Trinity Health

September 11, 2017

Seema Verma, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
CMS-1678-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1678-P; Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs

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

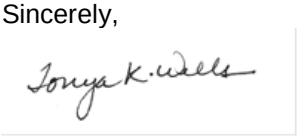
Dear Administrator Verma,

Trinity Health appreciates the opportunity to comment on the proposed policy and payment changes set forth in CMS-1678-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 innovation and consumer engagement that all stakeholders, including CMS, wish to inspire. **Please refer to our comprehensive letter in response to the request for information focused exclusively on specific regulatory improvement topics for further detailed recommendations. Additionally, please consider how many of the comments articulated throughout this letter on the proposed Hospital Outpatient Prospective Payment System changes are related to concerns on the impact the specific proposal would have in creating regulatory burden and inefficiency—including those related to 340B, appropriate use criteria, the inpatient-only list, and drug administration add-on codes—rather than flexibility and efficiency.**

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.

Payment Reductions for Drugs Purchased under the 340B Drug Pricing Program

Trinity Health is deeply concerned by the substantial cut that CMS has proposed to Medicare Part B payments for 340B drugs under OPPS. We strongly oppose this proposal and the proposed cut in payments for 340B drugs from the current rate of Average Sales Price (ASP) plus 6 percent to ASP minus 22.5 percent. The proposed payment cut is inconsistent with the Congressional intent of the 340B Program, represents a further assault on safety-net institutions, and will have a devastating impact on our patients and communities. CMS should rescind this proposal in its entirety.

Congress created the 340B Program in 1992 to enable entities participating in the 340B Program to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services".[1] Trinity Health is committed to fulfilling the purpose of the 340B Program through the implementation of 340B programs at each of its 340B-participating entities and use of revenue generated from drug savings under the 340B Program. 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, much of this deriving from 340B revenue. Most importantly, the 340B Program allows us to offer more comprehensive patient services to the most vulnerable uninsured and underinsured patients in our communities.

If implemented as proposed, the cut to payments for 340B drugs would result in a reduction in Medicare payments for Part B drugs to Trinity Health hospitals that participate in the 340B program and are paid under OPPS of approximately $10-$15 million per year. The additional administrative cost of implementing systems changes necessary to place a modifier on claims to identify non-340B drugs and related operational changes are significant. And even before the modifier component can be implemented, we would need to develop system workarounds in the absence of technology enhancements from the vendors. These are real and substantial reductions to our revenue and additional regulatory and cost burdens that would alter our financial stability and force Trinity Health to make significant changes – including most prominently, changes to subsidized services that benefit the health of the communities we serve.

As a result of the payment cuts and increased administrative costs and regulatory burdens, Trinity Health will be forced to reduce current programs that are supported by savings generated by participation in the 340B Program. We have used 340B savings to open new outpatient pharmacies that, due to access to the reduced 340B prices, are able to dispense free or reduced cost prescriptions to low income patients. We have also used 340B savings to support additional ambulatory care pharmacists at certain outpatient clinic locations, which has allowed us to increase access to essential, often non-reimbursed, services such as anticoagulation, heart failure, smoking cessation and discharge clinics for these vulnerable, at-risk populations.

Most directly threatened by the proposed payment cuts, our hospitals also use discounts available on certain 340B-priced drugs to provide access to medications that would otherwise be financially infeasible to provide. The proposed cuts to Medicare Part B payments for 340B drugs will seriously challenge our ability to continue to offer these and many other programs, challenging our ability to support access to critically-needed drugs. When Trinity Health analyzed the top 20 most commonly

[1] See Health Resources and Services Administration, 340B Drug Pricing Program, https://www.hrsa.gov/opa/index.html.

used drugs in the Medicare hospital outpatient setting covered under Part B, we learned that the current level of reimbursement of ASP + 6% does not cover our acquisition costs for seven of these high volume drugs. In most cases, the magnitude of the loss per patient treatment is significant; in some cases near $1,000/case. Reducing these already insufficient reimbursement rates by such a significant amount may make provision of these drugs financially infeasible. Trinity Health is concerned that a reduction in the current payment rate for these more expensive drugs could compromise our ability to offer certain therapies, which could compromise beneficiary access and health. **Trinity Health is already aware that many hospitals and physician practices that do not have access to 340B pricing have ceased offering certain drugs with Medicare payment rates that do not cover the cost of acquisition and administrating. Cutting the rates for 340B-participating hospitals, may result in certain therapies not being available to Medicare beneficiaries in any setting.**

Additionally, a likely–though unintended–effect of this proposed policy would be an increase in the cost of Medicare Part B drugs. Medications purchased under the 340B Program are excluded from the ASP calculation, and non-340B hospitals must generally purchase branded Part B drugs at full price due to pharmaceutical company class of trade pricing that does not grant voluntary discounts to hospital class of trade. Therefore, as hospitals lose access to 340B these purchases shift to full price and become part of the ASP calculation at the highest price paid. This will directly drive up ASP, the bedrock of the Part B payment model, and therefore Part B drug expenses across the board will increase.

While we strongly oppose implementation of the proposed payment cuts, if CMS does move forward, we encourage CMS to ensure that the funds generated by the reduction in Part B payments for 340B drugs are redistributed on a budget neutral basis to hospitals that operate in a manner consistent with the intent of the 340B Program–that is, those hospitals that demonstrate a strong commitment to charity care and services to underserved populations, and that are not-for profit hospitals. We remind CMS that the intent of the 340B Program is to allow participating entities and their patients to benefit from the saving generated from 340B pricing. Therefore, we believe any redistribution of funds to hospitals other than those participating in the 340B Program would be directly counter to the Congressional intent of the 340B Program. Specifically, we recommend that the funds be redistributed in a manner consistent with the intent of the 340B Program, that is, to stretch scarce federal resources to provide more comprehensive services to our patient population.

If CMS moves forward, we also encourage CMS to implement the proposed changes over a multi-year period to provide affected hospitals with time to adjust to the payment changes and prevent abrupt discontinuation of programs vital to our patients and communities we serve. We also ask that CMS exclude certain hospitals and drugs from the scope of the cuts. We believe that Sole Community Hospitals, for example, should be excluded from the cuts, as these hospitals provide an important safety net function in isolated rural communities, and are essential for delivery of health care services in the communities they serve and the proposed cuts could result in these already fragile facilities being forced to close their doors and result in severe health care access issues to the surrounding communities. As discussed above, we also have significant concerns that the proposed cuts will force difficult decisions regarding provision of drugs for which payment below current rates will be less than the costs associated with acquiring and administering the drugs. Therefore, we believe CMS should exclude from the payment cuts all drugs that would result in a net loss to a hospital when paid at the proposed reduced rate.

Regardless of whether or not CMS implements this proposed policy, we believe that the significant administrative burdens and likelihood for errors associated with the required reporting of actual acquisition cost on Medicare claims for Part B drugs would make such a policy extremely costly and challenging for most hospitals to implement.

These 340B cuts will be devastating to our patients and communities. Prior to moving forward, we ask CMS to thoughtfully consider the negative impact the proposed cuts will have across the health care system and to not allow the views of one sector of the 340B Program stakeholder community to determine the future of the 340B Program and to place the lives of our most vulnerable patients at risk. We urge CMS to, instead, abandon the 340B drug payment proposal and redirect efforts toward direct action to halt the unchecked, unsustainable increases in the cost of drugs.

Changes to Site-Neutral Payment Policy for Off-Campus Departments of a Provider

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 non-excepted items and services furnished by non-excepted off-campus provider-based departments or PBDs (the "Physician Fee Schedule or PFS Relativity Adjuster"). For 2018, CMS proposes to pay non-excepted off-campus PBDs at 25 percent, rather than 50 percent, of the OPPS rate for non-excepted services. **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. Please refer to Trinity Health's comments on CMS-1676-P (Medicare Physician Fee Schedule) for further details on our concerns related to this proposal.**

Changes to the Inpatient-Only List

Procedures Proposed for Removal – Total Knee Arthroplasty (TKA)

The inpatient-only list (IPO) is a series of procedures for which Medicare will reimburse hospitals only if the procedures are provided in the inpatient setting. The list is updated annually in the OPPS Final Rule. Currently CPT code 27447 – Total knee arthroplasty (TKA) or total knee replacement – is on the IPO list. CMS is now proposing to remove TKA from the Medicare IPO list thereby allowing it to be performed on an outpatient basis.

Trinity Health has discouraged CMS from removing CPT code 27447 from the IPO list in the past, and continues to believe that it is ill-advised. We do not agree that the clinical characteristics of a TKA justify its selection as an appropriate procedure to be performed in the outpatient setting and are concerned about the risks and potential for poor quality outcomes particularly for vulnerable Medicare patients. Trinity Health recommends that TKA remain an inpatient-only procedure.

Our clinical concerns have not changed since CMS first asked this question. TKA is a large operation with the potential for multiple days in the hospital, arduous rehabilitation, and prolonged time for recovery. TKA patients are generally hospitalized 72 hours or more, often have significant post-operative pain, and are often dehydrated. In general, these patients have more post-operative medical conditions and complications that require extended stays.

Furthermore, we are significantly concerned by the vulnerability and functional risks of this Medicare population if this procedure were done in an outpatient setting. The significant post-operative pain and the ability to get appropriate and timely ancillary support is exacerbated by socioeconomic barriers that can often result in delays in care. We believe that there likely would be few, if any, Medicare beneficiaries who could safely be discharged home the same day after undergoing a total knee replacement, as would occur if this procedure were furnished in a hospital outpatient setting. There is significant concern with ensuring that Medicare patients would be able to be discharged into a safe home environment. Pain management is also a significant issue with these patients. After the procedure is performed, patients typically receive pain management medication through an epidural and require several hours of observation.

Trinity Health is aware of an increase in volume in TKA being done in the outpatient setting on younger patients. However, we do not believe that this information is relevant given the demographics of the Medicare population. In a review of our own claims data (October 1, 2015 – July 31, 2016) for TKA, we found that Medicare patients are more likely to have a major complication or comorbidity (MCC) than non-Medicare patients (35 percent versus 21 percent). Our data also show that Medicare patients tend to have longer on average length of stay (5 days versus 4 days). We believe that this further illustrates that the clinical needs of the Medicare population are distinguishable from the non-Medicare population. Data on the younger cohort of non-Medicare patients cannot be extrapolated to Medicare patients. As TKA is one of the most common surgical procedures performed on the Medicare population, any change in policy will have a broad and wide impact on Medicare beneficiaries. Changing this policy is fraught with significant risks for this vulnerable population and CMS should not move forward without compelling evidence specific to the Medicare population.

If CMS were to move forward, however, more time would be needed to carefully develop the evidence-based patient selection criteria to identify appropriate candidates and to develop the accompanying, appropriate documentation and communication around these criteria as CMS has suggested. This development and communication across the health system is significant. Additionally, while CMS is proposing to prohibit recovery audit contractor (RAC) review for patient status for TKA procedures performed in the inpatient setting for two years, we remain concerned by the ability to very quickly deny any inpatient total joint replacement admitted as inpatient. We also believe that the Medicare Administrative Contractors (MACs) need to be similarly halted. There is also the additional concern for patients who might later have a skilled nursing facility (SNF) admission but would not have qualified for the 3-day stay. **CMS needs to make guidance clear on this 3-day stay concern and whether a waiver would be utilized.**

Additionally, if CMS were to move forward, we strongly urge the agency to redistribute payments and implement this proposal in a budget neutral manner. Medicare's inpatient and outpatient prospective payment systems, and the payment systems of many private payers, are premised on the idea that payments are based on the cost of caring for a patient whose disease and overall health are *average*. If this proposal were to be implemented, the healthiest patients would be "cherry picked" for these procedures leaving more expensive cases for community hospitals, who serve a charitable mission and fulfill community needs. **Therefore, if this proposal were to be implemented and the less medically complex, healthier patients move to the outpatient setting with sicker patients in the inpatient setting, this would result in significant loss of inpatient payment not adequate to cover the case mix. We would specifically urge CMS to recalibrate the DRG weights and payments to reflect this shift of less complex cases to outpatient.**

Lastly, CMS did not address the impact of finalizing this proposal on two current inpatient bundling models that include TKA: the Comprehensive Joint Replacement (CJR) model and the Bundled Payments for Care Initiative (BPCI). Establishing an accurate target price based on historical data would become more complicated if CMS allowed this procedure to be furnished on an outpatient basis because some patients who previously would have received a TKA procedure on an inpatient basis may receive the procedure on an outpatient basis if the procedure is removed from the IPO list. CMS must be able to immediately address the consequences of this change on the CJR and BPCI programs. Trinity Health is concerned that CMS will not be able to appropriately adjust for these changes since there is no historical claims data to estimate the impact of any potential policy change on practice patterns. Moreover, the response to the policy may not be consistent throughout the country and could vary from location to location. **Because of the enormous number of resources and time that both CMS and providers have already invested into both of these inpatient bundling programs, we believe it is critical that this issue is addressed prior to any implementation of change in policy regarding TKA.**

Solicitation of Comments on the Possible Removal of Partial Hip Arthroplasty (PHA) and Total Hip Arthroplasty (THA)

CMS does not make a proposal but requests comments on whether to remove partial and total hip replacement from the IPO list. As with TKA, Trinity Health is equally concerned about the ramifications and risks to Medicare patients if partial and total hip replacement were removed from the IPO list. **Therefore, for all of the reasons stated above, we also urge CMS to ensure that the safety of Medicare beneficiaries is given the highest priority and the agency also not move forward with removing Partial Hip Arthroplasty (PHA) or Total Hip Arthroplasty (THA) from the IPO list.**

Drug Administration Add-On Codes and Unconditional Packaging

CMS is seeking comments on potential future conditional or unconditional packaging of add-on drug administration codes such as additional hours or additional IV push. Specifically, CMS is asking whether the agency should conditionally or unconditionally package drug administration add-on codes and related recommendations.

Trinity Health is concerned by this proposal as it would be extremely difficult to set one payment for a therapeutic infusion when the length of the infusion can vary greatly depending on the drug. Furthermore, payment for many of the drugs are already packaged into the medication administration payments; therefore, packaging the additional hours would be layering onto that financial impact. **We are concerned that this multi-level packaging could distort appropriate payment.**

Appropriate Use Criteria for Advanced Diagnostic Imaging Services

Trinity Health supports the use of Appropriate Use Criteria (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. Trinity Health is greatly concerned about the potential impact of the coming requirements, as proposed, on the furnishing professional and the performing facility. **We strongly recommend that the requirement to attest that AUCs were consulted be on the ordering professional, not on the furnishing professional nor the performing facility. Please refer to Trinity Health's comments on CMS-1676-P (Medicare Physician Fee Schedule) for further details on our concerns related to this proposal.**

Extension of Enforcement Moratorium on Supervision of Hospital Outpatient Therapeutic Services in CAHs

In 2009, CMS changed the supervision requirements for outpatient therapy services at all hospitals requiring that a supervising physician be physically present in the department at all times when Medicare beneficiaries are receiving outpatient therapy. In response to concerns expressed by critical access hospitals (CAHs) and small rural hospitals that they would have difficulty meeting established direct supervision guidelines, CMS did not enforce the standard for these hospitals for several years. This moratorium, however, expired on December 31, 2016. For calendar year (CY) 2018 and CY 2019. CMS is proposing to reinstate the moratorium on direct supervision enforcement instruction for outpatient therapeutic services for CAHs and small rural hospitals having 100 or fewer beds to allow for more time to comply with the supervision requirements for outpatients therapeutic services and to give all parties time to submit specific services to be evaluated by the Advisory Panel on Hospital Outpatient Payment for a recommended change in the supervision level.

Trinity Health is appreciative of CMS' recognition on this issue and supports CMS' proposal. However, Trinity Health urges CMS to make the enforcement moratorium permanent and to address the gap in non-enforcement for CY 2017. The non-enforcement of the direct supervision rules in CAHs and small rural hospitals with a 100 or fewer beds has been almost continuous since 2010, yet CMS indicates in the proposed rule that it is not aware of any quality of care complaints from beneficiaries or providers relating to general physician supervision as compared to direct physician supervision for outpatient hospital therapeutic services. This analysis provides a sufficient basis that CAHs and small rural hospitals with 100 or fewer beds not be subject to the direct supervision rules on a permanent basis.

Outpatient Quality Reporting (OQR) Program

Trinity Health supports the proposed removal of six measures from the OQR Program and agrees that OQR Program measures that are topped out, duplicative, or for which there is no clear benefit to public reporting do not have value and should be excluded from the program. Trinity Health strongly encourages CMS to remove redundancy when selecting measures across programs and evolve all quality reporting to focus on outcome rather than process measures. Harmonization across quality reporting programs, including utilization of the same definitions, is important. **We strongly believe that quality measurement should be focused on a small number of metrics that emphasize patient-reported and patient-generated data. Trinity Health urges CMS to focus on outcomes-based measures that are meaningful to patients and reflect successful performance against the desired outcomes of better health, better care and lower costs.**

Trinity Health also urges CMS to ensure that measures introduced to the Program are endorsed by the National Quality Forum (NQF) in order to fully address concerns about the reliability and validity of the measures. The NQF endorsement processes allow measures to be publicly vetted, and often these processes identify the need for major specification changes or minor refinements that will make for more effective implementation and results.

Lastly, Trinity Health takes a holistic view to caring for each patient – we are not only assessing the disease process but working diligently to understand the role that each patient's environment and social determinants play in his or her health status. We believe this is essential to delivering people-centered care. Trinity Health agrees with findings that current policy is unintentionally weakening the network of providers that serve disadvantaged populations, which could have the unintended consequence of worsening health disparities. Sociodemographic risk adjustment would level out the factors that are not under the control of the provider yet at the same time hold all providers accountable for high-quality care. In the absence of sociodemographic risk adjustment, quality measures reflect the underlying disparities of the populations served instead of the relative quality of the services delivered. **Trinity Health has long advocated that quality measure data be risk-adjusted for sociodemographic factors. Significant factors include: income, education, race (including ethnic background), payer type, patient travel distance (derived from their zip code), homelessness and language proficiency, all of which have been shown to have a significant relationship to a person's health outcomes.**