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June 25, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW, Room 314-G
Washington, DC 20201

Re: CMS-1694-P, Fiscal Year (FY) 2019 Medicare Hospital Inpatient Prospective Payment System (IPPS) Proposed Rule

Dear Administrator Verma,

The University of California Health System (UC Health) appreciates this opportunity to comment on portions of the Inpatient Prospective Payment System (IPPS) FY 2019 proposed rule concerning use of the Worksheet S-10 in calculating hospitals' Medicare Disproportionate Share Hospital (DSH) uncompensated care pool funding, as well as a portion of the proposed rule soliciting whether Chimeric Antigen Receptor (CAR)-T cell therapy should fit under an existing MS-DRG, such as under MS-DRG 016 (Autologous Bone Marrow Transplant with CC/MCC) or merit the creation of a new MS-DRG.

Throughout California, UC Health's medical centers are recognized as trusted, high quality safety net hospitals. Nearly 60 percent of UC Health's patients are publicly insured or uninsured. Presently, UC Health ranks as California's third greatest provider of inpatient Medicaid services, and the fourth greatest provider of outpatient Medicaid services. UC Health operates the nation's largest health sciences instructional program, as it includes 18 health professional schools and five academic medical centers comprised of twelve public hospitals located at the Davis, Irvine, Los Angeles, San Diego, and San Francisco campuses. UC Health trains nearly half of the medical students and medical residents in California. UC Health's medical centers provide half of California's organ transplants and one-fourth of its extensive burn care. Consequently, UC Health's capacity to fulfill its tripartite mission of providing high quality patient care, training the next generation of physicians, and innovating medical cures would be compromised by an allocation of Medicare DSH uncompensated care payments that is based on a not-yet-verified data source that may not accurately reflect the extent of uncompensated care provided by hospitals across the country.

Our medical centers continue to express great concern about relying on the Worksheet S-10 data to calculate the Medicare DSH uncompensated care funds that are so critical to support UC Health's hospitals ability to treat low-income patients. Last year, we urged CMS not to use the Worksheet S-10 data because it was not ready for prime time, citing significant inexplicable anomalies and distortions in the data hospitals were including in the S-10.

Alternatively, we urged CMS to share all of its assumptions behind the S-10 through rulemaking, including the actuary's inflation update factors, so our hospitals could try to replicate the calculations and verify for themselves whether CMS accurately capturing the level and extent to which our hospitals provide uncompensated care.

UC Health continues to think the S-10 remains unready for prime time. The release of Transmittal 10 last October left most hospitals with only a few short months to amend their cost reports and re-submit their S-10s, and numerous hospitals across the country have varying interpretations as to how to fill out the individual lines comprising the Worksheet S-10. The data therefore continue to be unreliable and have not yet been verified by audit. That can mean that hospitals located just a few minutes apart from each other with similar payor mixes, patient demographics, and inpatient volume having highly disparate results in uncompensated care funding resulting arising from the calculation of Factor 3.

UC Health System continues to find the S-10 methodology for calculating hospitals' Medicare uncompensated care costs to be extremely flawed. We believe the Worksheet S-10 needs great improvement before its ready for universal use in assessing hospitals' uncompensated care costs. We do not believe that CMS's issuance of Transmittal 10 in October 2017 was sufficient for helping hospitals update and revise the instructions under which they will calculate their uncompensated care costs. We continue to believe that CMS should audit Worksheet S-10 data, as it has done to area wage index data, prior to its use. We appreciate CMS's announcement that it has plans to do limited desk audits in the future, but this past year's results of hospitals' use of the Worksheet S-10 in part to calculate their uncompensated care costs demonstrate the need for more verification of the data being used by CMS.

We at UC Health System also strongly believe the data being collected by CMS through the Worksheet S-10 is insufficient for accurately assessing DSH hospitals' uncompensated care costs. CMS should additionally account for Medicaid shortfalls, GME costs, and research costs that our teaching hospitals regularly incur. For example, while California opted into the Medicaid expansion and therefore, has fewer people who meet the definition of uninsured, UC Health System, as a highly sought-after safety net provider of tertiary and quaternary services, often treats Medicaid patients with complicated conditions and multiple co-morbidities in need of those high-cost specialty services, some of which require a greater length of stay. Increasing volumes of Medicaid beneficiaries in conjunction with decreasing Medicare revenues undermine the financial well-being of UC Health hospitals. Consequently, we strongly believe that our Medicaid shortfalls (Line 19 of the Worksheet S-10) should be included in CMS's calculation of uncompensated care. Annually, our UC Health hospitals train over half of California's medical residents. UC Health system absorbs fully the costs associated from training the nearly 500 medical residents that exceed our medical centers' Graduate Medical Education (GME) caps. The GME costs which UC Health hospitals bear to train the next generation of physicians should be included in the Cost to Charge Ratio Line 1 of the Worksheet S-10. While CMS has addressed previously the issue of including GME costs in the CCR, it has opted not to incorporate GME costs when converting uncompensated care charges to costs. Its decision to not include these GME costs will disproportionately hurt teaching hospitals by reducing their share of the uncompensated care pool in relation to other hospitals. Finally, as teaching hospitals linked to medical schools we play an integral role in innovating medical cures through our clinicians' ground-breaking biomedical research. CMS should consider including the research costs which our hospitals bear in calculating UC Health's overall uncompensated care costs.

For all of these reasons, UC Health recommends that CMS take the following actions.

1) Slow the transition towards relying wholly on the Worksheet S-10 data for calculating uncompensated care costs of hospitals. We urge CMS to lengthen the time frame for the transition to at least five years.
2) During the transition, reduce the weight CMS attributes to Worksheet S-10 data in relation to proxy data.
3) Routinely audit Worksheet S-10 data from DSH hospitals across the country, as well as similar hospitals located just a few miles from each other, analyze any inconsistencies in data reporting, and provide more detailed guidance to hospitals to improve clarity and consistency in reporting.

Because CMS's distribution of Medicare DSH uncompensated care pool dollars cannot be reconciled or appealed, it is imperative that CMS not proceed further in relying upon the Worksheet S-10 data for calculating hospitals' uncompensated care costs until it can ensure such data is reliable and verifiable. CMS cannot now certify the data upon which it is relying, which is extracted from multiple DSH hospitals' differing interpretations of how to fill out the Worksheet S-10, is accurate. The result of continuing to use unreliable and unverifiable data will be less resources to some hospitals that truly fit the criteria of being safety net hospitals and a distribution of uncompensated care payments in a manner that does not accurately reflect the levels and extent of uncompensated care provided by those hospitals. We urge CMS to continue investigating discrepancies in how hospitals across the country are submitting data in the Worksheet S-10. The Worksheet S-10 should only be used once the data extracted from it is verifiable, accurate, and reliable. To achieve this outcome, CMS must produce clear instructions for filling out the Worksheet S-10. Such instructions need to be uniformly understood and regularly tested.

Determining Payment for Chimeric Antigen Receptor (CAR)T-Cell Therapy

CMS solicits feedback from hospitals carrying out CAR T-cell therapy as to how these services should be paid for under Medicare. Specifically, CMS asks whether CAR T-cell therapy should be assigned to an existing MS-DRG, suggesting patients receiving CAR T-cell therapy have similar clinical characteristics and comorbidities to those patients receiving treatment for other hematopoietic carcinomas who are treated with autologous bone marrow transplant therapy currently assigned to MS-DRG 016 (Autologous Bone Marrow Transplant with CC/MCC). CMS proposes assigning ICD-10-PCS produced codes XW043C3 to Pre-MDC MS-DRG 016 for FY 2019 and revising MS-DRG 016's title from "Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy." Alternatively, CMS suggests there may be merit in creating a new MS-DRG for procedures involving the utilization of CAR T-cell therapy drugs and cases representing patients receiving CAR T-cell therapy to which CMS would assign the aforementioned ICD-PS codes for discharges occurring in FY 2019.

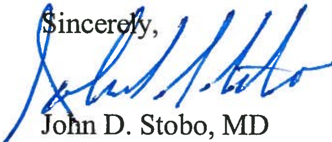
UC Health strongly supports CMS's efforts to develop a Medicare reimbursement policy that reflects the breakthrough innovation – and significant costs – of providing CAR T-cell therapy. Today, two of UC Health system's medical centers, UCSF Health and UCLA Health, are embracing their capacity as top-ranked academic medical centers, with some of the country's most preeminent physicians and cancer facilities, to offer CAR T-cell therapy treatment to both adults and children. We think CAR T-cell therapy is an innovative procedure with life-saving potential, and consistent with our public mission, our medical centers are committed to making this treatment available to patients regardless of their insurance status. CAR T-cell therapy represents a potential cure for patients facing lethal cancers and no remaining care alternatives. For example, we find there is a 78 percent survival rate of six months following targeted CAR T- cell therapy. Reimbursement ambiguity has resulted in slow adoption and treatment delays. Providers must appropriately balance substantial financial exposure with administering life-saving CAR T-cell therapy. However, without Medicare and other payor reimbursement methodologies that adequately reflect the resources required to provide this therapy, and perhaps even more critically, to treat any adverse side effects that patients may experience as a result of the treatment, UC Health medical centers may incur substantial financial losses for providing these services.

UC clinicians describe that in general, the procedure for providing CAR T-cell therapy is similar to autologous bone marrow transplants (MS-DRG 016). However, UC clinicians have observed at least two significant clinical differences between these group groups of patients. First, whereas patients undergoing autologous bone marrow transplants usually have a manageable level of toxicity, CAR T-cell therapy patients that experience adverse side effects as a result of the therapy often have highly unpredictable, and high levels of toxicity, which may require admission for an inpatient stay and may even require intensive care unit (ICU) services. Second, the typical length of an inpatient stay for a CAR T-cell therapy patient

is much shorter than for patients who require a transplant: CAR T-cell therapy patients inpatient stays typically last between 7-14 days, autologous bone marrow transplant patients typically have a length of stay of 14-21 days. Our oncologists have found that a CAR T-cell therapy patient's disease burden is determinative of whether the patient needs an inpatient admission and its length.
When compared with an autologous bone marrow patient (MS-DRG 016), the resources required to provide CAR T-cell therapy to a patient are also significantly different because of the extremely high cost of the two FDA approved pharmaceuticals for this therapy. Traditional Medicare outlier payments would not be enough to cover the costs a hospital providing CAR T-cell therapy to a Medicare beneficiary in the inpatient setting would incur. Will CMS create a special outlier payment for CAR T-cell therapy cases? If so, will the outlier payment be enough to cover most of the cost a hospital incurs providing CAR T-cell therapy? Will the outlier payments provided for CAR T-cell therapy count against our medical centers' capacity to recover payment for other high cost patient cases? How will Medicare account in its payment levels for the uniqueness of each patient who receives CAR T-cell therapy?

Conclusion
We thank you for allowing UC Health to share its concerns about CMS's methodology for calculating Medicare DSH uncompensated care payments in FY 2019 and Medicare reimbursement for inpatient hospital services furnished to patients in connection with CAR T-cell therapy should be classified for purposes of paying for CAR T-cell therapy to Medicare beneficiaries. Please refer any questions you may have about our comments to UC Health System's Federal Governmental Relations Director Julie A. Clements, J.D., M.P.P. (julie.clements@ucdc.edu/(202)-974-6309).

Sincerely,



John D. Stobo, MD
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