PERSONALIZED MEDICINE COALITION

September 11, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1784-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies, etc. (CMS-1784-P)

Dear Administrator Brooks-LaSure:

The Personalized Medicine Coalition (PMC), a multi-stakeholder group comprising more than 200 institutions from across the health care spectrum, thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to submit comments on payment policies under the *CY 2024 Physician Fee Schedule (PFS) Proposed Rule*.[i] While PMC recognizes there are numerous important payment issues addressed in the *CY 2024 PFS Proposed Rule*, our comments are limited to the impact of specific proposed policy changes to CMS' Merit-based Incentive Payment System (MIPS) on beneficiary access to personalized medicine. We support CMS' proposals for certain quality measures that promote biomarker testing in cancer care and screening under MIPS Value Pathways (MVPs). Including these measures and activities could improve beneficiaries' health care by incentivizing the delivery of personalized medicine. Furthermore, we believe that encouraging health care providers to utilize personalized medicine technologies that are already available will help advance the Biden administration's Cancer Moonshot goals to improve cancer care for patients. Our comments also highlight opportunities to advance personalized medicine in mental health and medication management.

PMC defines 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.

Personalized medicine is helping to shift the patient and provider experiences away from trial-and-error toward a more streamlined process for making clinical decisions, which will lead to improved patient outcomes, a reduction in unnecessary treatment costs, and better patient and provider satisfaction. PMC's members are leading the

way in personalized medicine and recommend that patients who may benefit from this approach undergo appropriate testing and tailored treatment as soon as possible during their clinical experiences.

By incentivizing health care providers to improve and standardize the delivery of care through payment adjustments, the MIPS program provides important opportunities to set national benchmarks for the quality of health care in the United States. Historically, there has been a lack of quality measures promoting personalized medicine.[ii] In cancer, for example, even though personalized medicine has launched a paradigm shift in testing and treatment, traditional quality measures have focused on surgery and radiation, but not appropriate biomarker testing that informs treatment selection.[iii, iv]

Personalized medicine helps target treatments to only those who will benefit, sparing expenses and side effects for those who will not. Thus, by incentivizing personalized medicine, CMS can advance its goals of achieving better health outcomes and lowering costs. As CMS transitions to MVPs, which we understand will align MIPS reporting requirements around specific clinical specialties, medical conditions, or episodes of care, we urge CMS to finalize its proposals to incorporate quality measures that would enhance patients' and the health care system's ability to benefit from this approach to care.

Statement of Neutrality

Many of PMC's members will present their own responses to the Medicare *CY 2024 PFS Proposed Rule* and will 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 the proposed rule.

Incorporating Biomarker Testing into Cancer Diagnosis and Treatment

We commend CMS for proposing to continue its MVP for "Advancing Cancer Care," whose finalization PMC previously supported in CY 2023.[v] Personalized medicines have accounted for more than a quarter of all newly approved drugs for each of the last eight years, including many in oncology.[vi] Biomarker tests that play a critical role in helping patients evaluate their treatment options are increasingly being incorporated into clinical guidelines for cancer. Timely treatment targeting biomarkers in a patient's tumor can offer better health outcomes than non-targeted drug therapy, such as chemotherapy.[vii] Thus, PMC appreciates CMS' continued prioritization of the role of diagnostics in directing patients to treatments from which they are most likely to benefit.

Even though personalized medicine approaches for testing and targeted treatment have been included in updated clinical guidelines for cancer, patient access to personalized medicine remains varied because of clinical practice gaps. One PMC study found that medically appropriate genomic profiling for advanced cancers was inconsistently utilized across the U.S. due to a broad range of administrative, educational, and technical challenges that are likely discouraging the use of genomic testing in clinical settings.[viii] Another analysis conducted by PMC showed that due to the influence of testing and treatment difficulties throughout the precision oncology pathway, diagnostic testing-informed treatment strategies benefitted only 36 percent of patients with advanced non-small cell lung cancer (aNSCLC) in a cohort of 38,068.[ix]

We support CMS' proposal to modify the "Advancing Cancer Care MVP" to include:

- ***PIMSH13: Oncology: Mutation testing for stage IV lung cancer completed prior to start of targeted therapy:*** This qualified clinical data registry (QCDR) measure would assess the use of mutation testing for all actionable biomarkers with appropriate mutation-directed therapy, in accordance with current National Comprehensive Cancer Network (NCCN) guidelines for stage IV non-small cell lung cancer (NSCLC).

PMC's previous comments on CMS' CY 2023 proposed rule supported the inclusion of a related measure in the MVP and recommended CMS update the measure to include testing for all biomarkers recommended for screening in patients with NSCLC according to guidelines published by NCCN, the American Society of Clinical Oncology (ASCO), the College of American Pathologists (CAP), and the International Association for the Study of Lung Cancer (IASLC). We understand that CMS ultimately removed the quality measure from the final MVP in its CY 2023 final rule because substantive changes to the quality measure were being considered simultaneously that were not included in the proposed rule. For CY 2024, we thank CMS for proposing to include an updated measure in the "Advancing Cancer MVP" that could facilitate broader utilization of biomarker testing for patients with aNSCLC and testing that is more consistent with actionable biomarkers currently recommended for screening.

In future years, we encourage CMS to consider opportunities to expand the applicable guidelines for PIMCSH13 beyond NCCN to include ASCO, CAP, and IASLC and to consider revising the language in PIMSH13 from "prior to start of targeted therapy" to "prior to start of first line therapy." While the use of immunotherapies with or without chemotherapy does not require testing of all actionable biomarkers upfront, the increasing number of actionable genomic targets, the scarcity of available tissue for multiple rounds of genomic testing, and the clinical outcomes associated with targeted therapies approved in the front-line setting would support fully genotyping tumors prior to initiation of first line treatment when it is clinically feasible.

Furthermore, we thank CMS for retaining the following quality measures previously finalized in the "Advancing Cancer Care MVP:"

- ***Q450: Appropriate Treatment for Patients with Stage I (T1c) – III HER2 Positive Breast Cancer*:** This MIPS quality measure could help ensure certain patients with HER2-positive breast cancer receive treatment in accordance with guidelines.

- ***Q451: RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy:*** By assessing if gene mutation testing was performed prior to therapy, this MIPS quality measure could help improve concordance with RAS (KRAS and NRAS) testing guidelines for metastatic colorectal cancer patients.

- ***Q452: Patients with Metastatic Colorectal Cancer and RAS (KRAS or NRAS) Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies:*** This MIPS quality measure could help ensure patients with metastatic colorectal cancer and a RAS (KRAS or NRAS) gene mutation are not treated inappropriately with anti-EGFR monoclonal antibodies.

Incentivizing physicians' appropriate utilization of biomarker testing in cancer care through multiple measures in the MVP could help to close implementation gaps impacting cancer patients' access to personalized medicine. **We encourage CMS to continue to consider and incorporate future quality measures advancing biomarker testing in cancer care.**

Biomarker testing helps patients identify characteristics, targetable findings, or other results originating from their malignant tissue or blood. On the other hand, genetic testing for an inherited mutation (also known as germline testing) can help patients understand whether there are genetic factors contributing to their conditions, inform treatment selection, identify opportunities to prevent and manage risk for developing other types of cancer, and highlight the need for testing of other family members' cancer risk. Thus, germline testing in patients with cancer provides important opportunities to improve their health care. It also provides opportunities to better manage their cancer risks, as well as those of their family members. **To ensure cancer patients are able to benefit from both kinds of testing, we encourage CMS to also develop and incorporate into the "Advancing Cancer Care MVP" future quality measures advancing genetic testing for an inherited mutation, or germline testing, in cancer patients.** Facilitating broader implementation of genetic testing for an inherited mutation aligns with the Biden administration's goals under the Cancer Moonshot to prevent cancer and to improve the experiences of cancer patients and their families.

In addition, we support CMS' proposal elsewhere in the *PFS* proposed rule to provide new billing codes and establish a reimbursement pathway for Principal Illness Navigation (PIN) services, which could help patients navigate a complex health system to access personalized medicine approaches in cancer care. As the proposed rule notes, patient navigation is integral to patient care and can be particularly important for patients who experience barriers to care due to socioeconomic factors. Providing patients with PIN services, in combination with coordinated care, may not only improve patient access to clinically recommended care and health outcomes but also mitigate the emotional and mental burden facing patients with a new cancer diagnosis.

CMS' proposal to establish reimbursable PIN services appears to be broad enough to include testing services for cancer that occur before diagnosis and treatment. However, patient navigation is commonly referred to as a service that accompanies treatment plans. For example, although the CMS Innovation Center's Enhancing Oncology Model (EOM) incorporates patient navigation, EOM episodes of care begin when a patient starts chemotherapy or other anti-cancer therapy. Thus, EOM-required services, including patient navigation, do not extend to any care that takes place prior to starting treatment, such as biomarker testing. **To ensure PIN services help patients navigate the health care system and access clinically appropriate testing services at the beginning of their cancer care journeys, thereby guiding them toward the most effective treatments as soon as possible, we urge CMS to explicitly clarify that PIN services may begin when a health care provider suspects a patient may have cancer.**

<u>Promoting Earlier Detection of Cancer Through Blood-Based Biomarker Tests</u>

PMC appreciates CMS' continued focus on screening for various cancers under the proposed "Value in Primary Care MVP," which we understand would consolidate the previously finalized "Promoting Wellness MVP" and the "Optimizing Chronic Disease Management MVP" to provide a more comprehensive assessment for primary and preventive care. As part of this consolidation, CMS proposes

a new composite measure for "Preventive Care and Wellness" combining seven measures for preventive screenings and wellness services.

Molecular screening tests, including blood-based cancer tests, are emerging as an additional way to screen for cancer. While PMC would like to see blood-based cancer screening tests included for more cancer types, we recognize that these tests are currently only covered for colorectal cancer (CRC) screenings under National Coverage Determination (NCD) 210.3.[x]

Despite strides made to increase survival rates, colorectal cancer remains the second leading cause of cancer death in the United States. Nearly half of CRC cases and deaths would be preventable with improved screening.[xi] In addition, there are significant racial inequities in CRC screening rates and outcomes, resulting in higher rates of mortality among Black Americans.[xii] For CRC, blood-based biomarker tests can provide additional options for patients who otherwise may not be screened with available screening tools such as colonoscopy, sigmoidoscopy, and fecal occult blood testing.

PMC previously supported inclusion of "Q113: colorectal cancer screening" under the "Promoting Wellness MVP" in CMS' CY 2023 proposed rule. This quality measure would help ensure patients have received appropriate screening for CRC. For CY 2024, CMS is proposing to remove this measure but capture its quality actions in a new composite measure for "preventive care and wellness." **As CMS moves forward with the consolidated "Value in Primary Care MVP," we support CMS' proposal to capture "Q113: Colorectal cancer screening" in the new composite measure to help ensure patients have received appropriate screening for CRC. If, however, CMS does not finalize the new composite measure with the consolidated MVP, we encourage CMS to retain "Q113: Colorectal cancer screening" as a stand-alone measure.**

Improving Medication Management for Mental Health Conditions and Other Diseases Through Pharmacogenomics

Medication management can optimize care for patients across diseases and conditions and can also help in the management of comorbidities. Many of the previously finalized MVPs in CMS' *PFS* proposed rule include the improvement activity "IA_PM_16: Medication Management," which incentivizes managing medications to maximize efficiency, effectiveness, and safety. Activities related to this improvement activity include the reconciliation and coordination of medications; providing medication management across transitions of care settings and eligible clinicians or groups; integrating a pharmacist into the care team; and conducting periodic, structured medication reviews.[xiii]

In addition, CMS is proposing a new "Quality Care in Mental Health and Substance Use Disorders MVP" focused on promoting prevention of and quality care in mental and behavioral health. To help ensure meaningful and comprehensive clinical care is provided to patients, CMS proposes to include "Q009: Anti-Depressant Medication Management." This MIPS quality measure assesses adult patients diagnosed with major depression treated with antidepressant medication and who remained on an antidepressant medication treatment.[xiv]

Certain personalized medicine tests, called pharmacogenomic (PGx) tests, may be able to predict which medications at which doses will be most effective and least likely to lead to adverse events for individuals, based on their genetic makeup and known drug-gene interactions.[xv] This information can help guide the application of medicines for many health conditions, including in mental health. For

example, one case study in retirees over age 65 found that leveraging pharmacists' expertise to recommend medication changes based on patients' genetic information and known PGx implications resulted in a 7 percent decrease in emergency department visits and a 15 percent decrease in inpatient hospitalizations. This shift in health care resource utilization away from acute care services and toward more cost-effective primary care options led to a reduction of about $7,000 per patient in direct medical charges. For 5,288 patients over 32 months, this yielded an economic savings of $37 million.[xvi]

In mental health, numerous medications approved by FDA to treat mental health concerns are impacted by genetics. A growing body of evidence supports the value of PGx-based testing to inform the treatment of mental health disorders. As a briefing recently organized by PMC in collaboration with the Congressional Personalized Medicine Caucus demonstrated, mental health applications for PGx have garnered the attention of lawmakers as Congress grapples with how to address the ongoing mental health crisis in the United States.[xvii] Supporting evidence includes the *PRIME Care* study, which was conducted by the U.S. Department of Veterans Affairs and utilized PGx testing in the treatment of veterans with major depressive disorder (MDD). This study found that after providing PGx testing results to health care providers, patients showed a meaningful decrease in symptoms.[xviii] Among 1,944 patients who were randomized between treatment guided by PGx testing versus usual care, the estimated risks for receiving an antidepressant with none, moderate, and substantial drug-gene interactions for the pharmacogenomic-guided group were 59.3, 30.0, and 10.7 percent compared with 25.7, 54.6, and 19.7 percent in the usual care group. Notably, PGx testing helped veterans with MDD reach quicker symptom remission, with remission rates over the first 24 weeks being higher among patients whose care was guided by PGx testing than those who received usual care.

We encourage CMS to consider opportunities to promote more comprehensive medication management and incentivize the clinical adoption of PGx testing based on a drug's FDA-approved label or clinical guidelines in its MVPs for mental health and other diseases through "IA_PM_16: Medication Management," "Q009: Anti-Depressant Medication Management," and/or other quality measures and improvement activities. In mental health and other conditions, the broad-based clinical integration of PGx testing could help patients achieve better outcomes and reduce avoidable health care costs attributed to poor disease management.

Addressing Health Inequities Through Need-Based Interventions

PMC appreciates CMS' continued focus on how to address disparities in health throughout the new and previously finalized MVPs as part of its larger health equity strategy. Delivering personalized medicine successfully depends on consideration of patients' biology, medical history, values, and circumstances. Unfortunately, clinical care is too often delivered, and therapies prescribed, based on one-size-fits-all assumptions that do not account for the needs of underserved groups of patients. This approach risks disease progression and can exacerbate health inequities.

PMC supports CMS' proposal to include "Q487: Screening for Social Drivers of Health," such as food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety,[xix] across new and previously finalized MVPs. Later this year, PMC will release the findings of a recent project that convened leaders from underrepresented communities to discuss the future of research in personalized medicine. Participants in the initiative have identified improving the collection and use of inclusive health data as a priority area for addressing disparities in research informing personalized medicine. Capturing and sharing data on social determinants of health can ensure that

patients' unique circumstances are accounted for in their electronic health records. Supporting the process of collecting data on drivers of health and the performance of clinicians who choose to submit this measure provides a step towards defining, addressing, and allocating supportive resources to patients based on unique circumstances and needs that can impact their ability to benefit from personalized medicine.

Conclusion

PMC appreciates CMS' commitment to improving the quality of care for its beneficiaries. We look forward to working with you and your colleagues to continue fostering the clinical adoption of personalized medicine in cancer and other disease areas through payment incentives under the MIPS and MVP programs. If you have any questions about the content of this letter, please contact me at 202-499-0986 or cbens@personalizedmedicinecoalition.org, or David Davenport, PMC's Manager of Public and Science Policy, at ddavenport@personalizedmedicinecoalition.org or 804-291-8572.

Sincerely yours,

Cynthia A. Bens
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