PERSONALIZED MEDICINE COALITION

June 10, 2021

Michael Chernew, Ph.D.
Chairman
Medicare Payment Advisory Commission
425 I Street NW, Suite 701
Washington, DC 20001

Sent electronically

Re: Medicare Payment Advisory Commission (MedPAC)'s *March 2021 Report to the Congress: Medicare Payment Policy;* Chapter 14: Telehealth in Medicare After the Coronavirus Public Health Emergency

Dear Dr. Chernew and members of the commission:

The Medicare Payment Advisory Commission (MedPAC) recently released a report to Congress supporting continued flexibilities for Medicare coverage of telehealth services after the coronavirus public health emergency in order to collect more information on related access, quality, and cost considerations and inform any permanent changes.[i] The Personalized Medicine Coalition (PMC), a multi-stakeholder group comprising more than 220 institutions across the health care spectrum, appreciates the commission's support for the expansion of telehealth services after the pandemic. However, in response to fraud concerns, the report proposes a requirement for patients to meet in-person before their provider orders a "high-cost clinical lab test." This requirement would deem certain tests, based simply on their high cost, not orderable in conjunction with a telehealth encounter and would apply to many of the diagnostic and genetic tests underpinning personalized medicine, which can make health care more effective and efficient by guiding patients to the right treatments, sooner. We are concerned that implementing the proposed in-person requirement based simply on a test's cost would create an additional access barrier for patients requiring medically necessary diagnostic and genetic tests and, thus, limit the ability of telehealth services to provide timely patient access to care. Instead of shifting the burden of fraud prevention onto patients, we urge MedPAC to prioritize leveraging and investing in existing pathways for detecting and preventing Medicare fraud, waste and abuse.

PMC, which represents innovators, scientists, patients, providers, and payers, promotes the understanding and adoption of personalized medicine concepts, services, and products for the benefit of patients and the health care system.

We define personalized medicine as an evolving field in which physicians use diagnostic tests to determine which medical treatments will work best for each patient or use medical interventions to alter

molecular mechanisms that impact health. By combining data from diagnostic tests with an individual's medical history, circumstances and values, health care providers can develop targeted treatment and prevention plans with their patients.

PMC's members are leading the way in developing and delivering personalized medicine for patients. Our comments on MedPAC's recommendations to Congress are intended to highlight how the expansion of telehealth services after the coronavirus public health emergency can better support this growing field, which requires access to genetic and other diagnostic tests.

Statement of Neutrality

PMC's members may present their own responses to MedPAC and may actively advocate for those positions. PMC's comments are designed to provide feedback so that the general concept of personalized medicine can advance, and are not intended to impact adversely the ability of individual PMC members, alone or in combination, to pursue separate comments with respect to MedPAC's recommendations to Congress on coverage policies for telehealth in Medicare after the coronavirus public health emergency.

Requiring in-person visits to order certain tests would prematurely limit the ability of telehealth to improve Medicare beneficiaries' access to personalized medicine.

Personalized medicine is helping to shift the patient and provider experiences away from trial-and-error treatments in favor of more streamlined approaches to disease prevention and treatment, which will lead to improved patient outcomes, a reduction in unnecessary treatment costs, and better patient and provider satisfaction.[ii] Diagnostic tests, including the laboratory and genetic tests referred to in MedPAC's report, are the foundation for personalized medicine's approach to health care in cancers as well as some common chronic, mental health, rare and infectious diseases. For example, genetic tests used to assist in medication selection for patients with depression have demonstrated improved patient outcomes[iii] and reduced costs.[iv] Despite the consensus that personalized medicine approaches have significant value, their implementation – and consequently patient access – across the United States is highly variable.[v]

Telehealth can improve patients' access to personalized medicine by making it easier for a patient to connect with a health care provider, including providers a patient would not normally have access to at their current health care institution, to discuss appropriate treatment and prevention options, which may involve diagnostic testing. Telehealth promises quicker, timelier, and broader access to personalized medicine, which may be especially helpful for individuals who have to travel long distances to a provider or may face logistical or other challenges to accessing care in-person, such as the stigma often associated with seeking mental and behavioral health care.

In order to fully benefit from personalized medicine, however, patients must have access to the appropriate diagnostic tests from the beginning of their diagnosis and treatment journey. Even though MedPAC's proposal allows a provider to order a test if the provider has held an in-person visit with the Medicare beneficiary on the date they order a "high-cost lab test" for that beneficiary or within six

months before such date, this look-back period fails to consider that the most appropriate time for a provider to order a test for a patient may be during their first consultation. For example, in cancer, which disproportionately impacts the Medicare beneficiary population,[vi] after receiving a new diagnosis, a patient may want to get a second opinion or access health care services, such as biomarker testing, to identify targetable characteristics in the tumor. These services may not be available through the patient's current health care institution. Furthermore, in behavioral health, which has seen a dramatic increase in prevalence among Medicare beneficiaries given the social isolation of the pandemic, telehealth encounters have been instrumental in creating access to these services.

Patients already face many challenges in accessing personalized medicine and the appropriate testing services, ranging from coverage and reimbursement policies and socioeconomic determinants of health, to providers' varying levels of expertise with genomics and with navigating related testing options for patients.[vii] For patients with rare diseases, for example, it can take over a decade and visits with more than 16 specialists to obtain a correct diagnosis.[viii] Imposing an in-person requirement for ordering certain tests, based solely on the costs of the tests, would prematurely defeat the flexibilities created by telehealth that may actually help patients mitigate some of these challenges.

Instead of shifting the burden of fraud prevention onto patients before the benefits of telehealth are fully understood, including benefits to individuals from underserved communities, CMS should leverage and invest in its existing programs to detect and prevent fraud.

Protecting the Medicare program and its beneficiaries from unnecessary spending and potential fraud is important, but not before promoting Medicare beneficiaries' access to high-quality, appropriate care. Adding the in-person requirement now would create a new barrier for patients to access tests critical to personalized medicine and make it more difficult to understand the full extent to which telehealth may improve patient access to testing services. Introducing restrictions before the benefits of expanded access to telehealth services on patient care are fully understood could have long-term consequences for patients and be harder to undo if codified in statute prematurely.

MedPAC's recommendation is based on the hypothesis that telehealth arrangements would make it "easier to carry out fraud on a large scale" because "clinicians can speak with many beneficiaries from many parts of the country in a short amount of time, and beneficiaries do not need to see a clinician in person to receive an order for … a lab test." Higher utilization of testing services and the remote ordering of such tests via telehealth, however, does not constitute fraud on its own, nor will restricting access to certain tests based only on their costs prevent fraud.

Instead of instituting an in-person visit requirement for ordering certain tests, Medicare should leverage its existing program integrity tools to prevent fraud, waste, and abuse. Additional resources from Congress could also help Medicare bolster its efforts to distinguish between a health care provider fraudulently ordering high volumes of tests and a provider ordering legitimate tests. The cases MedPAC points to where bad actors were already caught fraudulently ordering tests show that this system works. Clinicians and patients should not be penalized for ordering legitimate personalized medicine tests.

Permitting continued ordering of medically necessary genetic and diagnostic tests via telehealth, without an in-person requirement and regardless of the test's cost, would help CMS to better understand which types of providers would benefit from using telehealth to order these tests and how telemedicine may improve patients' access to such tests. Collecting this information would be in line with MedPAC's larger goal of expanding telehealth coverage flexibilities for a limited duration after the public health emergency to gather more evidence about the impact of telehealth on access, quality, and cost considerations. This approach would also help CMS ensure that Medicare beneficiaries are able to receive high-quality, appropriate care and take full advantage of telehealth's potential benefits.

Telehealth has the potential to address disparities in access to personalized medicine by mitigating barriers for patients in rural and other difficult-to-treat health care settings, such as distance to a treating physician, and by mitigating barriers that disproportionately impact individuals from minority and low-income communities, like transportation. In order to become a tool for addressing health disparities, however, telehealth coverage and payment policies must be designed and implemented in ways that prioritize and meet the needs of individuals from disadvantaged communities. Imposing restrictions on telehealth services now, such as the in-person requirement for ordering certain tests, could reinforce disparities before we fully understand how expanded flexibilities around telehealth services could improve underserved communities' access to personalized medicine.

Conclusion

PMC appreciates MedPAC's support for improving beneficiaries' access to telehealth services after the coronavirus public health emergency. We welcome the opportunity to serve as a resource for you as you consider telehealth coverage policies related to certain tests that may impact Medicare beneficiaries' access to personalized medicine. If you have any questions about the content of this letter, please contact me at 202-499-0986 and cbens@personalizedmedicinecoalition.org or David Davenport, PMC's Manager of Public Policy, at 804-291-8572 and ddavenport@personalizedmedicinecoalition.org.

Sincerely,

Cynthia A. Bens
Senior Vice President, Public Policy

cc: Senator Ron Wyden (D-OR)
Chairman, Committee on Finance
U.S. Senate

Senator Mike Crapo (R-ID)
Ranking Member, Committee on Finance
U.S. Senate

Congressman Lloyd Doggett (D-TX-35)
Chairman, Ways and Means Health Subcommittee
U.S. House of Representatives

Congressman Devin Nunes (R-CA-22)
Ranking Member, Ways and Means Health Subcommittee
U.S. House of Representatives

[i] http://www.medpac.gov/docs/default-source/reports/mar21_medpac_report_ch14_sec.pdf?sfvrsn=0
[ii] https://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/PMC_The_Personalized_Medicine_Report_Opportunity_Challenges_and_the_Future.pdf
[iii] https://doi.org/10.1016/j.jpsychires.2019.01.003
[iv] https://doi.org/10.2217/pme-2018-0074
[v] https://doi.org/10.3390/jpm11030196
[vi] https://www.fightcancer.org/sites/default/files/2013-Medicare-Chartbook-Online-Version.pdf
[vii] https://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/PMC_Understanding_Genomic_Testing_Utilization_and_Coverage_in_the_US2.pdf
[viii] https://everylifefoundation.org/burden-study/