Trinity Health

September 23, 2019

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1717-P
P.O. Box 8016
Baltimore, MD 21244-1850

Re: CMS-1717-P Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children's Hospitals -Within-Hospitals

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-1717-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. Our People-Centered Health System puts the people we serve at the center of every behavior, action and decision. This brings to life our commitment to be a compassionate, transforming and healing presence in our communities. Trinity Health includes 94 hospitals as well as 109 continuing care locations that include PACE, senior living facilities, and home care and hospice services. Our continuing care programs provide nearly 2.5 million visits annually. Committed to those who are poor and underserved, Trinity Health returns $1.1 billion to our communities annually in the form of charity care and other community benefit programs. We have 35 teaching hospitals with graduate medical education (GME) programs providing training for more than 2,000 residents and fellows in 184 specialty and subspecialty programs. We employ approximately 133,000 colleagues, including more than 7,800 employed physicians and clinicians, and have more than 15,000 physicians and advanced practice professionals committed to 16 Clinically Integrated Networks (CINs) that are accountable for approximately 1.5 million lives across the country through alternative payment models (APMs).

Price Transparency

CMS proposes to require hospitals to post a list of all of their standard charges – both gross charges and all negotiated rates – for all items and services in a machine-readable format on their websites. In addition, CMS proposes requiring hospitals to post negotiated rates for 300 "shoppable" services, both inpatient and outpatient, in a consumer-friendly way that is both easily understood and searchable. CMS specifically identified 70 services that hospitals would need to provide rates for across the categories of evaluation and management, laboratory and pathology, radiology, and medicine and surgery; hospitals would need to identify the remaining 230 services based on populations they service.

The proposed rule would require hospitals to publish complicated data that would be confusing for patients and significantly increase burden. For the reasons outlined below, Trinity Health strongly urges CMS not to finalize the proposed rule as drafted and offers alternatives below. If finalized, CMS should extend the timeframe for compliance by a minimum of 18 months. In addition, we urge CMS to take comments into consideration and develop work groups that include representatives from hospitals as they continue to develop their price transparency policies.

Consumer Engagement

Trinity Health is committed to working with consumers, payers and policymakers to develop solutions for achieving price transparency. Delivering people-centered care requires consumers have access to meaningful information about the price and quality of their care. Our hospitals are regularly working with patients to provide a deeper understanding of their potential out-of-pocket costs. Depending on the hospital across our 22 state footprint, this is done either via an online price estimator or a call-center. Trinity Health hospitals also post important policies online, including financial assistance and charity care policies.

Transparency efforts should focus on providing up-to-date and meaningful cost information—such as an estimate of the out of pocket expense for patients. If the goal is to help patients better understand out of pocket costs, we recommend CMS require providers and insurers provide an estimate using data on a patient's insurance type, copayments and coinsurance, deductible met, and in/out of network nuances.

It is critically important that patients understand the basic components of their insurance plan coverage to be well-informed consumers; therefore, insurance plans must also participate in price transparency efforts. **Payers best know the plan benefits for patients and, therefore, should be held accountable for sharing information with providers so we can better assist our patients in receiving an accurate estimate of out-of-pocket costs. Trinity Health recommends that payers provide this information to providers via a web-based portal or API. Ideally, information would include where a patient is within their deductible so providers can relay accurate cost estimates.**

We caution, however, that providers cannot always estimate what services a patient will need, how they will respond to treatment, and whether complications as a result of co-morbidities or other issues will arise that would require additional services.

In addition, publishing charges solely for employed physicians instead of all physicians does not provide the opportunity for consumers to compare out of pocket costs widely. If this policy is finalized, we recommend requiring all physician charges be published.

CMS argues the proposed policies will facilitate shopping by patients; however, publishing gross charges and payer-specific will not help patients understand out of pocket costs. **As drafted, the requirements outlined in the proposed rule will provide patients confusing data that is difficult to understand and compare. Instead of helping patients, requiring hospitals to publish all of this information would create an entirely new industry to intake this data and sell it, adding even more complexity to the health care industry.**

Shoppable services

CMS has asked for feedback on the number of proposed shoppable services. **Trinity Health does not believe 300 shoppable services is reasonable and recommends CMS allow hospitals to identify 70 of their standard services over time. This requirement should be phased in, such that hospitals can start with simpler and more straightforward visits initially, and then include surgeries, DRGs, and services that are more complicated. Further, we recommend hospitals only be required to provide a plain language description of service, CPT/revenue codes and a way to request the hospital and insurer provide an estimate based on a patient's insurance coverage.**

Burden of publishing Gross and payer-specific negotiated rates

The policies as outlined would create significant burden for providers at a time in which CMS is working to simplify and reduce administrative complexity. In addition, current payer contracts may prohibit disclosure of rates, creating expensive and substantial legal problems for hospitals. CMS grossly underestimates it will take hospitals only 12 hours to comply with the requirements. However, given the complexity of the policy, it would take months.

Our hospitals do not have a systematic way to pull the proposed information; we would need to do this manually in order to compile reimbursement rate information by payer, product, and hospital. As an order of magnitude, the industry-wide average of codes in chargemasters is 20,000-50,000. In addition, we do not have a way to show reimbursement by HCPCS, CPT or CDM code level as a one-to-one match. Adding further complexity, services are paid many different ways, and in multiple combinations, including case rates, per diems, carve outs, grouper methodology, fee schedules, percent of charge, etc.—it may even be the case that the same service is paid at different rates based on the other services with which it is combined.

CMS also wants hospitals to display this information for service packages. Proving helpful information for service packages presents its own challenge, as patients may not require or receive all services in a package or bundle.

If we do identify a feasible way to compile this information, each file would be incredibly complicated with many inputs and each organization would display it differently—rendering the information hard to use and unhelpful for consumers.

The amount of work required to comply with the regulation may require us to develop a whole new department and would ultimately increase both administrative and service costs.

Additional Clarity
To fully analyze the rule's impact on our health system, CMS needs to provide more clarity. Specifically, do the price transparency requirements include services rendered by a physician employed by a medical group with a separate TIN, and not employed directly by the hospital? Or Article 28 facilities?

Final price has many variables—physician services; variation in implants; variation in time/OR recovery; variation in length of stay; variation in labs, drugs, therapy, etc., based on patient needs and response. Given this, what qualifying language or disclaimers should be used to enable patients to truly understand the rate information they are reviewing and the out of pocket costs they can expect to incur?

340B Payment Cuts
Notwithstanding a defeat in a federal district court, CMS proposes to maintain ASP minus 22.5 percent as the payment rate for drugs purchased under the 340B program.

Trinity Health remains deeply concerned by the substantial cuts that CMS enacted to Medicare Part B payments for 340B drugs under OPPS in last year's final rule and continue to oppose the reduction in payments for 340B drugs from the current rate of Average Sales Price (ASP) plus 6 percent to ASP minus 22.5 percent. These cuts are inconsistent with the Congressional intent of the 340B Program, represent a further assault on safety-net institutions, and continue to strain our ability to better serve our patients and communities. Trinity Health continues to urge CMS to immediately restore payments to the appropriate statutory levels—and to not implement any future reduction. Instead, CMS should follow the direction of the federal judge by determining remedy that will pay back 340B hospitals that have been impacted by cuts Medicare has imposed since 2018 and redirect efforts toward direct action to halt the unchecked, unsustainable increases in the cost of drugs.

The 340B Program provides essential savings critical to helping our eligible hospitals comprehensively serve the most vulnerable, and improve the health of communities across the country. 340B enables these statutorily eligible Medicaid participating facilities to purchase certain outpatient drugs at discounted prices from manufacturers. Congress created the 340B Program to enable participating entities to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services" and we believe this intent remains relevant today.

In addition to supporting important un-reimbursed and under-reimbursed services for the community, including mental health, cancer and obstetric care, our hospitals use discounts available on certain 340B-priced drugs to provide access to medications that would otherwise be financially infeasible to provide. The cuts to Medicare Part B payments for 340B drugs challenge our ability to continue to offer these and many other services and programs.

CMS Phase in of Site Neutral Payments

Generally, Medicare pays more for services when furnished in a hospital outpatient setting than in a physician office setting. In the CY 2019 OPPS proposed rule, CMS described "unnecessary" increases in the volume of hospital outpatient clinic visits in excepted off-campus provider-based departments (PBDs) and, citing its authority under section 1833(t)(2)(F) of the Social Security Act (SSA), proposed to pay for clinic visits furnished in excepted off-campus PBDs at an amount that equals 40 percent of the OPPS rate. CMS further proposed to implement this proposal in a non-budget neutral manner over two years, which the agency estimated would result in a CY 2019 reduction of $760 million in hospital payment under the OPPS.

Section 603 of the Bipartisan Budget Act (BBA) enacted in 2015 addressed these CMS concerns by precluding payment under the OPPS effective January 1, 2017 for new off-campus PBDs that opened after November 2, 2015 (with limited exceptions). These reimbursement cuts will continue to hit outpatient clinic visit (code G0463) at off-campus PBDs that were explicitly excepted from section 603 of the BBA.

The proposed expansion of site-neutral policy fails to recognize several significant factors with respect to the critical role that hospital outpatient departments play in delivering services in our communities and why that often results in additional cost under OPPS. CMS has previously identified increased utilization of OPPS services but has not identified those services as unnecessary. Rather, CMS believes these services do not need to be furnished in the hospital outpatient department. Without analyzing the clinical circumstances of these cases and the acuity of the patients, CMS is not in a position to determine whether the cases were of sufficient severity and complexity that a visit in the hospital outpatient department was unwarranted compared to a physician's office.

Hospital outpatient departments are providing a hospital-level of services but meeting people—with convenient access—where they want and need to have care in their communities. Hospital outpatient departments include higher capital and facility costs, higher digital health costs, additional quality monitoring, medical staff oversight, protocols, and investment in research that is consistent with a hospital-level of care. Hospital outpatient departments have costs associated with standby services incurred in 24-hour emergency department settings, which include around-the-clock availability of emergency services, cross-subsidization of uncompensated care, EMTALA and Medicaid, emergency back-up for other setting of care, and disaster preparedness. Physicians frequently refer complex Medicare beneficiaries to hospital outpatient departments for critical services, particularly when it comes to the most vulnerable, sickest, and medically complex patients. Having a clear, data analysist understanding of the level of acuity for patients receiving care at hospital outpatient departments is critical to continuing to move forward with such a policy decision.

The above demonstrates why continuing this payment cut jeopardizes hospitals' ability to support hospital-level care in the community, outpatient setting.

Trinity Health continues to strongly oppose these payment cuts. This policy is outside the scope of CMS authority and Congressional intent. CMS should not implement the second phase of the site neutral cuts and should immediately reimburse hospitals for withheld payments.

Wage Index Changes

The area wage index is used to adjust Medicare operating and capital payments for geographic variations in labor costs. CMS proposes a number of changes to how it calculates and applies the Medicare wage index to address disparities between low wage and high wage hospitals and improve payment to rural facilities. To mitigate these changes, CMS proposes a 5 percent cap on any decrease from a hospital's wage index in FY2019.

Wage index adjustment

CMS is proposing to adopt policies finalized in the FY2020 IPPS rule for in the CY2020 OPPS rule. Beginning in FY 2020, CMS proposes to increase the wage index for low wage index hospitals (wage index value below the 25th percentile). Instead of decreasing the wage index for high wage index hospitals (wage index value above the 75th percentile), as proposed in the IPPS NPRM, CMS will instead ensure budget neutrality by ensuring overall Medicare spending does not increase by decreasing a standardized amount across all hospitals. These adjustments would be effective for four years to allow time for increased wages to be reflected in the wage index calculation.

Trinity Health recognizes the need for policies to help support rural hospitals and the communities they serve and we urge the Department of Health and Human Services and Congress to continue to explore options. **However, we disagree with CMS' proposal, which would penalize all hospitals—especially when Medicare already pays far less than the cost of providing care.**

As disparities among geographic regions and challenges faced by rural hospitals continue to grow, **Trinity Health recommends CMS work with Congress to create a new designated pool of funding for low-wage hospitals that is not subject to budget neutrality as part of a comprehensive, long-term approach to help these facilities. If the proposal is finalized, the agency should use its existing statutory authority to increase the wage index for rural hospitals in a non-budget neutral way.**

Urban to Rural Reclassification

CMS is proposing to remove wage index data from hospitals that undergo urban-to-rural reclassifications from the calculation of the rural floor, such that, beginning in FY2020 the rural floor would be calculated without using the wage data of hospitals that have reclassified. Hospitals that reclassified did so under allowable HHS authority and as such, should not be penalized through this proposal. As outlined in the proposed rule, this policy creates a funding cliff for impacted hospitals, the extent of which the proposed 5 percent cap on wage index reduction will not mitigate. **Trinity Health recommends CMS does not finalize this proposal. Should CMS move forward with this policy, hospitals negatively impacted should be given a more reasonable phase down, while continuing to maintain a capped wage index reduction, so as not to inflict financial harm on these community hospitals.**

Hospital Outpatient Quality Reporting Program (OQR)

CMS proposes to remove the measure, External Beam Radiotherapy (EBRT) for Bone Metastases (OP-33), assesses the percentage of patients, regardless of payer, with bone metastases and no history of previous radiation who receive EBRT with an acceptable dosing schedule.

Trinity Health supports removal of measure EBRT from the OQR program because of the issues identified in the proposed rule, including the administrative burden and challenges in determining cases that qualify for the measure. We appreciate the acknowledgement of these issues by CMS and the recognition that the burden outweighs the benefits of the measure. **Trinity Health proposes that the removal occur with CY2021 payment determination rather than CY2022 payment determination.** We understand that some abstractions for CY2021 payment determination have been completed and there would be some work required to discontinue reporting. However, hospitals would significantly benefit from ending the complicated and confusing abstraction process as soon as possible. The work to modify information systems and reporting processes is far less than the abstraction burden and resources required to continue abstractions through September 2020 encounters.

Proposal of Four Patient Safety Measures in OQR Program in the Future
CMS seeks feedback on potentially adopting four patient safety measures in the OQR. These four measures were previously adopted for the ASC Quality Reporting Program (ASCQR), and include ASC-1: Patient Burn, ASC-2: Patient Fall, ASC-3: Wrong Site, Wrong Side, Wrong Procedure, Wrong Implant, and ASC-4: All-Cause Hospital Transfer/Admission.

Trinity Health supports the proposal to include safety measures for Patient Burn, Patient Fall, Wrong Site/Side/Procedure/Implant, and All-Cause Hospital Transfer in the OQR Program. However, we do not support using the QualityNet online tool for submission. Trinity Health would be supportive of claims based measures or electronic clinical quality measures (eCQMs) associated with patient safety in the outpatient setting. The proposed rule indicates that a claims-based approach was not successful for the ASC measures based on infrastructure within that setting. However, the OQR program would include the hospital outpatient setting, which has the infrastructure to ensure successful reporting through claims or eCQMs. Requiring the manual submission process of online submission would add an additional workflow within the reporting process and would not support CMS' strategy of reducing the burden of quality reporting. Initial feedback from the Trinity Health hospitals on OP-32, OP-35, and OP-36 that are claims-based measures is very positive.

The hospital-specific reports allow investigation into issues and opportunities for improvement. Facilitating streamlined quality reporting processes and allowing quality departments to focus on quality improvement rather than manual submission is key to ultimately improving the quality of care in all settings.

Proposed Removal of Total Hip Arthroplasty (THA) from the Inpatient Only (I/O) List
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. CMS proposes to remove CPT code 27130 (Total hip arthroplasty) from the inpatient-only list, making it eligible to be paid in both an inpatient and outpatient setting.

Trinity Health strongly discourages CMS from moving CPT code 27130 from the IPO list, we are concerned by the risks and quality of care for vulnerable Medicare patients. THA is a large operation with the potential for multiple days in the hospital, arduous rehabilitation and recovery.

Patients who undergo THA experience 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 hip replacement, as would occur if this procedure were furnished in a hospital outpatient setting. Providing this surgery in an outpatient setting will not afford patients enough time to recover properly or allow providers to address all post-surgical concerns—including any problems that arise with comorbidities. There is significant concern with ensuring that Medicare patients would be able to be discharged into a safe home environment, creating potential issues with patient safety and an increase in hospital admissions.

If CMS finalizes this policy, 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 is finalized, the healthiest patients would be "cherry picked" for this procedure leaving more expensive cases for community hospitals, who serve a charitable mission and fulfill community needs. 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**.**

In addition, we do not have data on quality outcomes for TKA since moving it from the inpatient only list. However, we do know from our experience with TKA that some payers routinely deny inpatient requests for patients for which it is determined by their physician that having the procedure done in an inpatient setting is most appropriate. This requires back and forth between providers and payers, wasting resources, increasing administrative costs, and creating uncertainty for patients and hospitals. **We urge CMS to develop national guidelines outlining patients who are appropriate candidates for inpatient vs outpatient authorization, as well as for patients who are reasonable candidates for same day discharge. We believe this would create standardization and help mitigate denials from payers.**

Proposed Changed to the List of ASC-covered Surgical Procedures

CMS proposes to add eight procedures to the ASC list of covered surgical procedures. Additions to the list would include a total knee arthroplasty procedure, a mosaicplasty procedure, as well as six coronary intervention procedures.

Trinity Health previously discouraged CMS from moving total knee arthroplasity (TKA) from the inpatient only list and we continue to have concerns with classifying this procedure as an ASC-covered procedure—we do not agree moving TKA to the ASC list of covered procedures is appropriate at this time. We continue to have the initial concerns we shared with CMS in our comments on the CY2018 OPPS proposed rule related to the risks and quality of care for vulnerable Medicare patients when TKA is provided anywhere other than in an inpatient setting. CMS has not shared data illustrating outcomes for TKA in an outpatient setting and these surgeries are still largely done on an inpatient basis, which CMS estimates were 82% of all TKA surgeries in 2018. In addition, CMS acknowledges that receiving TKA in an ASC will not be suitable for most beneficiaries

Further, most ASCs are only open during the day while most TKA patients stay out patient in a bed overnight for pain control, nausea control, and physical therapy assessments. **We urge CMS to develop national guidelines for screening patients to identify appropriate candidates to receive the proposed services in an ASC.**

Shifting TKA to ASCs would also increase costs for Medicare patients, as TKA is part of a comprehensive APC. As a result, cost sharing will be higher for beneficiaries in an ASC for this service.

Proposed Changes to Supervision Requirements for Hospital Outpatient Therapeutic Services

CMS proposes to change the minimum required level of supervision for hospital outpatient therapeutic services from direct supervision to general supervision for services furnished by all hospitals and critical access hospitals. This proposal would also establish a standard minimum level of supervision for each hospital outpatient service furnished incident to a physician's service.

Trinity Health recommends CMS identify standards to make the general supervision flexibility target-specific. While general supervision may be appropriate for certain therapies in an outpatient setting—such as chemotherapy administration—direct supervision is the most appropriate option for radiation oncology therapies.

Radiation therapy has become increasingly complex and more sophisticated due to new treatments, equipment and processes. Given risks, radiation oncology providers need to be immediately available—physically present—during treatment planning and delivery and able to furnish assistance and direction throughout the therapy. In addition, the majority of image guidance services in radiation therapy involve stereoscopic x-ray or computed tomography guidance, which are subject to the direct supervision requirement.

Trinity Health appreciates CMS working to reduce provider burden; however, we believe existing direct supervision standards should be retained for radiation oncology to protect patients and ensure the continued delivery of safe and high-quality radiation therapy services.

Prior Authorization Requirements for Certain Outpatient Services

Citing "unnecessary increases in the volume" of certain covered outpatient department services, CMS proposes to implement a prior authorization requirement for five categories of services: blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty and vein ablation.

In general, Trinity Health supports requiring prior authorization for the services outlined in the rule, as these are largely cosmetic and we agree with exempting providers from the process if they demonstrate compliance with Medicare coding, coverage, and payment. However, if finalized, this requirement should be for all settings, including ASCs. CMS should also work to ensure the process is not unnecessarily burdensome and reevaluate whether the requirement as necessary based on input from providers. We applaud CMS for proposing to extend the effective date and acknowledging additional time is necessary to ensure operational updated and sufficient understanding of the proposed process.

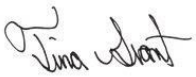
Proposed Payment for Hospital Outpatient and Critical Care services

CMS seeks public comments on that should be considered for future rulemaking. **Trinity Health recommends CMS develop a national standard for ED evaluation and management (E&M) algorithms. Absent such a standard, payers are creating their own criteria and are downgrading higher-level ED E&Ms, resulting in a loss of resources and increased administrative burden.**

Conclusion

We appreciate CMS's ongoing efforts to improve payment systems across the delivery system. However, we have significant concerns with many of the proposed policies. If you have questions on our comments, please feel free to contact me at granttw@trinity-health.org or 734-343-1375.

Sincerely,



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