



October 1, 2020

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

Re: CMS-1736-P Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-owned 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-1736-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. 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 106 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 \$1.2 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 123,000 colleagues, including more than 6,800 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.

Trinity Health participates in 11 markets with Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs), which includes five markets partnering as an MSSP Track 3 ACO. We also have three markets partnering as a Next Generation ACO and 2 participating in CPC+. In addition, we have 33 hospitals participating in the Bundled Payments for Care Improvement Advanced (BPCIA) initiative, and three hospitals in the Comprehensive Care for Joint Replacement (CJR) program. Our work—and experience in value-based contracting—also extends beyond Medicare as illustrated by our participation in 123 non-CMS APM contracts.

### Price Transparency

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.

**Trinity Health supports the underlying goal to bring price transparency to patients; however, the price transparency requirements finalized last year created a significant burden at a time in which hospitals have been focused on responding to the ongoing COVID pandemic.**

We are in the midst of a pandemic and have had to divert resources to preparing to comply with the price transparency requirements and expect the challenges of COVID will remain with us throughout the remainder of the calendar year and into CY2021. **We urge CMS to delay the implementation date of the final hospital price transparency regulation by one year to January 1, 2022.**

### Site Neutral Payments

CMS proposes to continue its policy of site-neutral payments for clinic visits in CY 2021. **Trinity Health continues to strongly oppose these payment cuts and believes this policy is outside the scope of Congressional intent.** This 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 OPSS. CMS has previously identified increased utilization of OPSS 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 analysis 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. In addition, hospital-based ambulatory centers incur more regulatory requirements—and higher costs in meeting these regulatory requirements—compared to other outpatient settings.

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

### 340B Payment Cuts

CMS proposes to pay for drugs acquired under the 340B program at ASP minus 28.7 percent, or ASP minus 34.7 percent plus a 6 percent add-on for services associated with drug acquisition costs not separately paid for (compared to the current policy of ASP minus 22.5 percent).

**Trinity Health is deeply concerned by the substantial cuts CMS continues to make for 340B drugs and strongly opposes the proposed reduction. These cuts are inconsistent with 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 refrain from implementing any future reduction.**

Trinity Health is Committed to those who are poor and underserved, we return \$1.2 billion to our communities annually in the form of charity care and other community benefit programs. We care for a significant number of vulnerable populations, including low-income patients and those on Medicaid or who are uninsured. 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. Further, the program 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.

While CMS has proposed to add the 6% for services associated with drug acquisition that are not separately paid for, such as handling, storage, and other overhead for parity with non-340B drugs, **CMS does not take into consideration that there are many instances in which CEs must purchase drugs at WAC and not 340B.** Additionally, the process for adding the payment modifiers is so administratively burdensome that our systems are set up to bill with a modifier that triggers a lower payment even when these drugs are purchased at the much higher WAC cost.

CMS asks if maintaining the current cuts of ASP minus 22.5 percent for 340B-acquired drugs is preferred. While we strongly oppose any reduction to 340B payment for reasons mentioned above, of course the lower of the two cuts is preferable. In addition, any cuts should remain budget neutral.

### Proposals to Change the Calculation of the Wage Index

CMS proposes to continue its past policies of assigning the wage index that would be applicable if the hospital were paid under the IPPS, including adjustments to the wage index finalized in the FY21 IPPS rule.

Trinity Health recognizes the need for policies to help support rural hospitals and the communities they serve. **We continue to urge the Department of Health and Human Services and Congress to develop a comprehensive, long-term approach to help these facilities.**

As disparities among geographic regions and challenges faced by rural hospitals continue to grow, **HHS should work with Congress to create a new designated pool of funding for low-wage hospitals that is not subject to budget neutrality.**

#### Inpatient Only (IPO) List

CMS proposes to eliminate the IPO list over a three-year period, beginning in CY 2021 with the removal of 266 musculoskeletal-related services. Many services on the IPO list are surgical procedures that may be complex and require high levels of care and coordinated services. **While we do believe physicians should be able to use their clinical judgement in determining where patients receive care, we have concerns with the inconsistencies and barriers to care this proposal may create.** If not implemented correctly, this policy may lead to delayed care and unintended consequences.

**Prior to eliminating the IPO list, Trinity Health recommends CMS provide more clarity around appropriate settings.** For example, for non-inpatient services, when is a hospital outpatient department more appropriate compared to an ambulatory surgical center (ASC)? **In addition, we recommend CMS create ASC exclusion criteria for services removed from the IPO list and national guidelines for screening patients to determine appropriate setting.**

CMS must acknowledge the administrative burden this proposal will create from MA plans and commercial payers. As evidenced by services removed from the IPO list in recent years, health plans use less expensive settings as the default that require lengthy appeal and prior authorization processes to override these defaults; this makes it harder to ensure patients receive care in the safest, most appropriate setting. If a physician determines a patient would be best served in a specific setting, MA plans (and commercial payers) should not create barriers to receiving care. **To mitigate these practices, 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.**

Also worth noting is services that will fall under Part B as an outpatient procedure instead of Part A may also increase beneficiary out of pocket costs as they will be held to their 20% co-payment requirement. CMS should educate Medicare beneficiaries of these changes.

#### Supervision of Outpatient Therapeutic Services

Trinity Health supports changing the minimum default level of supervision for non-surgical extended duration therapeutic services to general supervision for the entire service. **However, we urge CMS to also allow for general supervision for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services as well.**

#### Specimen Collection

As result of the COVID public health emergency (PHE), CMS established a temporary specimen collection policy—HCPCS code C9803 (Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2). **Trinity Health supports retaining these changes beyond the PHE to support COVID testing.**

#### Ambulatory Surgical Centers (ASC)

The proposed rule would add 11 procedures to the ASC list of covered procedures list (CPL), including total hip arthroplasty, and outlines two new alternative processes for updating the ASC CPL. For the processes

proposed, Trinity Health has concerns there will not be enough quality review of procedures if CMS adds more than 200 services to the ASC. In addition, the alternative process would shift payment from Part A to Part B. **CMS should share how they plan to allocate funds between these two Parts and anticipated spend out of the fund, as well as anticipated impact on beneficiary out of pocket costs, prior to finalizing a new process for updating the ASC CPL.**

#### Prior authorization

The proposed rule would add two new categories of services to the prior authorization process finalized last year-- Cervical Fusion with Disc Removal and Implanted Spinal Neurostimulators. While Trinity Health supported the services last year as they were largely cosmetic,

#### Overall Hospital Quality Star Ratings

In general, Trinity Health supports the proposed changes for the Hospital Quality Start Ratings. However, we have concerns with replacing Latent Variable Modeling (LVM) with simple average of measure scores to calculate measure group scores.

As noted in the Proposed Rule, the LVM methodology was selected by the Technical Expert Panel (TEP) after consideration of several methods, including simple average. The TEP selected LVM as the optimal method to account for: relationship between measures, measures that are not reported, and sampling variation. These measure factors continue to exist – there is still relationship between measures, measures that are not reported, and sampling variation. In addition, LVM allows for confidence intervals to assign hospital measure groups to “above,” “same as,” or “below the national average.” **The proposal to replace the methodology with simple average negates the prior evaluation by the TEP. We understand that the proposal is in response to comments requesting a simpler methodology; however, such a significant change should be addressed through a TEP.**

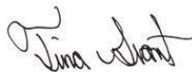
#### Proposed Payment for Hospital Outpatient and Critical Care services

**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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Trinity Health