December 13, 2019

Amy Bassano
Acting Director, Center for Medicare and Medicaid Innovation
Centers for Medicare & Medicaid Services
Mailstop WB-06-05
7500 Security Blvd.
Baltimore, MD 21244

Sent electronically

Re: Oncology Care First (OCF) Request for Information

Dear Ms. Bassano:

The Personalized Medicine Coalition (PMC), a multi-stakeholder group comprising more than 200 institutions across the health care spectrum, thanks the Center for Medicare and Medicaid Innovation (CMMI) for releasing an informal request for information (RFI) on its proposed Oncology Care First (OCF) model.[i] We appreciate CMMI utilizing lessons learned from the Oncology Care Model (OCM) to inform the OCF model's design. We also appreciate that the OCF model will be a new, voluntary model aimed at promoting value-based payment in cancer care. Our comments on the RFI are intended to guide OCF model design so that it recognizes and supports advances in personalized medicine.

Personalized medicine is an evolving field that uses diagnostic tools to identify specific biological markers, often genetic, to help determine which medical treatments and procedures will be best for each patient. By combining this information with an individual's medical history, circumstances, and values, personalized medicine allows doctors and patients to develop targeted prevention and treatment plans.

Personalized medicine is helping to shift the patient and provider experience away from trial-and-error treatments of late-stage diseases 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. 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.

Experts have highlighted that personalized medicine is delivering better efficacy, improvements in overall survival, and a reduction in adverse events for patients.[ii] PMC is helping to build the evidence base necessary to further demonstrate the clinical and economic value of personalized medicine to inform policies that promote its widespread adoption.

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The following comments on the OCF RFI build on issues raised by PMC in 2014[iii] and 2015,[iv] when PMC called for payment models that encourage the rapid adoption of new personalized treatments and technologies, support health outcomes that matter to patients, and expand efforts to accurately capture the quality of personalized care.

Statement of Neutrality

Many of PMC's members will present their own responses to the Centers for Medicare & Medicaid Services (CMS) 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 OCF RFI or related issues.

Ensuring That the OCF Model Encourages the Rapid Adoption of New Treatments and Technologies

In February of 2019, PMC released *Personalized Medicine at FDA: A Progress & Outlook Report*, which documented a record number of new personalized medicine approvals by the U.S. Food and Drug Administration (FDA) in 2018. Forty-two percent of all new drugs approved by FDA in 2018 were personalized medicines, and half of the personalized medicines approved in 2018 treat certain cancers. This marks the fifth consecutive year that personalized medicines accounted for more than 20 percent of all new drug approvals and the second year that one of every three drugs approved were personalized medicines. That ratio represents a sharp increase from just 10 years earlier, when personalized medicines accounted for less than 10 percent of the new molecular entities approved annually.[v] In order to support continued biomedical innovations, payment models like OCF must align with the principles of personalized medicine, and, by extension, with high-quality, patient-centered care, which has the power to improve outcomes and deliver value to the health system.

We understand that the OCF model, like the OCM, would hold providers accountable for the total cost of care, including drug costs, over a six-month episode period. Depending on quality performance and costs relative to benchmark and target amounts, providers would receive a performance-based payment or owe a repayment to CMS. However, in some OCM practices there are many episodes that are over target amounts despite very little hospitalization use, emergency department care, or post-acute spending. Spending on pharmaceuticals is driving much of the cost for these practices. Because many of the drugs being prescribed are necessary to treat patients' episodes, providers in these practices are powerless to decrease these costs without sacrificing the quality of the care they provide.[vi] We therefore fear that the OCF approach may only incentivize the delivery of the current standard of care, unintentionally discouraging the adoption of newer personalized treatments, which may increase short-term costs but yield long-term benefits.

The OCF model would also bundle payment for certain services into a monthly prospective payment (MPP). The MPP replaces certain Medicare fee-for-service (FFS) payments and would be paid to OCF practices in advance based on their expected volume of patients with cancer or cancer-related diagnoses. This change

would amount to a capitated payment for the evaluation and management services, drug administration services, and enhanced care coordination services required under OCF.

We understand that CMMI is considering whether other FFS payments, such as those for laboratory services, should be wrapped into the MPP. Laboratory services are crucial to the diagnosis and management of many cancers and are an essential component of personalized medicine. We are concerned that adding laboratory service fees to the MPP may cause providers to view them as expenses that are part of the total cost of delivering care, rather than an integral part of the solution to attain high-value care. Before making a final decision on bundling laboratory service payments into the MPP, PMC recommends that CMMI seek further input from the laboratory and provider communities on how best to contain costs within the OCF model while ensuring the proper deployment of diagnostics and other laboratory services. Proper deployment of diagnostics should not only focus on the costs of a diagnostic testing technology itself, but also the inclusion of cancer care team experts (such as pathologists, genetic counselors, etc.) who may order and interpret results.

Thoughtful consideration must be given to the crucial role personalized medicine testing pays in oncology management. Predictive testing can inform therapy selection for late-stage cancer patients and prognostic testing can provide alternatives in the management of early-stage cancer patients. If a patient measurement period for the OCF model begins with either an evaluation and management service, hormone therapy, or chemotherapy, CMMI should explore inclusion of all expenses directed by a treating physician as the basis for performance evaluation.

Ensuring That the OCF Model Supports Outcomes that Matter to Patients

In an environment of intense pressure to contain health care costs, it is vital that payment models like OCF do not lose sight of the importance of patient-centered care. We appreciate that CMMI shares this view and is considering ways to gather information from patients to inform their care. Providers and patients must be actively engaged in order to make informed decisions about personalized medicine based on an assessment of all available diagnostic and treatment options. OCF should facilitate the use of patient-centered tools and create opportunities to support shared decision-making at the patient level.

When evaluating the care provided to a patient, it is important that the patient's perspective and opinion is at the center of the evaluation. Patient-reported outcome (PRO) measures that evaluate a patient's perspective can provide invaluable information about an individual's health maintenance and progress — or lack thereof. We believe these measures have the potential to provide insight into patient treatment and outcome achievement.

While PRO measures are being more commonly used in clinical practice, not all PROs are validated for use outside of a research setting. We recommend that CMMI release a list of PRO tools being considered for inclusion in OCF and provide additional opportunities for comment on the validity of these tools for use in the clinic, as well as the adequacy of the tools for capturing an adequate measure of patient experiences, the burden of the tools on patients and providers, and how the collected PRO data can be used to tailor or improve patient care.

Ensuring That the OCF Model Captures Accurate Assessments of the Quality of Personalized Health Care

There are fundamental tensions between personalized medicine and the traditional approach to quality measurement.[vii] Quality measures typically assess whether a standard of care has been met for a broad patient population, while personalized medicine focuses on approaches to care that are tailored

to individuals and subgroups of patients meeting specific clinical criteria. As clinical criteria become more specific, the number of applicable patients meeting the inclusion criteria decreases, affecting measure reliability at the provider-level. Further, the speed with which new diagnostics and targeted therapies are developed and utilized presents challenges for ensuring that clinical guidelines and quality measures derived from those guidelines keep pace with the science.

PMC understands that the OCF model would tie quality measures to provider payments in order to balance cost reduction with incentives to maintain or improve care quality. The payment amount providers would be eligible to receive, and the amount of any repayment that providers would owe, would be based, in part, on their performance on each of the measures in the potential OCF Quality Measure Set. The OCF RFI states that "the OCF Quality Measure Set could be the same as the measures currently used in OCM.22." The RFI also recognizes that "these existing measures have room for further improvement." As the OCF model design is finalized, we urge CMMI to identify and address measures in the OCF Quality Measure Set that would not accurately capture the quality of individualized care and may penalize providers for delivering personalized medicine. Since some personalized therapies often confer benefits to patients over a longer time period, CMMI should also consider episode timeframes beyond six-month intervals to capture improved patient outcomes that would otherwise fall outside an episode.

Conclusion

Thank you for releasing the request for information and for considering our comments. PMC welcomes the opportunity to serve as a resource for you in continuing to shape OCF and other alternative payment models so that they achieve the goal we share with CMS of delivering appropriate, efficient, and accessible health care to all patients. If you have any questions about the content of this letter, please contact me at 202-589-1769 or cbens@personalizedmedicinecoalition.org.

Sincerely yours,

Cynthia A. Bens
Senior Vice President, Public Policy

CC: Lara Strawbridge
Director, CMMI Patient Care Models Division of Ambulatory Payment Models

[i] Center for Medicare and Medicaid Innovation. *Informal Request for Information: Oncology Care First Model*. November 1, 2019. https://innovation.cms.gov/Files/x/ocf-informalrfi.pdf

[ii] Charles River Associates. *The Benefits of Personalized Medicine to Patients, Society and the Healthcare System: Final Report*. Prepared for the European Biopharmaceutical Enterprises and the European Federation of Pharmaceutical Industries and Associations. July 6, 2018. https://www.ebe-biopharma.eu/wp-content/uploads/2018/07/CRA-EBE-EFPIABenefits-of-PM-Final-Report-6-July-2018-STC.pdf

[iii] Personalized Medicine Coalition. *Comment Letter on The Centers for Medicare & Medicaid Services Request for Information on Specialty Practitioner Payment Model Opportunities*. April 10, 2014. http://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/pmc_specialty_practitioner_payment_models.pdf

[iv] Personalized Medicine Coalition. *Comment Letter on the Center for Medicare and Medicaid Innovation Oncology Care Model Request for Applications*. May 4, 2015. http://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/centers-medicare-medicaid-oncology-care-model.pdf

[v] Personalized Medicine Coalition. *Personalized Medicine at FDA: A Progress & Outlook Report*. February 12, 2019. http://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/PM_at_FDA_A_Progress_and_Outlook_Report.pdf

[vi] Community Oncology Alliance. *Letter to CMMI Regarding Challenges That Need to Be Addressed in the OCM and Future Payment Reform Models*. May 31, 2019. https://www.communityoncology.org/coa-letter-to-cmmi-regarding-challenges-that-need-to-be-addressed-in-the-ocm-and-future-payment-reform-models/

[vii] Discern Health. *Quality Measurement of Personalized Medicine: Tensions Between Personalization and Standardization*. November 2018. http://discernhealth.com/wp-content/uploads/2018/12/Quality-Measurement-of-Personalized-Medicine-Issue-Brief.pdf