September 27, 2019

Administrator Seema Verma
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, District of Columbia 20201

RE: Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations (CMS-1715-P)

Submitted electronically

Dear Administrator Verma,

Biocom appreciates the opportunity to offer comments on the Centers for Medicare and Medicaid Services' (CMS) CY2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies ("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].

[1] *Biocom 2019 Economic Impact Report Databook*

Summary of Recommendations

- Biocom strongly encourages CMS to issue sub-regulatory guidance on the use of remote physiologic monitoring (RPM) in Medicare to answer stakeholders' questions on how to properly use and bill the new RPM codes, and what business models are required by Medicare.
- Biocom supports CMS' proposed activation and payment for CPT code 994X0, however, we disagree with CMS' proposed rationale to value (RVU) of .50. Biocom urges CMS to change the proposed RVU to the RVS Update Committee (RUC)-recommended RVU of .61 for CPT code 994X0.
- Biocom strongly supports CMS' proposal to revert to the previous evaluation and management (E/M) coding structure, including retaining the 5 separate levels of coding for established patients and 4 levels for new patients.
- Biocom recommends CMS to modify the definitions outlining the reporting requirements for the Open Payments Program to ensure accuracy and consistency for healthcare providers.

Remote Physiologic Monitoring (RPM) Services

Health care is at the cusp of a sector-wide transformation due in large part to the development of connected health technologies that have enhanced the efficiency of health care delivery, enabled better health care resource utilization, and improved patient outcomes across a wide spectrum of diseases. Wearable devices that monitor a wide range of health data such as blood pressure, glucose levels, blood oxygen levels, heart rate, and electrocardiograms, and devices that deliver medicines directly to patients often reduce the need to physically visit a doctor's office or hospital, allowing patients to receive and transmit health care information instantly in a home setting and be active participants in their care. They can also alert a provider immediately in case of a medical crisis, even one the patient him or herself may not realize is happening. These technologies, in turn, contain costs, reduces the frequency of visits to medical institutions, and ensures the continuity of care.

CMS has taken important strategic steps to expand coverage of innovative virtual care services that should be available to patients, physicians, and qualified health care providers. In its CY 2019 Physician Fee Schedule (PFS), CMS finalized reimbursement for new CPT Codes 99453, 99454, and 99457 for remote physiologic monitoring (RPM) services. These new codes focus on the collection of patient-generated health data remotely, through devices and mobile health platforms that connect to the primary care provider or care team. The first two codes are reimbursement for the practice expense associated with furnishing RPM services. CPT Code 99457 reimburses 20 minutes of clinical staff, physician, or qualified health care provider time aggregated during a calendar month in monitoring, evaluating, and acting on patient-generated health data obtained through RPM. CMS also committed to issuing guidance to help inform practitioners and stakeholders on the types of technology that meet the requirements for RPM. Biocom strongly encourages CMS to issue sub-regulatory guidance on the use of RPM in Medicare to answer stakeholders' questions on how to properly use and bill the new RPM codes, and what business models are required by Medicare.

In the proposed CY 2020 PFS, CMS alters code 99457 to refer to the initial 20 minutes for RPM services and introduces a new add-on code, 994X0, to cover subsequent 20-minute intervals spent on RPM services. Biocom supports CMS' proposed activation and payment for CPT code 994X0, however, we disagree with CMS' proposed rationale to value (RVU) of .50. We believe the subsequent 20

minutes of RPM review is as valuable as the initial 20 minutes of RPM review. Patients that require an additional 20 minutes of RPM review have a need for a deeper analysis of their RPM data. An additional 20 minutes of RPM review also requires an analysis of more data points which would provide patients with greater insight into their health trends. Biocom urges CMS to change the proposed RVU to the RUC-recommended RVU of .61 for CPT code 994X0.

When the new RPM codes were established, the rule stated RPM could not be delivered incident to service, reasoning that CPT code 99457 describes professional time and therefore cannot be furnished by auxiliary personnel incident to a practitioner's professional services. An incident to service is defined as one that is performed under the supervision of a physician and billed to Medicare in the name of the physician. In April, CMS issued a technical correction allowing the incident to billing of RPM services by auxiliary personnel under direct supervision. Under the CY 2020 PFS proposed rule, RPM services reported with CPT codes 99457 and 994X0 may be furnished under general supervision rather than the currently required direct supervision. Biocom supports the proposed clarification that 99457 and 994X0 may be furnished under general supervision. This will significantly expand the potential operations and business models associated with RPM services, thus allowing more patients to enjoy the quality-improving benefits of RPM.

Evaluation and Management (E/M) Services Payment

In the CY 2019 PFS final rule, CMS finalized changes that would implement blended payment rates for office and outpatient visits coded as levels 2 through 4 starting on January 1, 2021. In the 2020 rule, CMS proposes to modify the policies that were finalized last year. CMS is aligning much of its forthcoming E/M policy with approaches from the American Medical Association's (AMA) CPT Editorial Panel, which was approved earlier this year. This would revise the E/M documentation guidelines by allowing providers to select a service based on medical decision-making or time. CMS proposes to retain 5 levels of coding for established patients and 4 levels for new patients. CMS also proposes to adopt the code definitions and other aspects of the CPT recommendations.

Biocom strongly supports CMS's proposal to revert to the previous E/M coding structure, including retaining the 5 separate levels of coding for established patients and 4 levels for new patients. Biocom is concerned that the blended payment rates may inappropriately incentivize multiple, shorter patient visits and harm practitioners who are treating complex patients who may more often bill level 4 and 5 E/M services. Providers may have to reduce the time they spend with patients if the additional time needed to fully treat more complex patients no longer earns payment commensurate with that time. The proposed changes more closely align reimbursement for E/M services with the time and expertise they require and will help ensure patients continue to receive these vital healthcare services.

Modification to Open Payments Reporting Requirements

The SUPPORT Act expanded the Open Payments reporting requirements to include payments and transfers of value to mid-level practitioners. Initially, pharmaceutical and device manufacturers were required to report certain payments and transfers of value made to physicians and teaching hospitals.

CMS is proposing to expand the definition of "covered recipient" which is currently defined as physicians and teaching hospitals. The SUPPORT Act amended the definition of "covered recipient"

under section 1128G(e)(6) of the Act with respect to information required to be submitted on or after January 1, 2022, to include physician assistants (PA), nurse practitioners (NP), clinical nurse specialists (CNS), certified registered nurse anesthetists (CRNA), and certified nurse midwives (CNM), in addition to the previously listed covered recipients of physicians and teaching hospitals. CMS proposes to include the categories specified in the SUPPORT Act.

Biocom has concerns about the potential confusion and inconsistency in the definitions being spelled out in the regulations for healthcare providers. For instance, some definitions reference the "performance" of a certain service as qualifying for reporting, while others only refer to certification or achievement of defined requirements. For example, the existing definition of a physician under the open payments system references the performance of certain functions or actions, but the Agency's FAQ document refers to current licensure as the threshold for reporting under the system. Biocom recommends CMS to modify the definitions in its regulations to ensure accuracy and consistency in the Open Payments program.

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