June 24, 2019

The Honorable Seema Verma
Administrator, Centers for Medicare and Medicaid Services
Hubert Humphrey Building
200 Independence Avenue, S.W. 445-G
Washington, D.C. 20201

Re: CMS-1716-P

Dear Administrator Verma:

The Healthcare Leadership Council (HLC) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to submit comments in response to the notice of proposed rulemaking entitled, "Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2020 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals."

HLC is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century healthcare system that makes affordable high-quality care accessible to all Americans. Members of HLC – hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, laboratories, biotech firms, health product distributors, post-acute care providers, home care providers, and information technology companies – advocate for measures to increase the quality and efficiency of healthcare through a patient-centered approach.

As a diverse coalition of healthcare stakeholders across the U.S. healthcare system, we believe innovation is essential to deliver pioneering drug and device therapies to the public. We applaud the proposed rule's alternative inpatient new technology add-on payment pathway for transformative new devices. This recognition by Medicare for the use of new devices can significantly improve patient outcomes and represents a much-needed change in the program's payment methodologies. We also commend CMS for its willingness to explore ways to provide more clarity and predictability to its substantial clinical improvement (SCI) criterion. As CMS contemplates such policy changes, we believe the highest priority should be to avoid impeding Medicare beneficiary access to new medical innovations and recommend maximum flexibility in the SCI standard given the continuous evolution of medical technologies and the need for any CMS criterion to apply to a broad range of devices.

Innovation in the treatment of cancer has led to transformative, lifesaving therapeutic options for patients whose care needs were previously unmet by contemporary treatments. Chimeric Antigen Receptor (CAR) T-cell therapies represent a marked advancement in the field of cancer care and have proven to be lifesaving in the treatment of patients with certain types of refractory or relapsed cancers. Medical centers, including both Prospective Payment System (PPS) Hospitals and PPS-exempt cancer hospitals, have been providing these innovative therapies which hold promising outcomes for patients that have few effective therapeutic options. While we are encouraged that the proposed rule continues the new technology add-on payments through FY 2020 for the two CAR T-cell therapies approved by the Food and Drug Administration (FDA), medical centers continue to face significant challenges related to reimbursement. It is critical that CMS develops appropriate reimbursement models to ensure that Medicare beneficiaries who require CAR T-cell therapy continue to have access to it, while also not negatively impacting reimbursement for or access to other valuable inpatient hospital services that may result from any budget neutral reweighting.

We applaud CMS's consideration to encourage value-based care and lower drug prices and believe the proposed rule is an important step toward addressing reimbursement challenges. However, the current reimbursement model is unsustainable for institutions providing CAR T-cell therapies. For FY 2019, CMS's payment policy for PPS hospitals leaves providers absorbing significant losses when administering CAR T-cell therapies to Medicare patients. While the new technology add-on payment offsets 50 percent of the cost of the therapy, PPS hospitals are still left to bear the remaining 50 percent of the cost – a shortfall of over $100,000 per patient. Additionally, for PPS-exempt cancer hospitals, which are ineligible for new technology add-on payments, the cap imposed by the Tax Equity Fiscal Responsibility Act of 1982 has proven inadequate to cover the actual direct costs of care for patients who receive CAR T-cell therapies. If medical centers continue to absorb substantial financial losses on a per-patient basis to treat Medicare beneficiaries with CAR T-cell therapies, the ability to provide access to this lifesaving treatment is at risk. We respectfully request CMS provide medical centers that deliver CAR T-cell therapies with an alternative reimbursement model that adequately reimburses both PPS and PPS-exempt cancer hospitals for product acquisition and clinical care costs so they may continue to deliver innovative, lifesaving cancer therapies.

HLC appreciates this opportunity to provide comments on this proposed rule. Please contact Tina Grande at 202-449-3433 or tgrande@hlc.org if there are any comments or questions about this letter.

Sincerely,

Mary R. Grealy
President