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September 11, 2017

Seema Verma, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
CMS-1676-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1676-P; Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program

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

Dear Administrator Verma,

Trinity Health appreciates the opportunity to comment on the proposed policy and payment changes set forth in CMS-1676-P. Our comments and recommendations to the Centers for Medicare and Medicaid Services (CMS) reflect a strong interest in public policies that support better health, better care and lower costs to ensure affordable, high quality, and people-centered care for all.

Trinity Health is one of the largest multi-institutional Catholic health care delivery systems in the nation, serving diverse communities that include more than 30 million people across 22 states. Trinity Health includes 93 hospitals, as well as 115 continuing care locations that include PACE, senior living facilities, and home care and hospice locations. Our continuing care programs provide nearly 1.9 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 35 teaching hospitals with Graduate Medical Education (GME) programs providing training for 2,095 residents and fellows in 184 specialty and subspecialty programs. We employ approximately 131,000 colleagues, including more than 7,500 employed physicians and clinicians, and have more than 15,000 physicians and advanced practice professionals committed to 22 Clinically Integrated Networks that are accountable for 1.3 million lives across the country.

We appreciate CMS' ongoing efforts to improve payment systems across the delivery system. If you have any questions on our comments that follow, please feel free to contact me at wellstk@trinity-health.org or 734-343-0824.

Sincerely,

Tonya K. Wells
Vice President, Public Policy & Federal Advocacy
Trinity Health

Overall Comments on Regulatory Flexibilities and Efficiencies

Trinity Health is pleased that the Administration is asking industry participants to describe opportunities to increase flexibility and efficiency in the regulatory process. The complexity and redundancy of many aspects of the existing regulatory scheme is not keeping pace with the evolution of health care and is hindering the innovation that all stakeholders, including CMS, wish to inspire. **Please consider how many of the comments articulated throughout this letter on the proposed Medicare Physician Fee Schedule changes are related to opportunities to further reduce regulatory burden and inefficiency—including those related to Evaluation & Management Codes, appropriate use criteria, and the Medicare Shared Savings Program (MSSP).**

Medicare has excellent mechanisms in place to hold providers accountable for the outcomes—not the processes—of care via value-based payment programs as well as transparency initiatives such as Hospital Compare and the star ratings system. We believe the greatest opportunity for change is for CMS to use these value-based and transparency mechanisms to drive provider innovation around the processes of care that can deliver the best outcomes. In general, CMS has gone too far with process details in many regulations and Trinity Health recommends that the agency instead focus on an outcomes-based regulatory scheme that identifies a small number of high-level key metrics that are meaningful to patients and that reflect successful performance against the desired outcomes of better care, smarter spending and healthier people as well as prudent fiscal management of public funds. Coupling measurement that is based on outcomes with transparency tools allows the marketplace to drive providers to develop and continuously improve upon the most effective care processes.

CMS should also provide more time to implement new regulations, and CMS should more fully consider hospital and health system comments and concerns prior to implementation. There have been an enormous number of regulatory changes over the last several years. CMS continues to add new forms and requirements, even in the face of universal opposition from stakeholders, without reducing, eliminating or condensing related regulations and requirements. Many of these regulatory efforts require significant changes in software, other technology, and processes; and these changes are multi-step endeavors involving stakeholders across hospitals and health systems as well as outside partners including vendors. We urge CMS to provide more realistic timetables for regulatory implementation and ensure that these timetables take into consideration the fact that hospitals and health systems are continuing to provide direct patient care 24-hours-a-day/7-days-a-week alongside implementation of regulatory changes.

We urge CMS to reduce front-end administrative burden. In many cases, hospitals and health systems have provided significant feedback and enunciated specific concerns to CMS; however, the agency often moves forward without giving proper consideration to these concerns. Recent examples of this include the two-midnight rule, the repeated reporting changes related to laboratory packaging, and now implementation of reporting related to appropriate use criteria (AUC). While Trinity Health often agrees with the intent behind proposed changes (e.g., beneficiary notification of observation status), the regulatory scheme is often conflicting and very administratively burdensome to implement (e.g., the NOTICE Act and MOON form). Further, the too often-used solution of CMS is to require the use of modifiers to collect information, which is typically extremely burdensome to implement.

Trinity Health strongly recommends that CMS rely more heavily on transparency, monitoring, and the creation of a more efficient marketplace that will drive self-correction through competitive means. In addition, we recommend that CMS give more credence to provider comments and concerns prior to implementing new regulations. Additionally, we recommend that CMS consider the creation of an advisory panel that includes hospital and health system participants to discuss impending regulations and assist in developing more realistic timelines and solutions. Furthermore, CMS should consider the aggregate burden of new regulations, not simply the individual burden of discrete regulations, on clinicians and other staff.

Evaluation & Management (E/M) Guidelines

Trinity Health appreciates the opportunity to provide input to CMS on how Evaluation & Management (E/M) documentation and coding guidelines could be reformed to reduce unnecessary burden and better align with the current practices of medicine. The detailed guidelines often cause clinicians to overdocument, creating a medical record that is an ineffective source of communicating patient acuity and care. In addition, we believe the current guidelines make it difficult for providers to assign the most accurate code for adequate reimbursement.

Trinity Health recommends that CMS could consider and evaluate the use of guidelines that would combine time and complexity of care. Time is straight forward and would need to be documented in the chart by the provider of the care. Complexity would be determined by the provider using medical decision making, and be based upon clinical interventions either provided or ordered along with diseases managed. **Trinity Health recommends that guidelines allow for 3 code levels aligning time and complexity similar to low, medium, high complexity. See table below for how our recommendation would work.**

Level 1 – Low Complexity	Level 2 – Moderate Complexity	Level 3 – High Complexity
1-2 interventions and/or 1 disease or problem	3-4 Intervention and/or 2 diseases or problems	5 or more intervention and/or 3 diseases or problems
10-15 minutes	15-25 minutes	Greater than 25 minutes

If CMS implemented our recommended approach, the provider would not be required to document unnecessary information to meet requirements of a code. And, documentation would be more focused on pertinent information related to the patient’s chief complaint, acuity and medical decision making.

Because E/M services are provided in high volume by almost all providers, any changes to the documentation guidelines that impact which E/M level is reported will have an enormous impact on the Medicare system as well as the administrative workings within practices across the country. Therefore CMS needs to take a transparent and collaborative approach as they launch into this multi-year effort to revise the E/M guidelines. The development of any proposals should be made with stakeholder input, all proposals should be open for public comment and vetted thoroughly, and finally and proposed guidelines should be tested prior to their implementation being mandated.

Medicare Telehealth Services

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 now proposing to expand the Medicare telehealth program for CY 2018. This expansion will increase access to these important services for a greater number of providers and the patients they serve. Over the years, telehealth has consistently demonstrated a wide range of positive outcomes including: better access to care regardless of the location of the patient, increased patient satisfaction, enhanced communication with providers and reduced costs. For these reasons, Trinity Health encourages the use of telehealth to promote health and well-being across outpatient, inpatient and community-based settings.

Trinity Health supports CMS’ proposal to eliminate the use of the GT modifier on professional claims for telehealth services.

Trinity Health supports CMS’ proposal to add two new services to the list of Medicare-payable telehealth services:

- Counseling visit to determine low-dose computed tomography (LDCT) eligibility (G0296).
- Psychotherapy for crisis (90839, first 60 minutes; 90840, each additional 30 minutes).

Trinity Health supports CMS’ proposal to add four services that describe additional elements to services already on the telehealth list:

- Interactive complexity (90785)
- Administration of patient-focused health risk assessment instrument (96160)
- Administration of caregiver-focused health risk assessment instrument for the benefit of the patient (96161)

- Comprehensive assessment of and care planning for patients requiring chronic care management services (G0506)

Proposed Payment Rules under the PFS for Nonexcepted Items and Services Furnished by Nonexcepted Off-Campus Provider-Based Departments of a Hospital

CMS adopted a set of payment rates for 2017 that are based on a 50-percent reduction to the OPPS rates (inclusive of packaging) for nonexcepted items and services furnished by nonexcepted off-campus PBDs (the “PFS Relativity Adjuster”). For 2018, CMS proposes to pay nonexcepted off-campus PBDs at 25 percent, rather than 50 percent, of the OPPS rate for nonexcepted services. CMS arrives at the new 25-percent rate based on a comparison of the payment rate for a hospital outpatient clinic visit (billed using HCPCS code G0463), which CMS says reflects greater than 50 percent of services billed using the PO Modifier, to the payments for similar outpatient visit services under the PFS (specifically, CMS compared the facility and nonfacility payments for Level III and IV office visits, as represented by CPT codes 99213 and 99214). CMS acknowledges that its proposed methodology does not take into consideration any comparison between the OPPS and PFS rates for other services commonly furnished in off-campus PBDs. CMS requests comments on its proposal, including whether the agency should adopt a different PFS Relativity Adjuster, such as 40 percent, that represents a middle ground between the adjusted used in 2017 and their proposed 25-percent adjuster.

Trinity Health urges CMS to not implement a change to the PFS Relativity Adjuster at this time. CMS is basing its proposal on an inadequate analysis with faulty assumptions, and with no assessment of the potential implications for beneficiary access.

CMS’s reliance on the payment differentials between facility and nonfacility payments for Level III and IV office visits for purposes of this proposed policy change is flawed for several reasons. First, CMS’s analysis incorrectly assumes that the payment differential between facility and nonfacility payments for Level III and IV office visits, and the relationship of those differentials to OPPS payment rates for comparable services is somehow a proxy for or reflective of the cost of furnishing these services in a hospital outpatient department. It can barely be said that the payment amounts established under the PFS or OPPS are reflective of costs. While derived from cost data, both payment systems are so contrived and influenced by so many policy applications that the resulting payment amounts cannot be said to credibly reflect the actual cost of furnishing services. As such, CMS cannot credibly conclude from this analysis alone that it would be adequately reimbursing hospitals for furnishing this service, let alone for *all* nonexcepted HOPD items and services.

Second, CMS’s analysis does not take into consideration the service mix variability among nonexcepted HOPDs. CMS relies on the fact that G0463 represents a significant number of claims, and maybe even most of the claims, billed using the PO Modifier. But CMS must recognize that many nonexcepted HOPDs may never bill a G0463. A diagnostic imaging center, for example, likely would not bill a G0463. Instead, this location will bill codes like 74177, 71260 and 71250, for which the CY 2016 PFS technical payment amount as a percentage of the OPPS payment is 63 percent, 71 percent and 115 percent, respectively. Similarly, a facility that principally furnishes radiation oncology services would principally bill using codes 77412 and 77386, for which the CY 2016 PFS technical payment amount as a percentage of the OPPS payment is 138 percent and 69 percent, respectively. If CMS were to set an across-the-board payment for these services based on 25 percent of the OPPS rate, CMS would be drastically under-reimbursing these facilities. In fact, if this proposed change is finalized it moves what was intended to be site neutral policy to policy that would be punitive to HOPDs.

This proposal would likely have the effect of driving these services into more costly settings, like excepted HOPDs, freestanding locations, or even ASCs (if CMS finalizes a proposal to allow ASCs to furnish radiation therapy services) where Medicare payment amounts would be higher. This shift could end up costing Medicare and its beneficiaries more. This

change also could lead some hospitals to discontinue offering services where the cost-to-payment is so obviously upside down. Communities could be left without adequate access to certain services if hospitals shutter certain facilities. CMS appears to have not considered or evaluated these important access considerations.

Lastly, CMS is proposing a change with barely adequate data on which to base an assessment. CMS implemented this policy in January 2017, and used CY 2016 volume data to identify G0463 for purposes of the comparison. CMS should allow at least several years of payment data from after the initial implementation to accumulate before making a change based on analysis of volume and payment differentials from these locations. It is our experience that the 50 percent Relativity Adjuster already results in a payment that is insufficient. Because the patients that seek treatment at PBDs tend to be sicker, lower income and uninsured, they incur higher costs than the average freestanding physician office. Oftentimes PBDs are providing the only source of primary and specialty care in safety net communities and incur higher costs in treating their patients. The clinical complexity of patients seen in PBDs and additional wrap around resources needed to serve this population certainly make the cost of care greater. Plus, these facilities support emergency departments and other critical community services despite inadequate reimbursement.

In addition to their complex patients, PBDs are required to comply with provider-based regulations, which include requirements pertaining to billing, medical records, and staffing. For example, to qualify as provider-based and receive Medicare reimbursement, an outpatient department must be clinically and financially integrated with the main provider. This includes a requirement that patients of a PBD have full access to services at the main hospital. Medical records of the PBD also must be integrated into the main provider's system. This integration allows for more coordinated care such as seamlessly transmitted patient information across clinicians that prevents duplicative services among other benefits. PBDs also have more stringent survey standards as hospital-based entities. These and other requirements impose additional compliance costs on hospitals that are not borne by freestanding physician offices.

For the foregoing reasons, **we urge CMS to withdraw its proposal and not implement any change to the PFS Relativity Adjuster at this time.** Nonetheless, should CMS go forward with a change, even if at a different percentage, CMS should phase in any such change over a period of years. CMS has a long history of phasing in changes, especially of this magnitude. Even in this same rulemaking, CMS limits changes in payment for PFS services to no more than 20 percent from one year to the next. CMS should not assume it okay to decrease payments for nonexcepted facilities by 25 percent in one year.

Additionally, we remain concerned about some of the decisions made in CMS's interim final rule that prohibit excepted HOPDs from relocating, rebuilding or changing ownership. **We do not believe that CMS is required by the statutory language of Section 603 to prohibit such actions, and there are many reasons, both within and outside our control, why an HOPD may need to relocate or rebuild.**

We are particularly concerned with the impact that this proposed policy will have on HOPDs that operate in leased space. If an HOPD is unable to relocate and retain excepted status, it is at the mercy of its landlord to remain in its current location. CMS's policy creates an incentive for landlords to raise rents or impose other onerous conditions on use of the leased space, knowing that an excepted HOPD will have to accept whatever conditions the landlord may impose. We appreciate that CMS established an exceptions policy, but by limiting those exceptions to "extraordinary circumstances outside a hospital's control," CMS is providing little relief for this concern. **We encourage CMS to revisit this policy generally, or the exceptions limitation at the very least, so that CMS does not create such a windfall for landlords or place hospitals in such an untenable position.**

As to changes of ownership, we do not believe that CMS has provided sufficient justification or detail regarding their policy to prohibit changes of ownership of excepted HOPDs. In responding to comments raised by stakeholders, CMS merely reiterated its concerns, authority and long-standing policy. There are circumstances where HOPDs may undergo organizational changes that are considered a change of ownership for Medicare purposes, but that are undertaken by related entities for purposes of increasing efficiency and reducing costs. For example services could be consolidated (provider numbers merged) to improve patient care, steward community resources and reduce costs, but these types of changes may be as likely to be undertaken if the consequence is loss of excepted status. There is little policy justification to support blocking these reasonable business transactional activities. **As such, we urge CMS to revisit its position on changes of ownership, and specifically to allow for reasonable changes in status. CMS could accomplish this through an exceptions process, much like it did with relocations.**

Appropriate-use Criteria (AUC) for Advanced Diagnostic Imaging Services

The Protecting Access to Medicare Act (PAMA) requires CMS to establish a program that promotes AUC for advanced diagnostic imaging. The statute requires that, beginning Jan. 1, 2017, payment may be made to the furnishing professional for an applicable advanced diagnostic imaging service only if the claim indicates that the ordering professional consulted with a qualified clinical decision support mechanism (CDSM) as to whether the ordered service adheres to applicable AUC. This policy applies only when applicable imaging services are provided in specific settings – a physician’s office, hospital outpatient department (including an emergency department), an ambulatory surgery center, and any other provider-led outpatient setting as determined by CMS. CMS now proposes that AUC consultation and reporting requirements would begin on Jan. 1, 2019.

In this proposed rule, CMS proposes that AUC reporting requirements include the following: 1) the ordering professionals will need to consult with a clinical decision support mechanism (CDSM) and (2) the "furnishing professional" would then need to include information about the ordering professional's consultation on their Medicare claim. In this Proposed Rule, for the first time, CMS is 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.

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, the requirement to report AUC information on every order will be extremely burdensome on all parties and run contrary to this Administration’s stated goal to reduce 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 is greatly concerned about the potential impact of the coming requirements on the furnishing professional and the performing facility and provides 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 ordered test on their claim and CMS could develop a non-payment modifier which would indicate the code is being reported for data collection. **This would maintain the responsibility for the**

AUC intent with the responsible party and not penalize the furnishing professional and the performing facility with additional extremely burdensome work and potential payment reductions.

- Under the proposal, all of the billing burden and risk of payment denial will fall to the furnishing professional and the entity providing the service and not on the ordering professional. We do not feel the burden of proof that the ordering professional followed regulation and consulted the CDSM should be placed on performing facilities. **If CMS chose to have the ordering professional report the G codes and modifiers, we strongly urge CMS to develop a verification mechanism that would be required of the ordering professional, perhaps a yearly attestation to indicate they consult the AUC for each advanced diagnostic imaging service that they ordered.**
- PAMA directs the Secretary through rulemaking to specify appropriate use criteria for imaging services only from those developed or endorsed by national professional medical specialty societies or other provider-led entities. PAMA requires the Secretary then to promote the application of such criteria by ordering professionals and furnishing professionals to imaging services furnished in a physician's office, a hospital outpatient department (including an emergency department), an ambulatory surgical center, and any other provider-led outpatient setting. Transmittal 1699 (CR 9707) SUBJECT: Appropriate Use Criteria for Advanced Imaging – Analysis and Design published on August 5, 2016, states: "The furnishing professional in these scenarios will be the radiologist that interprets the image. PAMA 218(b) identifies additional information that must be appended to the furnishing practitioner's claim." This information indicates the PAMA requirement should fall to the ordering professional and furnishing professionals. The requirement that hospitals and other performing facilities include the information on institutional claims does not seem to correlate with PAMA requirement and previous transmittals. **If CMS does not choose to retain the responsibility and the burden on the responsible party (the ordering professional), Trinity Health believes this requirement should strictly be placed on the furnishing professional's claim and not on the facility claim.**

In other areas of the proposed rule, CMS is requesting comments on efficiencies and ways to make reporting requirements less burdensome. This proposal will be extremely burdensome to implement and to sustain as an on-going process. It will greatly increase costs for the ordering professional, the furnishing professional, and the facility supplying the service. This proposed requirement is a perfect example of the increasing number of extremely burdensome requirements that CMS says they want to reduce. Trinity Health supports the intent of AUC, the use of evidence-based decision-making to address inappropriate utilization, but it must be implemented in a reasonable and sustainable manner.

If CMS chooses to overlook industry concerns and more forward as proposed, Trinity Health would strongly recommend the following:

- Delay this requirement for at least an additional year, until 2020. This would allow CMS time to work with physicians, hospitals and information system vendors to get a realistic idea of the length of time needed to revise information systems to provide this data.
- Include clear instructions in the final rule and in the Medicare Manuals that the ordering professional needs to include the necessary information, preferably the G code and modifier not a written description, on their orders. Hospitals still struggle today with obtaining complete orders including diagnostic information and physician signature.
- Ensure there is adequate time for electronic health systems to be updated. In order for this to work, there needs to be 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 on the order.

- Exempt any providers that are participating in ACOs from this requirement. The nature of the ACO model ensures the accountability of providers in a “total cost of care” model, thus making this additional AUC burden unnecessary.
- Ensure AUC criteria, however they are finalized, do not impede the ability of patient driven choice and ensure appropriate transparency.
- Exempt emergency department visits from AUC requirements. Since the advanced imaging services provided in the ED setting are 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.
- Identify advanced diagnostic imaging services at the HCPCS code level.
- Clarify what recourse the furnishing professional and performing facility have when the necessary information is not included on the order.
 - Should an ABN be collected and the patient be held responsible?
 - Should the patient be inconvenienced and the service not be provided?
 - Should hospitals assume the AUC was not consulted and report as such?
 - This will be the likely outcome as hospitals cannot take on the burden of chasing down AUC information when it is not provided with the order. Hospitals also cannot take the financial hit of not be paid if they do not report a G code and modifier. This will reflect poorly and possibly inaccurately on the ordering professional.
- Communicate with providers how CMS will handle inconsistent data. For example, 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 on the ordering professional. It is our belief that the ordering professional would want to be responsible for data that reflects their ordering practices to ensure accuracy. The proposed approach will not achieve that and instead burdens furnishing facilities and providers and puts them at risk for the actions and practices of the ordering professional. Another effect of this approach could constrict

Medicare Shared Savings Program (MSSP)

Trinity Health is currently participating in 14 MSSP ACOs and has 5 markets participating as a Next Generation ACO. We are committed to the ACO model and encourage CMS to provide as many pathways as possible to achieve success in the MSSP. Such a philosophy would be consistent with the overall intent of CMS to create a program that involves as many organizations as possible, allows many to be successful and encourages ongoing investments by making it easier in early years to earn sufficient funds for reinvestment in care. Our comments in this area are grounded in our support and belief in the Medicare ACO program.

Sustainability

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. The current design of MSSP program make it difficult for the ACOs to obtain a positive return. We urge CMS to improve the program to improve the deal to entice continued and expanded participation in the MSSP program. Trinity Health recommends that CMS develop a Track 1 MSSP model that includes an 80% upside-only approach and requires ACOs to demonstrate results by year 4 or be forced out. Expanded participation in the MSSP program is assured by design to bring savings to the Medicare Trust Fund.

Beneficiary Assignment

Trinity Health supports the proposed changes to the MSSP aimed to better account for primary care services when assigning beneficiaries to an accountable care organization (ACO), reduce the application burden for ACOs and better align the MSSP quality reporting program with the CMS Quality Payment Program (QPP).

Trinity Health supports the approach proposed by CMS to implement requirements imposed by the 21st Century Cures Act that requires CMS to assign beneficiaries to MSSP ACOs based not only on utilization of primary care services furnished by physicians, as is currently done, but also based on utilization of services furnished by RHCs and FQHCs, for performance years beginning on or after Jan. 1, 2019. We believe it will be effective to treat all services provided by an RHC or FQHC in the same way as a primary care service provided by a primary care physician. **We strongly agree with the direction of change proposed by CMS to alleviate the requirement of RHCs and FQHCs to identify through attestation the physicians who directly provide primary care services. Instead, any service provided by an RHC or FQHC, even if provided by a non-physician practitioner, would qualify as primary care for the purposes of beneficiary assignment.** We agree that this will reduce the burden for ACOs that include RHCs and FQHCs, and advance its goal of assigning beneficiaries to the ACO that is primarily responsible for the beneficiary's overall care.

In addition, Trinity Health applauds CMS for its more appropriate recognition of non-physician practitioners who provide valuable primary care services that should be factored into the assignment of beneficiaries to ACOs. Trinity Health has been a long-time advocacy of policies that support, empower and reimburse non-physician practitioners (RNs/APRNs/PAs) as decision-makers to improve care management and access to care, including refinements to Medicare and Medicaid that address inconsistencies in how services provided by non-physician practitioners within their existing scope of practice are treated for certification or reimbursement.

Trinity Health supports CMS proposal to add to its definition of primary care services new codes for chronic care management (99487, 99489, G0506) and behavioral health integration G0502, G0503, G0504, G0507) that were finalized in the CY 2017 PFS rulemaking. We support the inclusion of these services when calculating the amount of primary care provided for purposes of beneficiary assignment for performance year 2019 and beyond.

Application Process

Trinity Health supports CMS proposal to streamline certain documentation and certification requirements components of the MSSP program application and the application for Track 3 ACOs seeking a waiver of the skilled nursing facility (SNF) three-day stay rule. We agree that the requirement of a narrative describing financial relationships that exist between the ACO, SNF affiliates and acute care hospitals, and documentation demonstrating that each SNF on the ACO's list of affiliates has an overall rating of three or higher under the CMS 5-star Quality Rating System should be eliminated. These requirements do increase burden and do not add value to the agency's ability to review and approve SNF affiliates.

We encourage CMS to go further and give all ACOs the waiver for the SNF 3-day stay and waive the requirement of completing an application.

Trinity Health supports the elimination of the requirement of applicant ACOs to submit supporting documents or narratives regarding:

- specified processes, such as how the ACO will promote evidence-based medicine, promote beneficiary engagement internally report quality and cost metrics and promote coordination of care;
- the ACO's organization and management structure; and
- distribution of shared savings payments.

Trinity Health agrees with CMS, that it makes more sense for them to request such information only if it is needed to fully assess the ACO's application to determine program eligibility. Trinity Health appreciates this effort to reduce unnecessary and costly administrative overhead and burden.

Quality measures

We believe that ACO participants have ample incentive to improve quality and outcomes, but that measure reporting can be an expensive and burdensome activity. CMS should focus on outcome measures for high impact conditions for which there is evidence that improvement opportunities exist. Any new measure should be well-defined, tested and designed to fill gaps in measurement without adding undue burden on providers. Quality measures used for payment should be limited such that there are no more than 5 clinical measures and 2 patient experience measures. These measures should be primarily patient reported functional status outcome measures. Quality metrics should also include other components that are critical to accurately assessing the role of a provider in affecting patient outcomes, and ease provider burden across multiple programs.

There are significant costs, for providers and CMS, associated with the production and collection of reported metrics across multiple programs. These costs are especially acute for primary care practices that may be smaller or independent. As a result, CMS should do more to provide alternative reporting approaches (e.g., electronic reporting from certified electronic health records and q-data intermediaries) and align measures with other Medicare measure reporting programs.

Trinity Health strongly believes that there are too many measures on which to select from and report, and urges CMS to limit the number of measures to a manageable set (e.g., 5-7 measures) that emphasize patient-reported and patient-generated data.

Medicare Diabetes Prevention Program (MDPP)

In the CY 2017 PFS rule, CMS expanded the Center for Medicare & Medicaid Innovation's diabetes prevention program demonstration as a permanent program, beginning Jan. 1, 2018. Trinity Health supported that expansion in our comments because we believe that targeting efforts on preventing chronic conditions that affect a broad range of Medicare beneficiaries is wise policy to help prioritize resources. Selecting a program that has a proven track record in the Medicare population is a reasonable approach to addressing this high priority area for Medicare.

CMS now proposes to change the start date to April 1, 2018, in order to ensure that MDPP suppliers have sufficient time to enroll in the program after the final CY 2018 PFS rule is published. In addition, CMS proposes a number of new policies related to the MDPP.

Trinity Health supports the proposed changes to the covered services including a two-year limit on Medicare coverage for ongoing maintenance sessions, with a total of up to three years of MDPP services. Participants would receive core services

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for the first six months in the program, followed by core maintenance sessions in the second six months in the program, then up to two years of ongoing maintenance sessions.

Trinity Health supports the proposed adjustments/clarifications around beneficiary eligibility including that beneficiaries with a prior history of Type 1 or Type 2 diabetes are not eligible for MDPP services, beneficiaries with a history of gestational diabetes are not excluded. Further, the agency clarifies that beneficiaries who are diagnosed with end-stage renal disease after receiving MDPP services would lose eligibility. Finally, CMS proposes that beneficiaries who are diagnosed with diabetes after they have started the first core session would continue to be eligible for MDPP services.

Trinity Health supports CMS proposal to pay MDPP using a performance-based payment structure, which would tie payment to performance goals based on beneficiary attendance and/or weight loss. Total maximum payment per beneficiary would be \$810, made to MDPP suppliers periodically over the course of services. The periodic payments would be made based on factors including the beneficiary's completion of a specified number of MDPP sessions and achievement of the required minimum weight loss associated with a reduced incident of Type 2 diabetes. Once the required minimum weight loss is achieved and the 12-month core services period ends, suppliers would receive three-month interval performance payments for ongoing maintenance sessions, but those payments would be made only when the required weight loss is maintained.

Trinity Health supports CMS' proposal to allow MDPP suppliers to provide in-kind patient engagement incentives to promote improved beneficiary health and reductions in Medicare spending. The incentive must be reasonably connected to the curriculum taught by the MDPP supplier and be a preventive item or service, or an item or service that advances a clinical goal for an MDPP beneficiary. Such items or services could include things such as gym memberships, onsite child care, digital scales and pedometers.

