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June 24, 2019

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

Re: CMS-2019-0073-0003, Fiscal Year (FY) 2020 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 2020 proposed rule concerning revising calculation of the IPPS new-technology add-on payment for Chimeric Antigen Receptor (CAR)-T cell therapy, along with a solicitation for feedback on how CAR T-cell therapy should be financed, proposed changes to calculations for the Area Wage Index, and the data used to determine the allocation of the Medicare Disproportionate Share Hospital (DSH) Uncompensated Care (UCC) pool funds to hospitals.

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 (known as "Medi-Cal" in California), and the fourth greatest provider of outpatient Medi-Cal 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.

UC Health also has five National Cancer Institute (NCI)-designated Cancer Centers, bringing many of the world's top experts together for ground-breaking research, clinical trials and advanced patient care treatments. Nearly half of the patients seen at a UC cancer center have late-stage cancers. Cancer centers that achieve the NCI comprehensive cancer center designation

frequently see patients with rare and difficult cancers who cannot be treated in other hospitals due to a lack of specific expertise or clinical trials involving the latest experimental drugs.

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

Specifically, CMS asks whether CAR T-cell therapy should be assigned its own MS-DRG, versus its status quo of being under the same MS-DRG as patients with autologous bone marrow. Although UC Health supports CMS's proposal to continue assigning CAR T-cell therapy to MS-DRG 016 for federal fiscal year 2020, we think it is critical for CMS to continue to explore the most appropriate way to eventually create a new MS-DRG specifically for cases involving CAR T-cell therapy.

UC Health is encouraged by the discussion to address high-cost therapies such as CAR T-cell therapy and its impact on teaching hospitals. In considering ways to move forward, however, we are concerned that CMS's standard payment methodologies are unable to accurately value very high cost technologies, which have a significant effect on academic medical centers like ours.

Teaching hospitals are the institutions where beneficiaries receive CAR T-cell therapy. The teaching hospitals caring for these patients expect to have higher costs, as a result of their sophisticated infrastructure, the many medical residents they support, and the medically complex patients they treat. Patients undergoing autologous bone marrow transplants usually have a manageable level of toxicity, while CAR T-cell therapy patients who experience adverse side effects from the therapy often have highly unpredictable, high levels of toxicity, which may require admission for an inpatient stay with an increased amount of intensive care unit (ICU) services. 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; these are very resource-intensive patients who require teaching hospitals for their care.

CMS also solicits feedback from hospitals carrying out CAR T-cell therapy as to how these services should be paid for under Medicare.
CAR T-cell therapy is the innovative care of the future and offers significant treatment advances for previously untreatable, life threatening diseases. For example, our oncologists have found a 78 percent survival rate of six months following targeted CAR T- cell therapy. CAR T-cell therapy represents a potential cure for patients facing lethal cancers and no remaining care alternatives. Today, four of UC Health system's five medical centers are offering ground-breaking, life-saving CAR T-cell therapy treatment to adults and children. Currently, only about 30 academic medical centers in the United States offer this novel procedure to patients not participating in clinical trials. Due to the extremely high cost of the CAR T-cell therapy itself, the Medicare reimbursement that hospitals receive (even taking into account potentially available outlier payments) barely covers the cost of the drug itself, leaving little coverage for the myriad medical and nursing services that the hospital provides when it administers this therapy. UC Health remains committed to offering this life-saving therapy, consistent with our mission as a public institution but is very concerned that the lack of adequate Medicare reimbursement for this and future CAR T-cell therapies and other gene therapies currently in the pipeline could lead to unsustainable financial losses for our academic medical centers.

Consequently, we urge CMS to develop a Medicare reimbursement policy that reflects the breakthrough innovation – and significant costs – just a few top-ranked academic medical centers across the country incur providing CAR T-cell therapy. CAR T-cell therapy is an innovative procedure with life-saving potential. If CMS chooses to create a new MS-DRG for

CAR T-cell therapy cases, it must ensure adequate reimbursement that reflects the true costs of the treatment. Furthermore, if new CAR T-cell therapies currently in the pipeline do not qualify for the new technology add-on payment, then hospitals will face an even greater reimbursement shortfall in the coming years.

CMS questions whether Indirect Medical Education (IME) and Medicare DSH payments should apply if a new MS-DRG is created after FY 2020. IME's purpose is to be a proxy to account for a number of factors which legitimately increase costs in teaching hospitals. Even as new therapies and DRGs emerge, these costs continue to exist and must be paid on every MS-DRG. While Section 1886(d)(5)(I) of the Social Security Act (the Act) permits CMS to make other exceptions or adjustments, those adjustments would be *in addition to* the exceptions and adjustments that are specified in the statute, which include IME and DSH. The statute authority does not extend to modifying existing exceptions and adjustments, both of which are mandated by the clear language of the statute. Section 1886(d)(5)(B) of the Act states that the Secretary of Health and Human Services (HHS) "shall provide for an additional payment amount for subsection (d) hospitals with indirect costs of medical education." The statute's use of the word "shall" directs the Secretary to make the payment and does not leave this up to the Secretary's discretion.

IME and DSH payments made to teaching hospitals are based on a recognition that overall the costs are greater at teaching hospitals, specifically those comprising UC Health, due to numerous factors, including treating the most complex patients, the provision of trauma, burn, and cancer care and organ transplants, and being sites of clinical education and research studies. For these reasons, UC Health believes that CMS should continue the same policy for making Indirect Medical Education (IME) payments for cases involving CAR T-cell therapy treatment.

UC Health supports CMS's decision to increase the inpatient hospital technology add-on payment applied to CAR T-cell therapy drugs from the full MS-DRG payment plus 50 percent of the estimated costs of the CAR T-cell therapy drugs KYMRIAH® and YESCARTA® to a uniform add-on payment that is 65 percent of the technology's costs, thereby bringing the new technology add-on limit up to $242,450. However, UC Health does not think it goes far enough to compensate the few academic medical centers providing CAR T-cell therapy to ensure patient access to life-saving innovation.

Proposed Changes to Area Wage Index Threaten Our Public Mission

CMS seeks to increase wage index values for low-wage hospitals falling in the bottom 25th percentile by reducing wage index values for high-wage hospitals falling in the 75th percentile. Because CMS aims to make these changes in a budget neutral manner, hospitals across California will lose labor dollars meant to offset the higher costs of living in California. Data show this proposal would result in significant cuts hitting each of UC Health's five academic medical centers, thereby threatening UC Health's safety net provider mission.

For decades hospitals have relied on CMS's Medicare Area Wage Index, a balanced calculation that accounts for the very real and not easily altered geographic discrepancies in costs. This calculation has ensured that hospitals in high-cost areas are not overly burdened by the direct cost of employees or the ancillary services for which hospitals contract with local businesses. While we appreciate that CMS wishes to address the financial challenges of our nation's rural hospitals, UC Health believes that legislation is needed and is the appropriate mechanism to provide additional support to rural hospitals. The proposal in the IPPS rule would negatively harm *all* California hospitals — even rural hospitals. In 2017, the cost of goods and services in California were 14.8 percent above the national average, and it is abundantly clear why California hospitals must expend greater resources on staffing compared to other states. In addition, California, has significant regulatory requirements that contribute to its labor costs, including nursing staff ratios and limited scope of practice for a number of clinical specialties. Upwards of 57 percent of hospital spending statewide is on labor-related costs. In short, providing health care in California simply costs more, but we at UC Health remain committed to meeting our patients' needs.

Today, as the country's top-ranked public academic medical center system, UC Health uniquely delivers highly specialized services, like burn care, advanced stage cancer care, and organ transplants, that other providers lack the infrastructure and/or are not trained to provide. Consequently, patients residing throughout California, including in its most remote rural areas, come to UC Health's medical centers and clinics to access our highly-specialized services. If put into effect, the Administration's changes to calculating the Area Wage Index, would result in reduced Medicare payments to UC Health at a time when UC Health's five medical centers are already challenged to continue providing services to underserved patient populations.

CMS's proposal undermines the intent of the Area Wage Index
CMS's proposal violates the provision of The Social Security Act requiring CMS to adjust payments to reflect area differences in wages, and it is not supported by the exceptions provision on which CMS depends. The wage compression proposal would result simply in a shift of Medicare funds from high-wage states to low-wage states, inversely related to these hospitals' actual labor costs. By undervaluing the labor costs in California, the proposal is financially destabilizing to California's hospitals which stand to lose more than $100 million in fiscal year 2020 alone as a result of this policy. The Area Wage Index policy needs reform, but this proposed policy is not the solution.

In addition to opposing this policy for the cuts that will result to UC Health, thereby threatening our hospitals' capacity to provide vulnerable patient populations access to necessary medical services, CMS proposes to exclude 81 hospitals nationally from the fiscal year 2020 Area Wage Index. Seven of these hospitals are located in California. Including these seven hospitals, which have been excluded from this Area Wage Index file, would reflect the complex labor markets in California. Further, the exclusion of seven hospitals in the Area Wage Index files, whose data CMS notes is accurate, will decrease payments to hospitals in those combined statistical areas (CBSAs) by $5.7 million. CMS should reverse this exclusion and reinstate all health system hospital data for the purposes of calculating the fiscal year 2020 Area Wage Index.

Recommended Data Collection for Accurately Calculating Uncompensated Care Payments

UC Health also remains concerned that CMS continues to propose allocation of Medicare DSH UCC payments based on unverified and therefore potentially inaccurate data. In prior years, we have requested that CMS issue guidance clarifying how it calculates Factor 3 under the Worksheet S-10 and undertake steps to review data collected from hospitals to ensure the data being collected is reliable, verifiable, and accurate, and therefore that the Medicare DSH dollars being directed to hospitals better reflect the actual socio-economic characteristics of the patient population the hospitals treat. **We commend CMS for ongoing efforts to issue guidance to help hospitals understand and complete the Worksheet S-10. CMS is making progress but still has more work to do helping hospitals ensure the data they report in the Worksheet S-10 accurately reflects the socio-demographic information of patients whom they treat**, so the Medicare DSH UCC payments hospitals receive better align with the amount of safety net services they provide to vulnerable patients.

We support the agency's continued efforts to strive for means of data collection that will ensure more reliable, verifiable, accurate data is collected for each Medicare DSH hospital. We express concern about CMS using fiscal year 2015 data, because only a small number of hospitals were audited for this year. We are also concerned that a proposal to base UCC payments on only one year's worth of data will result in wide variations and unpredictability for hospitals as the data varies from year to year. Once CMS's guidance for calculating Factor 3 of the Worksheet S-10 to derive UCC payments is settled, and there is a standardized audit process that applies to all Medicare DSH hospitals, we recommend that CMS utilize three years' worth of Medicare cost report data and blend it to smooth variations in patient population from year to year.
Three years of cost report data will help ensure the cost report data collected within each hospital is more representative of the individual hospital's circumstances. For example, a full three years of data versus one or two can account for any outliers, allowing a better assessment of a hospital's typical cost report data.

Conclusion

We thank CMS for allowing UC Health to share its concerns about policy proposals concerning changes to new technology add-on payments for CAR T-cell therapy drugs KYMRIAH® and YESCARTA ®, calculation of hospitals' Area Wage Index, and data collected in the Worksheet S-10 to determine allocations for Medicare DSH UCC payments. Please refer any questions you may have about our comments to UC system's Office of Federal Governmental Relations Director of Health and Clinical Affairs Julie A. Clements, J.D., M.P.P. (julie.clements@ucdc.edu/(202)-974-6309).

Sincerely,

John Stobo, MD
Executive Vice President