June 24, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: 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

Submitted electronically

Dear Administrator Verma,

Biocom appreciates the opportunity to offer comments on the Center for Medicare and Medicaid Services proposed rule 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 ("the Proposed Rule").

Biocom is the largest, most experienced leader and advocate for California's life science sector, which includes biotechnology, pharmaceutical, medical device, genomics and diagnostics companies of all sizes, as well as research universities and institutes, clinical research organizations, investors and service providers. With more than 1,200 members dedicated to improving health and quality of life, Biocom drives public policy initiatives to positively influence the state's life science community in the research, development, and delivery of innovative products. California's life sciences industry generates nearly $346 billion in annual economic output, boosts the state's total gross product by $195.8 billion, supports almost 1.3 million jobs, and increases labor income by more than $104 billion per year[1]. Of the 12,000

[1] *Biocom 2019 Economic Impact Report Databook*

life science establishments in California, 18 percent (over 2,000) manufacture medical devices and diagnostics equipment.

Proposed Updates to the New Technology Add-on Payment (NTAP) System

Biocom commends CMS for proposing changes that would improve beneficiaries' access to life-saving technologies by encouraging innovation, allowing flexibility, and reducing unnecessary burden. The proposed rule reflects Biocom's priorities to ensure hospitals and patients have access to breakthrough innovations and care, and further incentivize transformational technologies.

Under the proposed ruled, CMS would increase the maximum add-on payment for new technology, including CAR-T cell therapy, from 50 percent to the lesser of: a) 65 percent of the costs of the new medical service or technology; or b) 65 percent of the amount by which the costs of the case exceed the standard diagnosis-related group (DRG) payment, beginning in fiscal year 2020. Additionally, CMS has proposed an alternative NTAP pathway for devices that have received a breakthrough designation from the Food and Drug Administration (FDA). CMS would consider such a device "new" and "not substantially similar" to an existing technology for the purposes of the NTAP. Under this proposal, the medical device would only need to meet the cost criterion to receive the add-on payment.

It is critical that CMS' reimbursement structures keep pace with new treatments and technologies to ensure both sufficient provider reimbursement and adequate patient access to novel therapies. Biocom thanks CMS for acknowledging feedback from stakeholders that the existing NTAP rate does not adequately reflect the cost of some therapies such as chimeric antigen receptor (CAR)-T cell therapy. Biocom believes that an increase to the payment rate is an important first step toward achieving a payment structure that covers transformative therapies for patients but the proposed maximum add-on payment of 65 percent is not sufficient to cover the cost of CAR-T therapies. Biocom recommends increasing the maximum NTAP to 80 percent.

Biocom is very supportive of the progress made toward CMS' reimbursement of breakthrough devices. We believe that the proposed rule is a move in the right direction, but unfortunately, it is limited to breakthrough devices for use in the inpatient and outpatient hospital environments. Many breakthrough devices address the treatment of irreversibly debilitating diseases and conditions in unique ways and therefore do not fit with traditional medical device reimbursement models. For example, many breakthrough devices are considered Software as a Medical Device (SaMD) or are intended for use in settings such as the home or long-term care facilities. In order to make breakthrough devices truly accessible to patients, we believe that further action is required to provide a clear pathway to reimbursement for all breakthrough devices, even those that do not currently fit into existing CMS benefit categories.

Biocom believes that the alternative NTAP pathway for devices reduces redundancy and improves government efficiency. Biocom encourages CMS to consider using this strategy not only for devices but for drugs and consider criteria such as: (a) results in a reduction of the length of a hospital stay; (b) improving patient quality of life; (c) creating long-term clinical efficiencies in treatment; (d) addressing patient-centered objectives as defined by the Secretary; or (e) meeting such other criteria as the Secretary may specify.

CAR-T Cell Therapy Reimbursement

CAR-T therapies represent a paradigm shift in the approach for cancer treatment. Over the past years, there has been significant progress in this space with the approval of two novel CAR-T treatments. Now our focus is toward ensuring that patients can access these life-saving treatments. CAR-T therapies are not easily compatible with traditional CMS payment models, which causes barriers to patient access. Biocom commends CMS for the discussion on ensuring adequate payment in the long-term for CAR-T therapies and will continue to work with the agency to shape a reimbursement environment that fosters optimal patient access.

In the proposed rule, CMS referenced a request to create a new Medicare Severity Diagnosis Related Groups (MS-DRG) for CAR-T cell therapies, which includes recommendations to use a cost-to-charge ratio (CCR) of 1.0 for the charges associated with CAR-T cell therapies and to develop a unique revenue code. Biocom appreciates the agency acknowledging that the existing structure does not adequately cover the cost for CAR-T therapies and supports opportunities to help CMS gain the best data insights for rate setting for a new MS-DRG.

PPS-exempt Cancer Hospitals

Solutions for CAR T-cell therapy proposed under IPPS have not applied to Dedicated Cancer Centers. Dedicated Cancer Centers are PPS-exempt hospitals that are structured in service to cancer research and care, and, as such, are subject to cancer hospital payment under the Tax Equity and Fiscal Responsibility Act (TEFRA). Cancer hospital payment under TEFRA was designed to address reimbursement challenges under a Medicare prospective payment system (PPS) based on averages which cannot appropriately configure payment for providers who only treat cancer patients and are at the forefront of care for the sickest patients. However, despite the fact that payment under TEFRA was designed to address these deficiencies, TEFRA reimbursement has eroded over time due to reimbursement levels that are based on cancer care treatment costs over 12–15 years old that do not account for dramatic changes in treatment modalities and related drugs and technology. Therefore, we appreciate the agency's request for comments this year on how to improve the process for reimbursement under TEFRA in light of the current environment and recommend that:

- CMS implement a prompt and automatic adjustment for cancer hospitals providing CAR T-cell therapy in recognition that it is a necessary cost directly related to patient care under TEFRA;
- the agency should ensure and expedite processes for reimbursement under TEFRA more generally, beyond the provision of cell and gene therapies, as there are many other shifts in care that have caused reimbursement to become severely outdated since 2004–2006; and
- the agency allow hospitals to apply for rebasing in a manner that more accurately reflects the current state of cancer care that now includes high-cost medications, such as CAR T-cell treatments.

Biocom is dedicated to improving patient access to innovative therapies and thanks you again for the opportunity to provide these comments. We look forward to a continued dialogue with CMS. If you

have any questions about these comments, please contact Brittany Blocker, Manager of Regulatory Affairs at bblocker@biocom.org.

Sincerely,

Joe Panetta
President and CEO
Biocom