October 5, 2020

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 2021 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; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy (CMS-1734-P)

Submitted electronically

Dear Administrator Verma,

Biocom appreciates the opportunity to offer comments on the Centers for Medicare and Medicaid Services' (CMS) CY 2021 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies[1] ("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 1,300 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

[1] 85 Fed. Reg. 50074 (August 17, 2020).

$372 billion in annual economic output, boosts the state's total gross product by $212 billion, supports over 1.4 million jobs, and increases labor income by more than $115 billion per year[2].

Summary of Comments

- Biocom supports CMS's proposal to continue audio/video telehealth services for the duration of the PHE, and encourage the Agency to expand the list of Medicare telehealth services permanently**.**
- Biocom opposes CMS' proposed clarification of "interactive communication" and calls on the Agency to align its interpretation of an "interactive communication" for purposes of CPT codes 99457 and 99458 to support a healthcare professional's time in a calendar month providing RPM.
- Biocom strongly supports CMS' proposal to adopt the E/M coding structure as revised by the AMA CPT Editorial Panel and accept the RUC-recommended values, including retaining the 5 separate levels of coding for established patients and 4 levels for new patients.
- Biocom urges CMS to add CPT code 96040 to the list of telehealth services and recognize genetic counselors as providers.
- Biocom applauds CMS for encouraging nonphysician practitioners, such as nurse practitioners, physician assistants, and clinical nurse specialists, and midwives, to order diagnostic tests. We are pleased that CMS has enabled pharmacists to order testing for COVID-19 during the current public health emergency and recommend extending this scope of practice further to other diagnostic tests, including pharmacogenomics tests so that they may further assist with medication management consultations.

Telehealth Expansion

Since the public health emergency (PHE) was declared earlier this year, telehealth has played a central role in the response to the COVID-19 pandemic. Implementation of telehealth has expanded rapidly during the crisis, as policymakers, insurers, and health systems have looked for ways to deliver care to patients in their homes to limit the transmission of the novel coronavirus.

The Administration issued interim final rules in March and May of 2020 to support the use of telehealth as a safe alternative to in-person services during the PHE. The policies included waivers to increase flexibility and reduce regulatory burden to help providers meet the demands of the pandemic such as expanding the list of services to be covered via telehealth, eliminating frequency limitations and other requirements associated with particular services furnished via telehealth, and clarifying payment rules that applied to other services. Most of the temporary flexibilities will sunset upon the expiration of the PHE.

The proposed rule maintains the expanded list of Medicare-covered telehealth services and remote service flexibilities until the end of the calendar year in which the COVID-19 PHE ends, or in some cases beyond. CMS proposes to add nine Healthcare Common Procedure Coding System (HCPCS) codes to the list on a Category 1 basis, meaning they will be permanent. The nine HCPCS codes are

[2] Biocom 2020 Economic Impact Report Databook. https://www.biocom.org/eir/

related to visit complexity, prolonged visits, group psychotherapy, neurobehavioral status exam, cognitive impairment care planning, rest home/custodial care visits, and home visits. Additionally, CMS proposes to add 13 HCPCS codes to the list of Category 3 services, which will be a temporary category to describe services added to the Medicare telehealth list during the public health emergency (PHE) for the COVID-19 pandemic. These services will only remain on the telehealth list through the calendar year in which the PHE ends.

Biocom supports CMS's proposal to continue audio/video telehealth services for the duration of the PHE, and encourage the Agency to expand the list of Medicare telehealth services permanently**.** The expansion of telehealth services helps facilitate public health mitigation strategies by increasing social distancing and reduces the strain on healthcare systems by minimizing the surge of patient demand on facilities. Telehealth services also help to maintain continuity of care and increase participation for those who are medically or socially vulnerable or who do not have ready access to providers[3].

Remote Physiologic Monitoring (RPM) Services

In the proposed rule, CMS clarifies payment policies related to RPM services described by CPT codes 99453, 99454, 99091, 99457, and 99458.

For CPT codes 99457 and 99458, CMS clarifies an "interactive communication" as a conversation that occurs in real-time and includes synchronous, two-way interactions that can be enhanced with video or other kinds of data as described by HCPCS code G2012. This interpretation of "interactive communication" contrasts the policies outlined in the CY2020 Physician Fee Schedule, which states:

> RPM services could be furnished under general supervision. Because care management services include establishing, implementing, revising, or monitoring treatment plans, as well as providing support services, and because RPM services include establishing, implementing, revising, and monitoring a specific treatment plan for a patient related to one or more chronic conditions that are monitored remotely, we believe that CPT codes 99457 and 99458 should be included as designated care management services.[4]

The intent of the codes was to assign a total of 20 minutes as the time needed for the entire service, including monitoring. The proposed change that "interactive communication" must include a total of at least 20 minutes of interactive time spent in "direct, real-time interactive communication with the patient" would not allow time for monitoring.

Biocom opposes CMS' proposed clarification and calls on the Agency to align its interpretation of an "interactive communication" for purposes of CPT codes 99457 and 99458 to support a healthcare professional's time in a calendar month providing RPM. These services are not Medicare telehealth codes that must be synchronous, live communications; and they are not virtual check-ins. CMS' proposed interpretations and equivalencies with respect to "interactive communication" run counter to stakeholder experiences and expectations, as well as the nature of RPM technology.

[3] Centers for Disease Control. (2020, June 10). Using Telehealth to Expand Access to Essential Health Services during the COVID-19 Pandemic. Retrieved 2020, from https://www.cdc.gov/coronavirus/2019-ncov/hcp/telehealth.html
[4] 84 Fed. Reg. 62568 (November 15, 2019)

Evaluation and Management (E/M) Updates

CMS is proposing to align its evaluation and management (E/M) visit coding and documentation policies with changes laid out by the American Medical Association's (AMA) CPT Editorial Panel for office/outpatient E/M visits, beginning January 1, 2021[5]. The agency proposes to revalue the following code sets that include, rely upon or are analogous to office/outpatient E/M visits commensurate with the increases in values finalized for office/outpatient E/M visits for 2021: End-Stage Renal Disease (ESRD) Monthly Capitation Payment (MCP) Services, Transitional Care Management (TCM) Services, Maternity Services, Cognitive Impairment Assessment and Care Planning, Initial Preventive Physical Examination (IPPE) and Initial and Subsequent Annual Wellness (AWV) Visits, Emergency Department Visits, Therapy Evaluations, and Psychiatric Diagnostic Evaluations and Psychotherapy Services.

Biocom strongly supports CMS' proposal to adopt the E/M coding structure as revised by the AMA CPT Editorial Panel and accept the RUC-recommended values, including retaining the 5 separate levels of coding for established patients and 4 levels for new patients. As noted in previous comments, we are concerned that eliminating different levels of payment for Levels 2 through 4 E/M services may inappropriately incentivize multiple, shorter patient visits and harm practitioners who are treating complex patients who may more often bill level 4 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. Therefore, we believe 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.

Genetic Counseling Services

Under the proposed rule, CMS omitted CPT code 96040 (genetic counseling services) from the Medicare telehealth services list. Genetic counselors are not among the practitioners who can bill Medicare directly for their professional services, and they are also not practitioners who can furnish telehealth services as specified in section 1834(m)(4)(E) of the Social Security Act.

Biocom urges CMS to add CPT code 96040 to the list of telehealth services. This is particularly needed during the PHE given the number of patients accessing genetic counseling and the number of genetic counselors practicing remotely via telemedicine. To the extent possible, we urge you to implement a policy that recognizes genetic counselors as providers and covers their telehealth services. Genetic counselors are vital in ensuring that complex genetic information is delivered accurately and in a manner that allows patients to understand the meaning of their genetic test results. There is growing evidence that genetic counselors significantly increase the likelihood that a patient and their healthcare provider will order the most appropriate test for their situation, which would not only improve the quality of care but also potentially decrease health care spending[6].

[5] American Medical Association. (2019, November 1). CPT® Evaluation and Management. Retrieved from https://www.ama-assn.org/practice-management/cpt/cpt-evaluation-and-management

[6] Kotzer KE, Riley JD, Conta JH, et al. Genetic testing utilization and the role of the laboratory genetic counselor. Clin Chim Acta 2014; 427:193-5.

One study by a reference laboratory found that 26 percent of all requests for complex genetic tests assessing germline mutations were changed following review by a genetic counselor[7]. The authors approximated that this resulted in a reduction in charges to the referring institutions of $48,000 per month. While another non-genetic provider may be billing an evaluation and management code, a study found that non-genetic providers have three times the error rate in ordering tests than genetics-providers, and with 30 percent of genetic tests ordered incorrectly, the authors determined there is an opportunity for an average of $2,200 in cost savings per case[8].

Non-physician practitioners (NPPs)

Biocom applauds CMS for encouraging non-physician practitioners, such as nurse practitioners, physician assistants, clinical nurse specialists, and midwives, to order diagnostic tests. We also are pleased that CMS has enabled pharmacists to order testing for COVID-19 during the current public health emergency and recommend extending this scope of practice further to other diagnostic tests, including pharmacogenomics tests so that they may further assist with medication management consultations. By enabling pharmacists to order laboratory tests, collect specimens, and interpret results, access to this critical healthcare service can be improved in underserved communities and rural areas where healthcare infrastructure is inadequate, but retail pharmacies exist.

Biocom is dedicated to improving patient access to innovative therapies and thank 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 Laure Fabrega, Director of Federal Policy and Government Affairs at lfabrega@biocom.org.

Sincerely,

Joe Panetta
President and CEO
Biocom

[7] Miller CE, Krautscheid P, Baldwin EE, et al. Genetic counselor review of genetic test orders in a reference laboratory reduces unnecessary testing. Am J Med Genetic A 2014; 164(5):1094-101.
[8] Haidle JL, Sternen DL, Dickerson JA, et al. Genetic counselors save costs across the genetic testing spectrum. Am J Manag Care. 2017;23(10 Spec No.):SP428-SP430.