to his or her practice.

Trinity Health recommends that CMS carefully review measure sets and defer to medical professional specialty society comments to ensure that measure sets are appropriately constructed. We also recommend that CMS work with the providers reporting these services to test the validity of the measure sets.

While Trinity Health supports the concept of measure sets, we do have some concerns with the construction of the proposed measure sets. We identified an instance where the measures proposed for inclusion in the specialty-specific measure sets are not appropriate for the designated specialties or sub-specialties. For example, Allergy/Immunology and Rheumatology should not be combined. There are numerous measures in that category grouping that do not apply to allergists. For example, ‘Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse)’ would not typically be ordered or reported by an allergist, but instead by an ENT specialist. While this is just one example, we believe it reflects a need that all of the measure sets should be more closely vetted by clinicians from the specialty providing the service.

Trinity Health urges CMS to improve the robustness of the MIPS quality measures. A key consideration in the effectiveness of the Quality performance category is the strength of the measures. We continue to be concerned with the robustness of the proposed measures. Trinity Health believes that many of the measures lack demonstrated improvement in patient care, create administrative burden for the provider to track, and will ultimately end up being monitored by a non-clinician staff member. Most measures currently utilized in the PQRS are process-based and thus provide little insight into the quality of care provided. Moreover, for many of the measures, the reporting criteria
are too complex. This unnecessary administrative burden discourages providers from selecting those measures.

Trinity Health believes that providing high-quality health care incorporates the patient’s health care experience. Various entities have begun to develop patient-reported outcomes measures (PROMs) and patient experience measures. As CMS continues to implement the MIPS program in future years, we encourage the agency to support the development of these measures, and to encourage clinicians and groups to include PROMs and patient experience measures when available. Existing infrastructure such as the Health Care Transformation Task Force, the Health Care Payment Learning and Action Network, the Center for Healthcare Transparency and the Measures Application Partnership can support CMS and accelerate the adoption of new measures (including PROMs). Collaboration with public and private sector stakeholders to design, test, and spread these measures is key for successful measure development and adoption.

Additionally, in today’s PQRS, data completeness is 50 percent for most reporting mechanisms meaning that physicians have to reach a 50 percent threshold to be successful. We recognize CMS’ desire to have information reported that is reflective of the entire patient population but recommend that data completeness remain at 50 percent for the first performance period of MIPS and is increased over time, rather than immediately jumping to 90 percent.

CMS Proposal: CMS requests comments on whether it should attribute a facility’s performance to a MIPS eligible clinician for the Quality performance category and under what conditions it would be appropriate and representative of the clinician’s performance. Additionally, MACRA authorizes the Secretary to use measures from other payment systems (e.g., inpatient hospitals) for the Quality and Resource Use performance categories for “hospital-based” MIPS eligible clinicians, but excluded measures from hospital outpatient departments, except in the case of items and services furnished by emergency physicians, radiologists, and anesthesiologists.

Trinity Health supports both of these related concepts: developing a method to attribute a facility’s performance to a MIPS eligible clinician for the Quality performance category and using measures from other payments systems for the MIPS program. Greater alignment of quality measures across programs will reduce the administrative burden for all providers and produce more actionable and relevant data for Medicare.

Trinity Health believes that there is value in reducing the redundancy in data provided to CMS by both the facility and the individual clinician. As a general principle in this area, we believe greater alignment of measures across programs will reduce the administrative burden for all providers and produce more actionable and relevant data. We believe both proposals provide the means for MIPS to be a more efficient way to collect data, and potentially to provide data that is more relevant to hospital-based MIPS eligible clinicians. Allowing a physician to use and adopt facility measures and using measures from other payment systems will make the MIPS program more efficient and reduce the reporting burden on MIPS eligible clinicians. Hospital-based physicians have less control over the administrative aspects of their environment and may have difficulty reporting measures through traditional PQRS.
reporting methods. Trinity Health believes greater emphasis on electronic health record (EHR) reporting as well as greater alignment of physician quality reporting with hospital-based quality programs may help to alleviate this problem.

We urge CMS to integrate into its quality measure development a strategy to operationalize these critical and important proposals. In terms of using facility scores as a proxy, while we support the concept, we believe more details are needed as to how this would be operationalized—especially considering that many physicians perform services in multiple facilities. With respect to the use of facility measures by hospital-based clinicians, Trinity Health urges CMS to harmonize MIPS measures with measures from existing Medicare quality programs. A key element of harmonization is to ensure that data collection is standardized so that it can be leveraged across programs. Potentially some modifications to the measures may be necessary to facilitate dual reporting by the facility and the clinician.

Advancing Care Information (ACI)

CMS Proposal: The ACI performance category replaces the current Meaningful Use program. ACI accounts for 25 percent of the total MIPS score. CMS is proposing significant changes from the current Meaningful Use program (e.g., no longer requires reporting on the Clinical Decision Support and the Computerized Provider Order Entry measures). Clinicians report on six objectives and measures (base score) and on select measures that emphasize patient care and information access (performance score).

Interoperability is a key strategic priority for Trinity Health, and we noted with interest that MACRA declared it a national objective to achieve widespread exchange of health information through interoperable certified electronic health record (EHR) technology nationwide by December 31, 2018. In general, Trinity Health believes that the ACI category remains highly complex and that eligible clinicians and the outside vendors and internal information technology professionals that support them will not have sufficient time to digest the Final Rule and make the necessary workflow and technology changes necessary to ensure a safe and effective transition to MIPS readiness by January 1, 2017. As noted elsewhere, Trinity Health urges CMS to change the first MIPS Payment Year to 2020 and to change the start date of the first Performance Year to January 1, 2018. This will facilitate success in the MIPS.

Trinity Health supports a number of proposals in the ACI category including the following:

- Moving away from the all-or-nothing approach in measuring a clinician’s use of interoperable technologies;
- Reducing the number of measures and transitioning to group-level reporting;
- Allowing MIPS eligible clinicians to submit partial year data; and
- Reducing the number of public health registries required for a provider to submit.

Trinity Health urges CMS to finalize these policies noted above as proposed.

In addition, Trinity Health urges CMS to incorporate the following changes into the ACI performance category and related programs:


• **Provide a 90-day reporting period for CY 2016 and CY 2017** for all Meaningful Use/ACI participants (both physicians and hospitals). Trinity Health strongly supports a 90-day reporting period;

• **Permit eligible clinicians to meet the ACI base score requirements that leverage the Modified Stage 2 objectives and measures and certified EHR technology already in use.** This would better align ACI requirements for eligible clinicians with Meaningful Use requirements for hospitals. While the proposed ACI requirements require much of the functionalities required in Meaningful Use Stage 3 in 2017, hospitals are not required to move to Stage 3 of the Meaningful Use program until 2018. Physicians should not be required under ACI to accelerate in 2017 to functionalities not required of hospitals until 2018; indeed, Trinity Health urges that reporting of Stage 3 and Stage 3-like measures should not be required of eligible hospitals or eligible clinicians until 2019;

• **Align Meaningful Use requirements for physicians and hospitals.** Parity across Meaningful Use and ACI requirements is essential and should be a priority of the Agency. Requirements for the use of certified EHR technology and the exchange of health information should be aligned across all providers through the provision of additional flexibility for hospitals (including Critical Access Hospitals) under the Medicare and Medicaid EHR Incentive Program. Although Trinity Health physicians and hospitals have enjoyed significant success in the Meaningful Use program, the tremendous effort required to successfully meet established Meaningful Use goals has diverted clinician and staff attention and resources away from activities with greater direct patient benefit, and away from efforts to advance interoperability. We anticipate even greater challenges if we have to work toward success in two disparate programs (ACI for physicians and Meaningful Use for hospitals). Thus, Trinity Health believes that alignment of eligible clinician and hospital requirements should be a priority for the Agency. While we were pleased to hear calls for “simplicity whenever possible” in the MIPS, simplifying the program for physicians while maintaining the same cumbersome program for hospital makes an already complex program even more nettlesome.

Lastly, Trinity Health continues to be concerned that clinicians are being penalized for the limitations in interoperability that are beyond their control. Vendors, not clinicians, must be held accountable for these issues. To make this pivot to holding vendors accountable, CMS should advance vendor requirements during the certification process to ensure that vendors are providing the software and technology necessary for providers to efficiently and effectively exchange information, and to fulfill the objectives of the QPP. We recommend that certification requirements have “use case” testing that is done in a complex integrated delivery system, which would include having vendors demonstrate that a particular attribute of their technology/software is working in many disparate EHRs across various settings of care. For instance, how easy is it for a patient to identify their care team when members are on different vendor platforms? We also recommend that vendors demonstrate usability in complex settings. For instance, how do care teams document their role in their native electronic medical record (EMR) and is it available in other EMRs as the patient crosses the care continuum?
Clinical Practice Improvement Activities (CPIA) Performance Category

CMS Proposal: CMS has proposed a list composed of 90 options for the 2017 Performance Year. Each activity is worth 10 or 20 points. The maximum points a clinician can earn is 60 points. For the 2017 Performance Year, CMS is requiring one activity to avoid a zero score.

Trinity Health believes these initial CPIA requirements are reasonable. We urge CMS to maintain this expectation through the first few years of the MIPS program and until clinicians become more familiar with this performance category.

In general, Trinity Health supports the proposals related to the CPIA performance category. We believe the CPIA performance category captures an important component of any strategy to enhance the quality of care provided to Medicare beneficiaries. We also appreciate that as a relatively new area for providers on which to report, the Agency has tried to create a reasonable threshold for the first year by requiring only one activity to avoid a zero score. We believe that this threshold should be maintained until MIPS eligible clinicians gain more familiarity with this performance category.

Trinity Health urges CMS to provide greater details on activities approved for the CPIA performance category, including a more detailed description of the activity and the minimum criteria associated with that activity.

In reviewing the list of CPIA activities provided in the MACRA Proposed Rule, only a general title was provided. There was no description of the activity. As such, we were not always clear on the specifics of the activity and what a clinician would need to do in order to have “performed” the activity. We believe MIPS eligible clinicians need more details on the specific activities for them to make informed choices about their CPIA activities and to be able to confidently attest that all of the criteria have been met and the activity was completed.

CMS Proposal: MIPS eligible clinicians or groups must perform CPIAs for at least 90 days during the performance period for CPIA credit.

Trinity Health recommends that CMS eliminate a minimum reporting time for an activity. The list of activities on the CPIA list ranges widely from participation in certain public health programs, to collecting patient satisfaction data or documenting that patients receiving warfarin are being managed according to validated electronic support and management tools. Trinity Health believes that with such a varied list of activities, an across-the-board minimum reporting time does not make sense. The proposed time of 90 days may not be appropriate for all activities on the CPIA list.

Resource Use

CMS Proposal: All Resource Use measures would be adjusted for geographic payment rate adjustments and beneficiary risk factors; a specialty adjustment would be applied to the total per capita cost measure. For future rulemaking they will be considering the ongoing work by the Assistant Secretary for Planning and Evaluation (ASPE) regarding risk adjustment of quality measures for socioeconomic status.
Trinity Health urges CMS to expand and increase the use of risk adjustment in the application of the Resource Use performance category. We urge CMS to consider the appropriateness of integrating the findings of the ASPE in this area as well as explore if there are other models to consider within the Department of Health and Human Services and in the private sector.

Trinity Health strongly supports greater use of risk adjustment. We believe when using measures to reward and penalize a provider, the context within which providers are working must be considered. Risk adjustment allows for fair cross-provider comparisons and does not penalize one provider over another or convey one provider is lower quality simply due to their willingness to treat any patient, despite that patient having an increased risk in poor outcomes due to endogenous factors that are captured in proxy measures such as socio-demographic variables. For example, we recommend CMS to look at the National Quality Forum’s Report on Risk Adjustment for Socioeconomic Status or Other Sociodemographic Factors as a resource to help expend their efforts in this area.

**CMS Request for Comments:** CMS requests comments on whether they should attribute a facility’s performance to a MIPS eligible clinician for the Resource Use performance category and under what conditions would be appropriate and representative of the clinician’s performance.

Trinity Health encourages CMS to explore methodologies to use a facility’s performance score as a proxy for a MIPS eligible clinician. Similar to our comments on the Quality performance category, Trinity Health believes that there is value in reducing the redundancy in data provided to CMS by both the facility and the individual clinician. Greater alignment of measures across programs will reduce the administrative burden for all providers and produce more actionable and relevant data. In addition to addressing the issue of reducing redundancy in data submission, we believe it may more appropriately reflect the administrative and clinical work flow of hospital-based MIPS eligible clinicians.

**MIPS APMS**

**Criteria for MIPS APMs**

*CMS Proposal:* CMS defines MIPS APMS as meeting the following criteria: (1) The APM entity participates in an APM under an agreement with CMS; (2) The APM entity includes one or more MIPS-eligible clinicians on a participation list; and (3) The APM bases payment incentives on performance (either at APM entity or individual eligible clinician level) on cost/utilization and quality measures. CMS also notes that these proposed criteria are independent of those proposed for its advanced APM track. CMS excludes the Comprehensive Care for Joint Replacement (CJR) model from being a MIPS APM because facilities (i.e., hospitals) are considered to bear the risk for performance. The agency specifically identifies and proposes scoring approaches for two APMs that meet its criteria for a MIPS APM, and that would therefore be eligible for alternative scoring:

- Medicare Shared Savings Program (MSSP)
- Next Generation Accountable Care Organization (ACO) Model.
The inclusion of a MIPS APM was not included in the MACRA statute, thus it is a new approach put forth by CMS in the Proposed Rule. As a result, we believe that CMS has ultimate authority on how a MIPS APM would be defined. **Trinity Health agrees with the inclusion of MSSP Track 1 in MIPS APMS, and we also strongly urge CMS to include MSSP Track 1 programs in the final list of Advanced APMs.** We believe that providers incur greater than nominal risk by simply becoming active ACO participants. The significant amount of financial investment, time, effort and operational risk to their business that result from transforming business and clinical models all represent the “greater than nominal risk” providers are making in pursuing CMS’ goal of transforming the delivery of care. Providers do this in the face of great programmatic immaturity and uncertainty for CMS, intermediaries and themselves. We believe requiring providers to accept medical cost and insurance risk on top of these risks is premature.

In addition, bundled payment programs such as BPCI and CJR have been excluded from this list of MIPS APMs. Trinity Health does not agree with this exclusion. By excluding facility-led APMs from MIPS APMs, clinicians employed by hospitals will not be able to use the APM scoring standard. This will ultimately discourage clinicians from participating in facility-led APM models. It would also jeopardize the sustainability of facility-led APMs in mandatory models as clinicians would be reluctant to engage in contracts based on the APMs quality and cost goals. **We urge CMS to allow facility-led APM entities (for example BPCI and CJR bundle programs) to qualify as APMs – specifically, see our points in the Advance APM portion of our comments for more details on this recommendation.**

**Alternative Scoring Approach for MIPS APMs**

**CMS Proposal: CMS proposes to calculate one Composite Performance Score (CPS) for each MIPS APM entity; the APM entity group score would then be applied to each eligible clinician in the APM entity. To determine an APM entity CPS, CMS proposes to:**

- **Use quality measure data submitted through the Web Interface to evaluate the quality performance category; for entities that do not submit data through the Web Interface the APM entity would not submit data for the MIPS quality performance category until the second performance period (2018);**
- **Not assess the resource use category since APMs usually assess resource use as total cost of care, rather than narrower claims-based measures in MIPS**
- **Aggregate the clinical practice improvement activity (CPIA) scores of TINs or individual eligible clinicians that participate in the APM Entity to determine an overall APM CPIA score; each TIN or individual clinician will automatically receive half the total points in this category.**
- **Aggregate the advancing care information (ACI) scores of TINs or individual eligible clinicians that participate in the APM Entity to determine an overall APM ACI score.**

Trinity Health recommends that APM Entities be allowed to choose to qualify for either MIPS APM status or Advanced APM status. The opportunity to choose would reward those entities that wish to push themselves forward while allowing others to remain at a level of transformation with which they are more comfortable.
In addition, Trinity Health recommends that MIPS APM scoring should only consider the quality and CPIA. Because we anticipate that providers could move back and forth between MIPS APMs and Advanced APMS depending on thresholds, increasing the consistency between them would avoid confusion. To ensure the greatest clarity between MIPS APMs and Advanced APMs, CMS should ensure no additional reporting is required in MIPS APMs. In addition, Trinity Health also recommends that MIPS APMs receive the highest possible score in the CPIA category. In order to effectively participate in an APM, the various clinical improvement activities must be undertaken. APM participation should be given full points possible. Finally, MIPS APMs should be allowed to use certified EHR technology instead of requiring ACI scoring.

III. Advanced Alternative Payment Models (APMs)

Through a combination of bonuses and higher annual updates, the MACRA legislation incentivizes physicians to participate in Advanced APMs. Trinity Health strongly supports provider incentives to participate in Advanced APMs that generate better health, better care and lower costs. In order to achieve these goals, though, all providers must have viable Advanced APM options available to them.

Transitioning a significant portion of payments from fee-for-service (FFS) to APMs will take time and significant effort to transition the existing Medicare delivery system, and therefore CMS must make every effort to incentivize physicians to participate in APMs, as well as make adequate Advanced APMs available for physicians who want to pursue this path. The path to Advanced APMs should be transparent and the barrier to entry must be reasonable. CMS must work to provide a clear pathway to APMs. While programs like MIPS provide some incentives towards value-based care, Advanced APMs will be more effective in improving care and lowering costs.

Standards for Advanced Alternative Payment Models (APMs)

CMS Proposal: According to the Proposed Rule, an Advanced APM must be a CMS Innovation Center model or a statutorily required demonstration and must: (1) Bear more than a nominal amount of risk for monetary losses with 3 dimensions; (2) Base payment on quality measures comparable to those used in quality performance category of MIPS; and (3) Require participants to use a certified EHR technology

Bear More than Nominal Risk

CMS Proposal: an Advanced APM would meet the financial requirements if CMS would withhold payment, reduce rates or require the entity to make payments to CMS if its actual expenditures exceed expected expenditures. The three dimensions of risk under an Advanced APM that must be met at a minimum are: total risk of at least 4 percent of the APM spending target, marginal risk of at least 30 percent and minimum loss rate no greater than 4 percent.

CMS proposes that financial risk for monetary loss must be tied to performance under the model as opposed to indirect losses related to financial investments made by Advanced APMs. Trinity Health would strongly disagree with this perspective and believes that this definition does not take into
account the significant investment and transformation taking place across existing APMs. A significant investment of capital is required to redesign care delivery to improve beneficiary health. These investments include the following:

- Care managers and patient educators – who provide non-billable services to beneficiaries
- Redesigning care delivery and training staff to change their approach to patient care
- Developing and using the right tools to identify and contact patients on a proactive basis
- Utilizing new population health management tools as well as advanced analytics and reporting
- Coordinating patient care via phone
- Upgrading appointment systems to ensure easy and timely access for high-risk patients
- Expanding access to caregivers in after-hours to meet patients' urgent needs.

For example, the average annual costs to start and run an ACO can be in excess of $1.6 million with no guarantee of achieving savings, even if an ACO reduces Medicare spending. ACOs incur ongoing costs for care management, consultation between different physicians, and other services that are not covered by Medicare FFS payments. This amount is consistent with CMS’ own estimates in the November 2011 Final ACO rule, “Our cost estimates for purposes of this Final Rule reflect an average estimate of $0.58 million for the start-up investment costs and $1.27 million in ongoing annual operating costs for an ACO participant in the Shared Savings Program.”

Beyond the initial investment costs and ongoing operating costs, facility-based providers also forego FFS revenue when they successfully reduce hospital admissions and readmissions. As a result, Trinity Health urges CMS to implement a definition of more than nominal risk in the final MACRA rule that considers the investments made as a critical component or risk, and thus allowing MSSP Track 1 ACOs to qualify as an Advanced APM.

To address concerns that CMS has stated about being able to quantify and verify the ACO costs, we recommend that CMS require ACOs to attest to the financial information and that the agency could conduct audits to ensure validity of this information.

Furthermore, we understand there are concerns that some ACO participants may be participating in the program but not aggressively managing care. Therefore, we believe that CMS could actively monitor the results of Track 1 ACOs that pursue Advanced APM status and allow a limited time frame – perhaps 3 years – for the ACO to produce shared savings. Advanced APM status could be removed if the providers do not achieve any shared savings in this defined time period.

**Base Payment on Quality Measures Comparable to Those Used in Quality Performance Category of MIPS**

*CMS Proposal:* an Advanced APM must base payment on quality measures that are evidence-based, reliable and valid and comparable to the quality measures under MIPS. Additionally, one measure must

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be an outcome measure unless there is not an appropriate outcome measure available on the MIPS measure list.

Trinity Health supports CMS’ approach to quality measurement for an Advanced APM. We especially appreciate the inclusions of outcomes measures as this has long been an approach that Trinity Health has urged. There is not a need for specific metrics here, since the Advanced APM requires metrics already, so the flexible approach is a good one.

Existing infrastructure such as the Health Care Transformation Task Force, the Health Care Payment Learning and Action Network, the Center for Healthcare Transparency, and the Measures Application Partnership can support CMS and accelerate the adoption of new measures (including PROMs). We believe that collaboration with public and private sector stakeholders to design, test and spread these measures is key for measure development and adoption.

**Require Participants to Use Certified EHR Technology**

*CMS Proposal:* an Advanced APM must require that at least 50 percent of the clinicians use a certified EHR technology to document and communicate clinical care information in the first performance year. Requirement increases to 75 percent in the second performance year.

Trinity Health supports the CMS proposal with its initial criteria of 50 percent and the second year criteria of 75 percent. This approach allows the Advanced APMs to expand upon the systems that they have in place today, and is preferred to the specific criteria in the ACI category of MIPS.

**Special Rules for Medical Home Models**

*CMS Proposal:* According to statute, for medical home models expanded by HHS (and exempt from risk standards for other Advanced APMs under MACRA). If either: (1) Actual expenditures for which the APM Entity is responsible exceed expected expenditures; or (2) APM Entity performance on specified performance measures does not meet or exceed expected performance CMS would require that Medicare: (1) withhold payment for services to the APM entity and/or ECs, (2) reduce payment for services to the APM entity and/or ECs, (3) require the APM Entity to owe payments to CMS, or (4) Lose the right to all or part of an otherwise guaranteed payment or payments.

For medical home models not expanded by HHS and that are operated by an APM entity with 50 or fewer ECs, CMS proposes to require that to be an Advanced APM, they would need to be at risk to forgo or owe CMS certain percentages of their revenue each year: 2.5 percent of the APM Entity’s total Part A and B revenue in 2017; 3 percent in 2018; 4 percent in 2019; and 5 percent in 2020 and beyond.

Trinity Health believes that medical homes must have a “total cost of care incentive” to be considered an Advanced APM. While we believe that primary care physician medical homes can be essential elements of successful ACOs, we do not believe that they are successful in delivering better health, better care and lower costs, if there is no explicit total cost of care incentive program. Trinity Health recognizes that the intent of CMS’ proposal on the Medical Home Model (that is not otherwise
under section 1115A(c) of the Act) is to support smaller organizations with 50 or fewer clinicians with unique risk standards, however, we have concerns that this treatment may put this program at a preferential status that could impact participation in other models that have demonstrated savings. This treatment could sway clinicians to choose less-effective or more narrow models and impair overall system transformation through participation in more global models. Trinity Health has concerns that setting the bar so much lower for medical homes to qualify as an Advanced APM will alter the course of transformation based upon accountability for total cost of care, which we believe to be the most effective way to bend the health care cost curve.

In order to remove this preferential position of medical homes, Trinity Health recommends that CMS lower the loss sharing limit for Advanced APMs from 4 percent to a more reasonable threshold, such as 1 percent of total Part A and B costs or 10 percent of physicians’ revenue for covered professional services under the Medicare Physician Fee Schedule.

List of Advanced Alternative Payment Models (APMs)

Qualifying Models Listed in Proposed Rule

CMS Proposal: The Proposed Rule lists the following models as Advanced APMs for the first performance year: (1) Comprehensive End Stage Renal Disease Care Model; (2) Comprehensive Primary Care Plus (CPC+); (3) Medicare Shared Savings Program (MSSP) Track 2; (4) MSSP Track 3; (5) Next Generation ACO Model; and (6) Oncology Care Model Two-Sided Risk Arrangement. Under the Proposed Rule, CMS would update this list annually to add new payment models that qualify.

Trinity Health urges CMS to expand this definition and thus this list of qualifying Advanced APMs — in particular we urge CMS to include the MSSP Track 1 model on the list of Advanced APMs.

As defined in the Proposed Rule, 90 percent of the ACOs would be excluded from consideration as an Advanced APM. In their recent survey, when NAACOs asked ACOs how likely they would be to stay in MSSP if they are not eligible for the 5 percent APM bonus, 56 percent responded that they would leave the MSSP.² To ensure long-term sustainability of the Medicare ACO model, we strongly recommend that CMS finalize a list of Advanced APMs under MACRA that includes all Medicare ACOs, including those in MSSP Track 1.

The current structure of the MSSP program, even with some of the changes in the Benchmarking rule, is unlikely to result in a financially viable payment model for many providers, which may dampen enthusiasm for participation and stall the early innovation and progress in the health care system today. The MSSP is still in the early stages of implementation and all participants are still learning about the complex interactions between the many different policy and operational aspects of the program. We believe it would be very premature to attempt to push all ACOs to accept risk in Tracks 2 and 3, given the many uncertainties inherent in the current state of the program’s development. We

also believe that ultimately the best road to having providers operate under risk arrangements in the future is to help them succeed in the absence of risk until they gain sufficient operational experience and confidence in their ability to be successful and in the financial viability of their ACOs under the program’s benchmarking and trending methodologies.

**Transition to Down-Side Risk**

As we have described in our comments to this Proposed Rule and several other rules over the past few years, the transition to assuming down-side risk in the ACO is not an easy or quick path for providers. CMS has established a policy of forcing providers to accept downside risk in order to have maximal opportunity to be successful. This approach is reinforced by the position CMS is taking in this MACRA Proposed Rule. We believe CMS should reverse this policy. Downside risk presents additional complexities for CMS and providers. For smaller organizations, this could represent a very real threat to the viability of their organizations. It was not part of the original ACO proposal as presented by Fisher et al.\(^3\) Given the added complexity it presents, we believe CMS should require risk only if the upside-only approach to risk has been fully tested and shown to be ineffective. We believe that CMS has not provided such an optimal test of the ability of ACOs to generate meaningful savings for CMS without downside risk. In fact many Track 1 ACOs have been successful to date even operating under the great uncertainty of a brand new program and constraints CMS has imposed regarding waivers for homecare, skilled nursing facility (SNF) use and telemedicine.

We also believe that, even if risk is demonstrated to be necessary, providers need a viable path to develop the capabilities needed to manage such risk. The assumption of such risk requires early success to maintain sustainability of continued participation. The lack of growth in the CMS risk-based models such as MSSP Tracks 2 & 3, Pioneer and the Next Generation models compared to the grown in MSSP Track 1 demonstrates this point. When ACOs were asked about their willingness to stay in the MSSP program once CMS requires it to take on downside risk in a recent NAACOs survey, 43 percent said that would definitely or likely not continue to participate.\(^4\)

While ACOs have described apprehension about taking on downside risk now in the recent NAACOs survey, 44 percent expressed a willingness to do so in 1-3 years and another 40 percent in 4-6 years.\(^5\) For these reasons, **Trinity Health requests that if CMS does not move to include MSSP Track 1 models in the final definition of an Advanced APM, at a minimum, CMS should adopt a policy that would establish a transition period policy that deems MSSP Track 1 ACOs as meeting the Advanced APM definition for 2 years with the expectation that those ACOs will transition to a two-sided risk model by the end of the transition period.** Alternatively, CMS could tie the transition period to the specific ACO contract term. This flexible approach would recognize the ongoing progress organizations are making in those models, while establishing an appropriate expectation that those organizations should continue to move forward toward two-sided risk models as quickly as possible.

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**ACOs Should Be Allowed to Switch Tracks at the Start of Performance Period**
Currently ACOs can only switch MSSP tracks at the beginning of a new three-year agreement and once the period begins they are locked in until the next agreement is signed. We strongly urge CMS to adopt a more flexible policy that will allow ACOs to move into two-sided models earlier than the start of their next agreement period. **Trinity Health urges CMS to adjust the rules so that ACOs may voluntarily move into a two-sided risk model at the start of any performance year rather than having to wait until the start of their next agreement.**

**Create a New Two-Sided Risk ACO Model**
Trinity Health recommends that CMS develop and implement a new MSSP Track 1.5, which moderates the level of risk that providers would need to accept, while at the same time includes accountability for downside risk. While we recognize that the development of a new MSSP model is not within the scope of the MACRA rule, we would like to offer our support as a resource to support this work in collaboration with other willing partners such as the National Association of ACOs (NAACOs) and the Health Care Transformation Task Force (HCTTF). We agree with the approach that NAACOs describes in detail in their comments to the MACRA rule.

**Bundled Payment Models**
*CMS Proposal: Proposed Rule does not specifically include any of the bundled payment models as Advanced APMs.*

According to the Proposed Rule, the Medicare BPCI and CJR programs meet the more than nominal risk standard to be an Advanced APM, however, BPCI does not meet the requirement for quality measurement and CEHRT and CJR does not meet the requirement for CEHRT. We recommend that CMS provide an opportunity in the Final Rule or other means for interested APM entities to amend their BPCI contract to require them to meet either or both of the CEHRT requirements and quality requirements. There may be some complexity and administrative overhead associated with making these changes to the BPCI program, but we believe that it is important to do so in order to allow those physicians participating in transformative models the opportunity to take the additional steps to be rewarded accordingly as an Advanced APM.

As it pertains to the CJR model, which is only missing the CEHRT piece — but in the end does not qualify as either a MIPS APM or an Advanced APM, we recommend that CJR programs should also be allowed to voluntarily assume CEHRT obligations to help qualify them for Advanced APM status. Alternatively, CMS could impose a CEHRT obligation on CJR programs similar to the EHR meaningful use program, which would then qualify all CJR programs as Advanced APMs.

**ACO/Bundling Overlap Concerns**
Trinity Health appreciates CMS’ recent letter that invited participants and stakeholders to offer suggestions about the interaction between bundled payment episodes and Medicare ACOs. Currently, the model defaults to the benefit of bundled participants and subjects the ACO to target pricing. We
continue to encourage CMS to look quickly into alternative approaches to this current overlap policy so both ACO and BPCI models can thrive in the important move to APMs. An alternative to the current overlap policy, that does not subject ACOs to BPCI target pricing, is particularly important now to support continued participation in ACO models. We recommend that beneficiaries attributed to new models that include accountability for care across the continuum be excluded from overlap – clinical or financial – with models that bundle or carve out episodes of care.

**Continued Challenges to Sustainability of ACO Program Related to Benchmarking Rule**

Trinity Health’s recommendations reflect a strong interest in seeing the MSSP achieve the long-term sustainability necessary to reduce health care costs, enhance care coordination and improve the quality of care for Medicare beneficiaries. Our specific comments here, as well as those we made in the proposed MSSP Benchmarking rule released in March of this year, reflect our concern with provisions that were finalized in the final Benchmarking rule and proposed in this rule that undermine the stability of the MSSP and other Medicare ACO programs.

**Beneficiary Assignment to Determine Regional Costs for Benchmarking**

In our comments pertaining to beneficiary assignment in the Benchmarking rule, we urged CMS to remove ACO-assigned beneficiaries from the regional service area population (reference population). We recommended that rather than comparing ACOs to themselves and other ACOs, CMS should compare ACO performance relative to FFS Medicare by defining the reference population as assignable beneficiaries minus ACO-assigned beneficiaries for all ACOs in the region. We believe that excluding ACO-assigned beneficiaries (those involved in MSSP ACOs and well as other CMS ACO programs such as Pioneer and Next Generation) allows for a truer comparison between ACOs and FFS. While CMS argued that inclusion of these beneficiaries in the calculation would reduce the chance of bias, particularly in the case of ACOs serving higher cost beneficiaries within the region, we argued and believe that without removal of ACO-assigned beneficiary population, the regional cost data will be skewed by reflecting ACOs’ efforts to coordinate care and reduce expenditures for the ACO population and will mute the performance of well-performing ACOs. We maintain concern for the potential implications this may have on ACO participation in the MSSP program as well as dampening performance or making it more difficult for ACOs that are participating in both MIPS and Advanced APMs. We urge CMS to reconsider the position in its final ACO Benchmarking rule by changing the definition of the reference population to exclude ACO-assigned beneficiaries.

**Including Savings in Benchmark**

In the July 2015 final ACO rule, CMS established a policy that adjusts the rebased historical benchmark to account for savings generated by an ACO during the prior agreement period. In the final MSSP Benchmarking rule, as proposed in the NPRM, CMS reverses previous policy and establishes that when calculating the rebased benchmark for a new three-year agreement period, savings generated in the previous agreement period will no longer be incorporated into the calculation. In the proposed rule, the agency argued that transitioning to a benchmark methodology that incorporates regional expenditures would mitigate the impact of no longer accounting for savings in subsequent agreement periods. In the preamble to the final rule, CMS notes:
We explained our observation that for ACOs generating savings, a rebasing methodology that accounts for regional FFS expenditures would generally leave a similar or slightly greater share of measured savings in an ACO’s rebased benchmark for its ensuing agreement period. By contrast, for ACOs generating losses, a rebasing methodology that accounts for regional FFS expenditures would tend to carry forward a significant portion of measured losses into their rebased benchmarks and push benchmarks lower than the current rebasing policy. We expressed our belief that in transitioning to a benchmark rebasing methodology that incorporates an adjustment for regional FFS expenditures, it is important to forgo the current adjustment to account for shared savings generated by the ACO under its prior agreement period. (p. 56)

While CMS reasons that using regional FFS expenditures in the rebasing methodology would accurately reflect savings and losses in an ACO’s rebased benchmark for its next agreement period, Trinity Health believes—as expressed in our comments to the proposed Benchmarking rule—that CMS will be best served by creating a benchmark that presents real opportunity for savings, thereby encouraging providers to aggressively invest and manage quality and cost. As such, we are concerned about continued participation given the greater potential for losses.

**Delayed Switch of Regional Benchmarks for 2012 and 2013 MSSP ACOs Until 2019**

As finalized in the final MSSP Benchmarking rule, ACOs that entered the Shared Savings Program in 2012 and 2013, which renewed their agreements beginning January 1, 2016 and running through December 31, 2018, will not switch to the revised rebasing methodology until their third agreement period, starting in 2019. CMS argues that applying the revised methodology to these ACOs in the middle of their agreement would disrupt these ACOs’ success as they have already structured their operations, legal and administration approaches around the previous benchmarking approach or may lead to termination of contracts.

Trinity Health, however, believes that this delay potentially penalizes early adopters. Specifically, these ACOs will not be able to assess their performance under the revised methodology until 2019, which will delay some ACOs’ ability to assess if they should stay in the MSSP program, move to MIPS or pursue another Advanced APM model—which potentially penalizes some of these earlier adopters, especially ACOs that participated in Tracks 1 for their first two agreements. Another concern is that ACOs that entered MSSP in 2012 and 2013 would be compared to ACOs that had been assessed using the rebasing methodology potentially putting these ACOs entering their third agreements at an even greater disadvantage.

**Qualified Participant and Partial QP Determination**

*CMS Proposal:* The Proposed Rule sets guidelines for qualifying as individual or group participant under an Advanced APM based upon only Medicare payments or patients for 2019 & 2020. Starting in 2021, qualifying participant (QP) requirements for Advanced APMs may include non-Medicare payers and patients.
MACRA creates two categories of physicians who meet certain thresholds of Advanced APM participation. Clinicians determined to meet the statutory Advanced APM participation as Qualified Participants (QPs) are exempt from MIPS and receive an Advanced APM payment incentive. Physicians who do not meet the threshold to become a QP but meet a slightly lower threshold of Advanced APM participation are deemed partial QPs. Partial QPs do not receive the APM incentives but are exempt from the MIPS, though they may choose to report and receive MIPS payment adjustments voluntarily. In 2019 and 2020, CMS may only consider Medicare Part B professional services attributable to an Advanced APM Entity when determining QP status; starting in 2021, there also will be an all-payer option.

CMS proposes to calculate QP determinations at the Advanced APM Entity level, collectively across all Eligible Clinicians (ECs). An EC would be in the QP calculation if they are on the APM Entity participant list at the end of the performance period (12/31/17 for 2019). QP determination would be calculated after the close of the APM/MIPS performance period.

Consistent with our feedback on the MACRA RFI, Trinity Health is pleased that CMS has offered both the Medicare payment and patient count options as a means for determining a clinician’s QP status. Trinity Health supports the definition of attributed and attribution eligible beneficiaries for calculating the percentages. Trinity Health also supports allowing Partial QPs to decide if they want to participate in MIPS.

Trinity Health recommends QP threshold calculations and qualifications be assessed at the provider or practice level, not at the level of the Advanced APM entity. This would align with payment of the Advanced APM bonuses. Additionally, Advanced APM entities do not have access to complete Part B payments at the provider level which makes it difficult for Advanced APM entities to assess their performance toward QP thresholds.

As it relates to the groups used for QP determination, first, Trinity Health urges CMS to automate the process of identifying the applicable NPIs within an MSSP based on those eligible clinicians billing underneath the TINs submitted to CMS during the performance period. If CMS is unwilling, it should use the NPI list provided by the Entities in February of each year. Secondly, Trinity Health urges CMS to allow Next Generation ACOs to continue updating the NPI list throughout the performance year for MACRA purposes knowing that CMS will not use those NPIs for attribution in the model until the next year. CMS should also consider a designation that can be routinely updated in PECOS to capture participation in an Advanced APM or Other-Payer APM Model. Third, Trinity Health urges CMS to reconsider its proposal to identify the QPs based on participation in the Model as of December 31 of the performance period. CMS may need to customize the determination depending on the model, but regardless, we suggest CMS automate where possible.