Trinity Health

September 24, 2018

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

Re: CMS-1695-P; Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model; Submitted electronically via http://www.regulations.gov

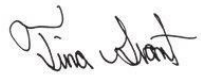
Dear Administrator Verma,

Trinity Health appreciates the opportunity to comment on the proposed policy and payment changes set forth in CMS-1695-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. This includes our comments on CMS's requests for information (RFIs) on Price Transparency and Interoperability.

Trinity Health is one of the largest multi-institutional Catholic health care delivery systems in the nation, serving diverse communities that include more than 30 million people across 22 states. We are building a People-Centered Health System to put the people we serve at the center of every behavior, action and decision. This brings to life our commitment to be a compassionate, transforming and healing presence in our communities. Trinity Health includes 94 hospitals as well as 109 continuing care locations that include PACE, senior living facilities, and home care and hospice services. Our continuing care programs provide nearly 2.5 million visits annually. Committed to those who are poor and underserved, Trinity Health returns $1.1 billion to our communities annually in the form of charity care and other community benefit programs. We have 35 teaching hospitals with graduate medical education (GME) programs providing training for more than 2,000 residents and fellows in 184 specialty and subspecialty programs. We employ approximately 133,000 colleagues, including more than 7,800 employed physicians and clinicians, and have more than 15,000 physicians and advanced practice professionals committed to 23 Clinically Integrated Networks (CINs) that are accountable for 1.4 million lives across the country through alternative payment models (APMs).

We appreciate CMS's ongoing efforts to improve payment systems across the delivery system. However, we have significant concerns with CMS's proposed site-neutral policies and oppose implementation of the off-campus provider-based department policy changes. If you have questions on our comments, please feel free to contact me at granttw@trinity-health.org or 734-343-1375.

Sincerely,



Tina Weatherwax Grant, JD
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Trinity Health

Changes to Site-neutral Payment Policy for Off-campus Provider-based Departments (PBDs)

Reduction in Payment for Hospital Outpatient Clinic Visits in Excepted Off-campus PBDs

The proposed rule argues that spending growth on services furnished in hospital outpatient departments appears to be the result of an unnecessary shift of services from lower cost physician offices to higher cost hospital outpatient departments. CMS suggests that these shifts in the sites of service are unnecessary and calls for payment rates for evaluation and management (E/M) visits provided in hospital outpatient departments be reduced so that total payment rates for these visits are the same, whether the service is provided in a hospital outpatient department or a physician office. In CY 2019, this physician fee schedule equivalent payment rate is proposed to be 40 percent of the OPPS payment amount. The agency proposes to implement this new policy in a non-budget-neutral manner.

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). CMS is now proposing to pay the same amount for an outpatient clinic visit (code G0463) at an off-campus PBD that was explicitly excepted from section 603 of the BBA. **Trinity Health believes that this proposed change is outside the scope and intent of Congress and is misdirected policy. We oppose this proposed change and urge CMS not to finalize it.**

Section 603 of the BBA of 2015 not only provided clear instructions to CMS to make specific defined changes to the law governing Medicare outpatient payment, but also reflected a deliberate compromise among the drafters as to the scope and reach of those changes. Executive branch agencies are unquestionably permitted some latitude to interpret ambiguities in statutes, but established judicial doctrine requires that agencies faithfully adhere to permissible constructions of a statute. These same doctrines provide that where Congress has spoken specifically on a matter, agencies cannot rely on general grants of authority to subvert specific Congressional intent. We recognize that CMS is here not relying on the changes made by Section 603 as authority for this proposed policy, and rather is relying on broader "adjustment" authority under section 1833(t)(2)(F) of the Social Security Act as its permission for making this change. But in this instance, Congress has spoken specifically, clearly and deliberately as to how CMS should revise OPPS payment policy to address the very same concerns that CMS now purports to be addressing with its proposed policy change. Congress provided grandfather protection to certain entities for a reason If Congress intended CMS to make similar site neutral payment adjustments to grandfathered facilities, it would have provided no or different grandfather protection in Section 603, or conferred additional adjustment authority through Section 603. **In this instance, CMS is clearly attempting to manipulate pre-existing authorities to subvert clear Congressional intent in a statute subsequently enacted.**

This 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 identifies 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. The implication of CMS' proposed rule is that the utilization increases observed by CMS were for services more appropriately furnished in a physician's office than a 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. Providing hospital

level services—but in an outpatient setting—results in a higher cost structure. 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 settings 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 analytic understanding of the level of acuity for patients receiving care at hospital outpatient departments is critical to moving forward with such a policy decision.

The above demonstrates important reasons for why the volume of services at hospital outpatient departments are necessary as well as why these services at hospital outpatient departments result in higher costs to provide. This 60 percent payment cut jeopardizes hospitals' ability to support hospital-level of care in the community, outpatient setting.

The additive punitive nature of these proposed OPPS payment reductions—on top of CMS' proposal to collapse the current five-level E/M visit codes into two levels for physician offices as proposed in the physician fee schedule (PFS)—is significant. And the impact will no doubt be felt by Medicare beneficiaries. Based on our experiences and assessment, Trinity Health believes that CMS' proposed changes to documentation, coding, and billing, in the PFS proposal, could negatively impact quality of care, coordination across providers, as well as physician payment that is needed to support the delivery of patient-centered care.

While we strongly oppose implementation of these site-neutral cuts, if CMS does move forward, we strongly urge CMS to enact this policy on a budget neutral basis—based on ambulatory payment classification or APC rates—rather than the non-budget-neutral manner in the proposed rule. In order to exempt the payment reduction from the budget neutrality requirements under the statute, CMS claims that the change is not an "adjustment. Yet, CMS arrives at the 40 percent payment amount by applying the "PFS relativity adjuster" to the full OPPS payment rate.

Expansion of Clinical Families of Services at Excepted Off-campus PBDs

Trinity Health is also concerned by the proposed policy to prohibit excepted hospital outpatient departments from expanding services. CMS proposes that excepted hospital outpatient departments would continue to be paid at OPPS rates only for those clinical family services furnished and billed prior to November 2, 2015. Consequently, the agency also proposes that any expansion of services beyond the clinical families of services that had been furnished prior to this date would be paid according to the site-neutral payment policy. For 2017, CMS did not finalize the proposal to limit the expansion of services in existing off-campus provider-based departments because it was deemed too complex to implement.

In this CY 2019 OPPS proposed rule, CMS is now proposing the same clinical family concept that was deemed too complex in 2017. The proposal also requires hospitals to perform analysis of the services provided four years ago in comparison to all services provided over a three-year period to look for service expansion. Additionally, CMS continues to focus on physician office practices that hospitals might purchase; there does not seem to be recognition that there are many other types of off-campus PBDs that are not physician office-type services (e.g., radiology, infusion centers) that would be penalized by these restrictions. CMS acknowledges that they are "guessing" what Congress intended around the locations exception from Section 603. Lastly, the level of acuity of patients receiving care at hospital outpatient departments is higher, with hospitals serving the most vulnerable, sickest, and medically complex patients.

CMS is not required by statute to impose this limitation, and we believe that CMS should not go beyond Congressional intent in this instance. Trinity Health encourages CMS to recognize that certain expansions in services are necessary for a hospital outpatient department to continue to provide appropriate services to its patients. The limitation of expanded services overlooks the fact that patient care needs are unpredictable and that a new patient may have a clinical need that is within the scope of services appropriately provided at the hospital outpatient department, but is incorporated into a clinical family of services not previously billed at an excepted hospital outpatient department. Without the ability to expand services, excepted hospital outpatient departments will be required to refer patients away from their community to receive services. CMS should have clear, consistent data if implementing policies that are not required by statute, especially when those policies will force patients out of their communities to receive care.

Therefore, Trinity Health urges CMS not to implement the proposed policy to prohibit excepted hospital outpatient departments from expanding services, as this prohibition is not required by statute and will force patients out of their communities to receive care.

If CMS does not heed comments and moves ahead, Trinity Health has a number of additional concerns related to this proposal:

First, the use of APC levels in creation of the clinical families (specifically Minor Imaging, Major Imaging, Diagnostic/Screening Tests and Related Procedures) is overly complicated and not logical for this purpose. For example, Minor Imaging includes CT without contrast and Major Imaging includes CT with Contrast. Ultrasound studies and Nuclear Medicine are also split between the two imaging families. It would be easier for planning and identification purposes to put all of a radiology modality into either Minor Imaging or Major Imaging. For example, put all CT procedures and Nuclear Medicine procedures in Major Imaging and all Ultrasound in Minor Imaging. Another example is that aerosol treatment and some respiratory therapy services are in the Cardio/ Pulmonary Rehabilitation clinical family while the rest of respiratory therapy/pulmonary function is in the Diagnostic/Screening Tests and Related Procedures clinical family. It is easy for CMS' purposes to use the APC level as a differentiator, but from the clinical and operations perspective it is very complicated and not appropriate for these reasons mentioned. **If CMS moves forward with clinical families, we recommend groupings that are not just based on APCs as the examples show these are not always logical for this purpose. APC groupings might be a start but then further refinement would be needed. In addition, grouping by APC does not help in operationalizing how modifiers would be applied. APC groupings are for payment purposes, while hospitals work at the CPT/HCPCS level for coding and modifier assignment.**

Secondly, we are very concerned that CMS wants to use a baseline of November 1, 2014 through November 1, 2015, as compared to any service provided in the three years since November 2, 2015. The burden of this data analysis will be extremely challenging. Further complicating this, there have been CPT code and APC assignment changes over the three years that would need to be addressed and reconciled in the analysis. When performing the analysis, hospitals cannot just use the APCs provided in the proposed rule; they must incorporate every APC assignment change over the last four years. For example, CMS' most common hospital outpatient department CPT code G0463 was assigned to APC 0634 in 2014 and 2015 but now it is APC 5012. So, if the analysis is performed from the APCs CMS lists in the proposed rule, it will look like G0463 was not provided in the baseline period. Also, for hospitals that have changed their information systems in this time period, it will be almost impossible to perform this analysis. The proposal will penalize hospitals for providing additional services to patients during a time when expansion was allowed. **If CMS does not heed comments and moves forward with this proposal, we would strongly recommend that CMS implement this on a go-forward basis with any "expanded services" provided starting January 1, 2019 instead of using a 4-year old baseline.**

Thirdly, while CMS was not specific enough in the proposed rule, we would assume modifier-PN would be required on any services in the expanded clinical families for each impacted off-campus

PBD. Generally the –PO modifier is automated and assigned based on a "location identifier" to all services in that location. This proposal would require hospitals to add the modifier at a CPT level for each specific location. This would be extremely burdensome as it may require either a coder or a biller to use a list of CPT codes for each applicable location that would require manual assignment of the alternate modifier. **There will be considerable on-going operational burdens around this proposal, so if CMS moves ahead, we would also ask that CMS delay implementation until at least 2020 to allow adequate processes to be developed.**

Lastly, in the proposed rule, CMS includes one generic but very impactful sentence: "In addition, items and services furnished by an excepted off campus PBD that are not identified below in Table 32 of this proposed rule must be reported with modifier "PN"." In reviewing the CPT codes that do not have a clinical family assigned, it appears that all status indicator N services do not have a clinical family. Also, the majority of laboratory codes, therapy codes, and drugs do not have a clinical family assigned. We hope that CMS does not intend for a –PN modifier to be reported for all of these services in excepted off-campus PBDs. Currently—per CMS instruction—therapy services provided in excepted locations do not need to even report –PO modifiers because the services are not paid under OPPS. CMS needs to fully understand the impact of their proposed information. Even this one sentence has major operational impact if taken at face value. **Trinity Health strongly encourages CMS not to move forward with this proposed, above referenced statement.**

Again, Trinity Health strongly urges CMS not to implement this proposed policy to prohibit excepted hospital outpatient departments from expanding services, as these prohibitions are not required by statute and will force patients out of their communities to receive care. As CMS noted itself in 2017, this policy is too complex to implement. Trinity Health has provided four examples above on this complexity. Should CMS move forward, we strongly urge the agency to specifically address and adequately accommodate our recommendations regarding these above areas of concern and complexity in the final rule.

Applying the 340B Drug Payment Policy to Non-excepted Off-campus PBDs

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. We continue to oppose this policy and 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 reimbursement 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 reverse the already-implemented Medicare payment reductions for 340B drugs—and to not implement those proposed this year for non-excepted off-campus locations. Instead, CMS should 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.

As the population grows and demographics change, our safety-net hospitals are working to meet these needs at the right place for the patient and community. Ensuring that 340B discounts are received at these new clinics in order to best serve communities, according to the intent of the program, is important. The types of patients treated in hospital outpatient facilities, particularly 340B hospitals, account for the higher per-patient spending, when demographics (or risk adjustment) are

not considered. As CMS continues to reduce reimbursement for 340B drugs, the critical benefits derived from this program are negated.

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. When Trinity Health analyzed the top 20 most commonly used drugs in the Medicare hospital outpatient setting covered under Part B, we learned that the previous 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 is straining our ability to provide these more expensive drugs and compromises our ability to offer continued access to certain therapies. 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 administration. Cutting the rates for 340B-participating hospitals is putting Medicare beneficiaries' access to these therapies at further risk.

While we continue to oppose implementation of the enacted and proposed payment cuts, if CMS does move forward, we strongly encourage CMS to continue to ensure that the funds generated by the reduction in Part B payments for 340B drugs are redistributed on a budget neutral basis—based on ambulatory payment classification or APC rates—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.

The administrative costs of implementing the systems changes that are necessary to place a modifier on claims to identify non-340B drugs and related operational changes have been significant, including the development of workarounds in the absence of technology enhancements from the vendors. These are real and substantial regulatory and cost burdens that continue to impact our financial stability, at a time when policymakers are working to reduce regulatory burden on hospitals. **The proposed rule does not indicate if the current JG modifier requirements will be applied to these non-excepted locations or if something entirely different will be required. Hospitals need that specificity and clarity in the November final rule. If CMS moves forward with these proposed changes, we strongly urge the agency not to wait until the sub-regulatory guidance to provide this needed clarity on related requirements or changes.**

Changes to the Inpatient-only 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. In last year's OPPS rule, CMS removed total knee arthroplasty (TKA) or total knee replacement from the IPO list allowing it to be performed on an outpatient basis. Trinity Health remains concerned by the consequences of this policy change, most importantly the impact it has had on patients.

Trinity Health strongly discouraged CMS from removing CPT code 27447 from the IPO list and does not agree that the clinical characteristics of a TKA justify its selection as an appropriate procedure to be performed in the outpatient setting. The confusion this policy has created for hospitals, physicians, payers and patients is significant. We remain particularly concerned by the risks and quality of care for vulnerable Medicare patients as a higher volume of cases have moved to the outpatient setting than was likely intended by CMS. Trinity Health continues to believe that TKA should be an inpatient-only procedure. We are pleased that CMS retained hip replacement on the IPO list.

Despite important clinical advances that have improved pain management and reduced length of stay, 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 often have more post-operative medical conditions and complications that require extended stays. There continues to be significant challenges and concern with ensuring that Medicare patients are able to be discharged into a safe home environment. Pain management is also a significant issue with these patients.

The unintended consequences of this change—and the lack of clarity and guidance from CMS—has resulted in a significant amount of confusion as hospitals, physicians, and payers work to interpret and implement this new policy resulting in inconsistency and frustration for patients, particularly stemming from application of the two-midnight policy in these cases. Additionally, 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*. **As this policy has been implemented and the less medically complex, healthier patients move to the outpatient setting, with sicker patients remaining in the inpatient setting, this is resulting in inpatient payment not adequate to cover the case mix. We continue to urge CMS to recalibrate the DRG weights and payments to reflect this shift of less complex cases to outpatient.**

Historically, CMS has also evaluated the ASC covered procedures list each year to determine whether procedures should be added or removed from the list, and changes to the list are often made in response to specific concerns raised by stakeholders. CMS states that it may be appropriate to re-evaluate recently-added procedures given that when the procedure is added to the list, the provider community has limited experience in performing the procedure on the Medicare population. Consequently, CMS is reviewing whether Medicare beneficiaries should have spine surgeries at ASCs and has asked for public comments on whether doing spine surgeries in an ASC is safe and effective. **Trinity Health is pleased that CMS is looking more closely at the 38 procedures removed from the IPO list for calendar years 2015-2017, 25 of which are spine procedures. We strongly encourage the agency to take the risks and quality of care for vulnerable Medicare patients, receiving these procedure outside of the hospital inpatient setting, into deep consideration upon this review of these spine procedures. Trinity Health believes that many of these procedures are most appropriate in the hospital-setting and CMS should consider these factors in ensuring they are done in the safest place possible.**

Changes to the Outpatient Quality Reporting Program (OQR)

Trinity Health expresses appreciation for CMS' continued implementation of its "Meaningful Measures" framework across the quality reporting and value programs. Trinity Health has long encouraged CMS to remove redundancy when selecting measures across programs, evolve all quality reporting to focus on outcome rather than process measures, and ensure harmonization across quality reporting programs, including utilization of the same definitions. **Trinity Health strongly believes that quality measurement should be focused on a small number of metrics that emphasize patient-reported and patient-generated data and urges CMS to continue this path of focusing on outcomes-based measures that are meaningful to patients and reflect successful performance toward improving care and outcomes and reducing costs.**

Trinity Health also continues to encourage CMS to accurately measure and incorporate social risk factors into the multiple quality and payment programs. 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 continues to urge 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.

CMS is proposing to modify Factor 7 for measure removal, which is currently: "collection or public reporting of a measure leads to negative unintended consequences *such as* patient harm" with the proposal to change to: "collection or public reporting of a measure leads to negative unintended consequences *other than* patient harm." CMS is also proposing to add Factor 8 for measure removal: "the costs associated with a measure outweigh the benefit of its continued use in the program." **Trinity Health supports this proposed update to Factor 7. Trinity Health also supports the addition of Factor 8 for measure removal as this modification has been proposed by CMS for other programs, including Hospital VBP and Hospital IQR programs. Consistency across programs is significantly important.**

CMS is proposing to remove ten measures from the Hospital OQR across the CY 2020 and CY 2021 payment determinations. This includes removal of OP-27 Influenza vaccination coverage among health care personnel because the administrative burden to calculate and report outweighs the benefit and nearly all hospitals already report this through the IQR program. Trinity Health supports this proposal, as all of our hospitals must duplicate the data reporting in NHSN for IQR and OQR. We also support removal of OP-5 Median time to ECG, OP-31 Cataracts, OP-29 Endoscopy/Polyp surveillance, and OP-30 Endoscopy/Polyp surveillance. Trinity Health similarly supports removal of the following: OP-9 Mammography follow-up rates, OP -11 Thorax CT, OP-12 Ability of providers with HIT to receive laboratory data, OP-14 Simultaneous use of brain CT and sinus CT, and OP-17 Tracking clinical results between visits; however, **we urge CMS to remove each beginning with CY 2020 payment determination, rather than CY 2021, as earlier removal would have minimal impact on data collection and serves to further reduce regulatory burden and more quickly advance the most meaningful measures.**

Inpatient Quality Reporting Program (IQR) HCAHPS Pain Questions

CMS proposes to remove the three communication about pain questions from the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) measure beginning with 2022 discharges (for FY 2024 payment).

Trinity Health remains very concerned by the staggering toll of the opioid epidemic on communities across our country and we have taken significant steps across our system to build awareness and education internally and externally on this important matter. We commend CMS, again, for previously removing the HCAHPS survey questions related to pain management from the Hospital Value Based Purchasing (VBP) Program. Removing the questions from scoring in the VBP Program was an important step in eliminating any perceived expectation that pain management should always include the use of powerful prescription drugs such as opioids.

Trinity Health also believes that the new pain questions—focused on effective communication about pain during the hospital stay—represented significant improvement in capturing the patient's perception of the care team's awareness of their pain and treatment options. We encouraged CMS to study these questions for their potential effect on clinician behavior and patient outcomes, and urged CMS to complete this work as quickly as possible because pain management is an important part of patient experience and the healing process. We don't want the pendulum to swing too far in the other direction when it comes to meeting a patient's pain needs, particularly palliative care patients. Toward this end, Trinity Health urged CMS to seek National Quality Forum (NQF) endorsement for the revisions and to continue to work with the Measure Applications Partnership (MAP) to address concerns about the reliability and validity of the new questions. The NQF endorsement and MAP processes allow the measure 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.

Trinity Health believes that patient experience data is important to hospitals and CMS – particularly with an emphasis on the importance of communication. However, if a measure is believed to have significant unintended consequences—as has been the case with the link between these questions and the opioid crisis—we believe that those questions should be removed from both payment programs (e.g., VBP) as well as public reporting programs (e.g., IQR). We, however, are concerned with CMS' proposal to remove the communication about pain questions from HCAHPS entirely, as understanding more about pain management communication and a patient's perception of it in relation to their care is an important part of patient experience and the healing process. Trinity Health also believes that the overall HCAHPS process has room for improvement to more holistically—and at a higher level—look at the goals of better health, better care, and lower costs.

Payment for Non-opioid Pain Management Therapy

CMS examined the packaged drug payment policy for 2019 in response to the President's Commission on Combating Drug Addiction and the Opioid Crisis to address the Commission's concern that the policy leads to incentives to prescribe opioid medications to patients for postsurgical pain instead of administering non-opioid pain medications.

Trinity Health has raised concern with CMS reimbursement policies, as well as those from other health insurance payers, that create barriers to the adoption of alternative pain management strategies. Trinity Health performs thousands of procedures a year in which patients' pain could be effectively managed through the use of non-opioids, which would reduce overall opioid use. While our system is deeply committed to these types of reductions, CMS reimbursement policies constitute a significant barrier in clinicians being able to consistently and more broadly embrace alternative and complementary pain management approaches. We have strongly urged that a broader range of pain management and treatment services – including non-opioid alternatives as well as non-pharmacological alternatives – be adequately reimbursed by payers, including Medicare and Medicaid, so as to encourage use of alternative therapies. **Specifically, we have urged CMS to review and modify rate-setting policies that discourage the use of non-opioid treatments for pain; and therefore, we very much appreciate this policy review by CMS. We urge CMS, however, to also un-package non-opioid drugs and provide for the separate payment in the hospital outpatient department setting, not just for ASCs, to ensure that the maximum potential reduction in opioid use is achieved.**

CMS cites as its basis for un-packaging bupivacaine liposome (Exparel) in the ASC setting, and not the hospital outpatient department setting, utilization data that shows a rapid increase in utilization in the hospital outpatient departments, and a corresponding decrease in utilization in the ASC. CMS cites utilization data from 2013 through 2017, where CMS observed an overall increase in OPPS Medicare utilization of Exparel of approximately 229 percent (from 2.3 million units to 7.7 million units). What CMS must acknowledge is that Exparel was first approved by FDA on October 28, 2011, so this rapid increase in utilization immediately following market introduction should be totally expected, especially when the market is hungry for a better, non-opioid pain management tool. We concur that given Medicare payment differentials, ASCs may be less able to embrace this therapeutic alternative than hospitals, and that steps should be taken to ensure that ASCs also utilize these alternative therapies, but the question CMS should be asking is whether uptake and utilization in hospitals would have been or could be greater but for the packaging deterrent. In this age of the opioid epidemic, where providers and the federal government alike are scrambling to arrest opioid reliance, CMS should be pursuing all available reasonable avenues to help in this fight.

Request for Information (RFI) on Price Transparency

Trinity Health is committed to working with consumers, payers and policymakers on developing the best solutions for achieving price transparency goals. Delivering people-centered care requires

consumers have access to meaningful information about the price and quality of their care in order to foster personal engagement that promotes self-management and shared decision-making. Trinity Health 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 either done via an online price estimator or via a call-center utilizing a patient payment estimation tool to aid patients in better understanding their financial responsibility**.** This assistance is extremely meaningful to patients compared to the confusion created by reviewing charge data. Trinity Health hospitals also post important policies online, including financial assistance and charity care policies. It is our belief that consumers desire transparency to determine two key aspects of price. First, what is my out-of-pocket cost for this procedure/treatment for this provider? And, second, how does this provider's price compare to other providers that I could choose?

When asked by patients about what a specific procedure/treatment will cost, it can be difficult for providers to fully estimate exactly what that procedure/treatment will entail for any given patient. For example, a basic knee replacement can vary greatly dependent on the patient's age and the existence of any chronic conditions. Patients have also expressed their desire in knowing the total cost of care for specific procedures – i.e., all costs associated with that knee replacement including consults, tests, and post-operative visits required as part of the total care experience. **In order to mitigate this variance and to ensure that comparability between providers does exist, Trinity Health recommends that CMS—working with provider groups and payer stakeholders—develops a bundle of the most common—perhaps the top 25-50 inpatient and top 100 outpatient—procedures as a reasonable starting point. This would create some standardization of typical procedures towards accomplishing the goal of comparison shopping. After identification of these "shoppable" services by population, payers should provide hospitals and health systems with accurate information for their enrollees.**

It is critically important that patients understand the basic components of their insurance plan coverage to be well-informed consumers. Consumers first need an understanding of in-network providers, including physicians, hospitals and outpatient centers. They also need an understanding that the price of patient care can vary, including out-of-pocket costs; and that out-of-network cost sharing is higher. **Payers best know the plan benefits for individual patients, and, therefore, should be held accountable to providing the information and tools to providers so that we can better assist our patients in receiving an accurate estimate of out-of-pocket costs.** The payers—whether Medicare, Medicaid or a private insurance plan—establish cost-sharing obligations, which takes into account whether the plan covers the service, whether the provider is in the plan's network, the plan's cost-sharing requirements, and, if applicable, where the individual is in their deductible. Providers, today, do not have access to this information. **Trinity Health recommends that payers provide this information to hospitals and health systems via a web-based portal that providers can use to respond to patient inquires. Ideally, the portal would contain information on where the patient is within their deductible so that the provider can relay cost estimates that are accurate and most relevant for that particular consumer based on their insurance coverage.**

Understanding health care terminology around price poses significant challenges for consumers. If you ask a group of people to define what "price" is, it is likely you will get a variety of answers. **Trinity Health urges CMS to consider the below definitions to help frame understanding on this issue and inform policymaking on price transparency:**

- Charge: The dollar amount assigned to specific medical services before negotiating any discounts from payers or providing discounts to uninsured patients. The charge is different from the price. As stated earlier very few patients pay the charge regardless of their insurance status; and, therefore, this data is not meaningful to consumers.

- Price: The negotiated and contracted amount to be paid to providers by payers (also called the "allowed amount") or the discounted amount for uninsured patients. An insured patient's

out-of-pocket liability for health care services is based on this allowed amount. Note that the price for a given service varies by insurance plan as these are separately negotiated by plan/employer.

- Cost: The definition of cost depends on the cost being referenced:
    - Patient Cost is the out-of-pocket cost to the patient, which includes the portion of payment for medical services and treatment for which the patient is responsible. This includes copayments, coinsurance, and deductibles.
    - Provider cost is the expense incurred to provide health care services to patients.
    - Employer cost is the expense related to insuring its employees, and this will depend on whether the employer is paying premiums to insure its employees or if it self-insured and paying claims for health care services.
    - Insurance plan cost take two forms, allowed and paid costs. The allowed cost is total price allowed by the contract. The paid costs is the portion paid by the insurer.

The above definition of price should guide policymaking on transparency so that data is meaningful to patients. To the extent that CMS is interested in price comparison tools, Trinity Health reiterates that only payers, including CMS for the Medicare population, have complete information about what their enrollees may pay for the same service at different in-network providers. **Payers need to work with providers to ensure meaningful disclosure of pricing information that is relevant to patients**. This should include consistent, standard, accurate and reliable information about plan options; including, covered benefits, prescription drug formularies, provider networks, and out-of-pocket patient liabilities. Also, as CMS notes, patients receive bills from the hospital facility and from the physician. It is not reasonable to hold hospitals accountable for physician bills. It is also important to note that multiple providers may provide services and bills to the patient, so it is likely that the patient will still need to go to more than one source to get all the information.

Given the challenges associated with making price information more easily accessible, Trinity Health discourages CMS from taking a punitive approach against providers who cannot meet all patient expectations for price transparency. **Instead, Trinity Health encourages CMS to convene hospitals, physicians, payers, consumers and employers to explore ways to increase consumer health care literacy, especially around their health plan benefit design, and develop the best framework for this sharing of out-of-pocket costs from payers to providers.**

Trinity Health had strongly agreed with CMS—in the proposed inpatient rule for fiscal year 2019—that charge data is not helpful to consumers. It does not solve the price transparency challenge. Very few patients pay the charge regardless of their insurance status; and, therefore, this data is not meaningful to consumers and serves to only further confuse patients as a result. Therefore, we were disappointed to see CMS finalize the requirement that hospitals make available a list of their current standard charges via the internet in a machine-readable format and to update this information at least annually. We have several specific questions in order to best implement this requirement. **Specifically, Trinity Health seeks clarification from CMS on the following:**

- **How is "machine-readable format" defined (i.e. Excel)? What software output would comply?**
- **Will CMS be creating a specific list of most common charges to be posted and required data elements (i.e. CPT codes)? Posting thousands of Excel rows of data would not be beneficial to a patient.**
- **For States with charge posting requirements, would complying with those state requirements meet CMS' new requirement or would hospitals have to post two listings of charges on its website?**

Request for Information (RFI) on Interoperability

Interoperability is a key strategic imperative for Trinity Health. We are building a People-Centered Health System to put the people we serve at the center of every behavior, action and decision. This brings to life our commitment to be a compassionate, transforming and healing presence in our communities. We believe that interoperability is essential to a high-performing People-Centered Health System because it allows the widespread exchange of structured and standardized health information through interoperable health information technology (health IT). This makes it simpler to place the patient at the center of an interconnected system of his/her own medical data and helps care providers meet a patient's needs in a more comprehensive and concise manner by eliminating barriers to data sharing and care coordination.

Trinity Health appreciates the commitment of CMS and the Administration to advancing interoperability, and we would be pleased to be a partner in that effort. We appreciate and agree with the efforts to improve the Meaningful Use program that were included in the IPPS rule, as included in our below comments. We recognize the laudable goals driving CMS's efforts to look for additional, and potentially streamlined, levers with which to accelerate the pace of progress toward our shared goal of interoperability.

In this spirit, Trinity Health supports requiring all acute care, post-acute care and skilled nursing facilities to attest that they are regularly transmitting Admit, Discharge and Transfer (ADT) HL7 compliant transactions to established community-wide, regional or state-wide health information exchanges (HIEs) or similar repository that act as vehicles for disseminating information, when such vehicles are available. We believe requiring such transmission is reasonable when a community resource is available and capable of receiving the transmissions. This is a reasonable and achievable expectation with the existing technology and market maturity. Everyday Trinity Health facilities are transmitting more than 200,000 ADTs. We believe that sharing of such data is essential for care coordination, particularly as it pertains to handoffs.

We strongly urge that facilities be accountable for transmission only, as it is not realistic to hold facilities responsible for assuring receipt of such transmissions, nor to hold them accountable to transmit to specific providers. Trinity Health believes that care coordination for patients is most effective when community-wide capabilities are available to all providers. Lastly, we do not support requiring transmissions to individual providers; investing to create a community information exchange is more efficient, effective and smarter spending of the health care dollar.

It is also our recommendation that regulatory guidance require that all participating providers attest annually that they are transmitting ADT notifications. This attestation requirement could be effectuated through the anticipated information blocking rulemaking or any other appropriate vehicle. Based upon review of industry compliance and adherence to an attestation standard, CMS can determine if more extensive regulatory requirements—such as tying this to Conditions of Participation, Conditions for Coverage or Requirements for Participation for long-term care facilities (CoPs, CfCs and RfPs)—is necessary.

Trinity Health believes strongly that federal leadership and action steps are needed to move the nation more expeditiously to interoperability. While the Medicare and Medicaid Electronic Health Record (EHR) Incentive Program (now the Promoting Interoperability Program) did successfully drive adoption of EHRs, the program remains largely government-driven rather than patient-centered, which has led to "tick the box" government requirements that have failed to advance patient care, improve clinician workflow, or make the substantial progress toward interoperability that was envisioned when the program was enacted. Following are our specific recommendations on which the Department of Health and Human Services (HHS) and the Administration can provide leadership, in concert with the private sector, to advance progress toward interoperability:

1. **Accelerate public and private sector efforts toward the consistent implementation of uniform national standards for health information technology.** Adherence to open-source, consensus-based, transparent standards that are sufficiently mature should be a priority, and should be an essential aspect of certification of electronic health record technology. While great progress has been made on standards, there is significant additional work to be done; for example, existing standards in areas such as lab, vital signs, and clinical documents need to be deepened. New areas such as scheduling, pathology reports and patient-reported data are needed. That said, it is important that we make use of existing standards whenever possible; we should not start over. Health IT vendors often provide tools designed to help with interoperability but too often providers are required to develop new workflows that add time without patient or other benefit. Vendors should be required to build new tools within existing workflows. Vendors should also be required to have easily available metrics to measure outcomes. Certification should test EHRs for usability in a broad array of settings, from complex academic medical centers to rural critical access hospitals. Post-installation testing should confirm that installed systems work as intended.

2. **Align Promoting Interoperability Program requirements (previously Meaningful Use and Advancing Care Information requirements) for physicians and hospitals.** Parity in program requirements is essential, and we appreciate CMS proposing steps in that direction in the FY 2019 IPPS proposed rule. Although Trinity Health physicians and hospitals have enjoyed significant success in the Meaningful Use program, the tremendous effort required to meet established Meaningful Use goals has diverted clinician and staff attention as well as considerable resources away from activities with greater direct patient benefit, away from activities with more significant clinician benefit, and away from efforts to advance interoperability.

3. **Accelerate movement toward value-based care, which would provide additional incentives for care coordination and data exchange.**

4. **Promote an effective national strategy for accurately matching patients to their data.** One of the primary challenges impeding the safe and secure electronic exchange of health information is the lack of a consistent patient data matching strategy. Consistency in patient data matching is foundational to interoperability and remains conspicuously absent. Consistency in patient matching is also essential to patient safety and to ensuring that the information in a patient's EMR actually belongs to that patient and includes all available information.

5. **Establish common national standards for privacy and security.** This will improve the appropriate and secure flow of health data. The current patchwork of state laws impedes information flow.

6. **Require consumer interoperability standards so that it is easy for consumers to access all their information, free of charge, and incorporate it into any certified tool they wish to use.** Make it easy for patients to collate data from multiple sources, creating useful information which is easy to understand and share with their care team. Consumer interoperability standards must be prioritized, and they should be a part of the government's certification program. Improvement in authentication standards for consumer applications is needed; for example, consumers should not be forced to sign in each and every time they access information.

7. **Work in cooperation with providers on health care cybersecurity, an essential public health concern.** Insist on greater security and resilience in medical devices. Take steps to assist and incentivize providers, particularly smaller providers, in developing and maintaining good cyber hygiene and in learning about and addressing current and emerging cybersecurity threats. Insist that device manufacturers incorporate patient safety into product design and work in partnership with providers and patients to make transparent a device's cybersecurity

capabilities. Make certain that device security is a shared responsibility of manufacturers and providers.

8. **Create a trigger mechanism for ending the Promoting Interoperability program for hospitals**. This is important because the program currently has no sunset date. While physicians have been moved into the MIPS program, which provides opportunity for bonuses and penalties, hospitals remain in the original Meaningful Use program (renamed the Promoting Interoperability Program), which now has only penalties. Consider the development of a mechanism that would trigger the sunset of the program once a sufficient number of Medicare hospitals successfully attest to Stage 3.

Trinity Health is committed to working across the health care continuum to advance interoperability and to help consumers easily and securely access their electronic health data, direct it to any desired location, and be assured that their health information will be effectively and safely used to benefit their health and the health of their community. As Trinity Health works toward a People-Centered Health System, we are also working to provide appropriate opportunities for patients to capture, use and share their health data electronically with providers through the use of personal health devices, personal health tracking tools and more traditional medical devices for remote monitoring. This is part of our commitment to putting the people we serve at the center of every behavior, action and decision.

Thank you, again, for the opportunity to submit our views on this topic. Without interoperability, the potential of health IT will not be fully realized and patients will continue to be stymied in their efforts to access their own electronic medical records.