PMC
PERSONALIZED
MEDICINE COALITION

May 4, 2015

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4159-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Request for Applications: Oncology Care Model

Dear Acting Administrator Slavitt:

I am writing on behalf of the Personalized Medicine Coalition (PMC) in response to the recent announcement of the Center for Medicare and Medicaid Innovation's Oncology Care Model.

PMC, which is comprised of more than 240 member institutions representing a wide range of stakeholders, appreciates CMS' work to advance high-value, individualized health care, and we believe personalized medicine has an important role to play in achieving this goal.[1] We also appreciate HHS' separate initiative to accelerate the advancement of precision, or personalized, medicine. In order to ensure that these advances reach patients and improve outcomes, we believe it is essential that reforms such as the Oncology Care Model align with the principles of personalized medicine.

Before focusing on the Oncology Care Model, let me first thank you for engaging with the personalized medicine community. Last year, Dr. Conway, Deputy Administrator for Innovation & Quality and CMS Chief Medical Officer, gave the 10th annual State of Personalized Medicine Address, during which he insisted that CMS policies were not designed to inhibit innovations and that if they did, the audience should inform the agency. Since his address, PMC and its member organizations have taken him up on his offer. Most recently, Dr. Von Nguyen spoke at a PMC event at which we examined the possible impact that alternative payment models could have on personalized medicine. We look forward to continued, productive engagement.

[1] Abernethy A, Abrahams E, Barker A et al. Turning the Tide Against Cancer Through Sustained Medical Innovation: The Pathway to Progress. *Clinical Cancer Research*. March 2014.

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The Oncology Care Model design includes several elements that have the potential to positively transform oncology care, including support for enhanced services such as 24/7 patient access to clinicians, patient navigators and enhanced patient care plans. However, some questions about the model's impact on patient-centered oncology care remain unanswered. We are concerned that, if improperly designed, this initiative might discourage advances in personalized medicine.

At a time of unprecedented scientific and medical breakthroughs, personalized medicine has the capacity to more accurately diagnose human diseases, predict individual susceptibility to disease based on genetic or molecular factors, detect the onset of disease at early stages, pre-empt its progression, target treatments, and increase the overall efficiency and effectiveness of the health care system. Personalized medicine has brought us major treatment advances that will improve patient outcomes, with the greatest impact felt by those with serious and life-threatening conditions and unmet medical needs, like cancer patients.

The field is at a critical juncture. While ongoing advances have the potential to turn the tide against cancer, changing market dynamics and policy initiatives, including the Oncology Care Model, run the risk of derailing progress. How personalized medicine is considered during the next set of payment reforms will be an important measure of how committed our nation's leaders are to curing a disease that 1.6 million Americans are expected to be diagnosed with this year. If care is not taken to recognize the impact of efforts to cut costs in oncology care, the growth of personalized medicines could be stunted, and hopes of patients dashed.

We briefly highlight several priority recommendations below. Other health care leaders have recently echoed several of these recommendations. For example, the *Turning the Tide Against Cancer* initiative, of which PMC is a co-convener, recently released a series of recommendations for supporting continued progress against cancer.[2]

Recognize personalized medicine in the Oncology Care Model.

Since the Oncology Care Model includes incentives that would reward providers for reducing spending below specified targets, it is essential that the model's design includes mechanisms to recognize and support advances in personalized medicine. Alternative payment models with payment incentives based on the current standard of care can have the unintended effect of discouraging the adoption and continued development of medical advances that may increase short-term costs but yield long-term clinical and economic benefits. CMS has already recognized the need to pay for innovative treatments differently in its Bundled Payments for Care Improvement demonstration.[3] As the agency moves forward with the implementation of

[2] Turning the Tide Against Cancer. A Pathway for Change: Supporting the Shift to Patient-Centered Cancer Research and Care and Addressing Value and Cost of Cancer Care. October 2014. Available from: http://turningthetideagainstcancer.org/sustaining-progress-discussion-paper.pdf

[3] CMS Bundled Payments for Care Improvement. "Updates to BPCI Payment Adjustments for Physician Fee Schedule 2015 Update and BPCI Exclusions." Distributed by email: February 5, 2015.

the Oncology Care Model, we urge it to include similar mechanisms to ensure that the model does not hinder future advances in personalized medicine and biomedical innovation. We appreciate CMS' recognition of the importance of addressing this issue in a recent FAQ on the Oncology Care Model. As CMS develops mechanisms to account for medical advances in the model, it should ensure that they allow for seamless adoption of personalized medicines by physicians.

Avoid incentivizing a "one-size-fits all" paradigm.

If alternative payment models like the Oncology Care Model base payment on narrowly defined episodes of care, they may restrict treatment choices based on implicit assumptions of equivalent effectiveness. This has the potential to discourage molecular testing, which illuminates the individual variations upon which personalized medicines depend. Personalized medicine targets care based on an understanding of what will work for whom. Based on the request for applications, it does not appear that CMS provides any adjustments for patient characteristics that can affect prescribing choices. In order to align with personalized medicine, payment episodes should account for the growing recognition that each patient's cancer has a unique genetic profile that requires individualized treatment.

Conversely, the Oncology Care Model may lock into place ineffective "one-size-fits-all" treatment options that could both undermine patients' abilities to access targeted treatments and restrict providers' abilities to tailor care to the individual patient. Such incentives would prevent the health care system from benefiting from the efficiencies derived from a personalized approach to health care.

Support outcomes that matter to patients.

In an environment of intense pressure to contain health care costs, it is vital that alternative payment models do not lose sight of the importance of patient-centered care. This includes ensuring that the Oncology Care Model facilitates the use of patient-centered tools, such as the shared decision-making principles referenced in the Affordable Care Act.[4] Given the recent advances in personalized medicine, physicians and patients must be actively engaged in order to make informed health care decisions based on an assessment of all available treatment options. The Oncology Care Model must include opportunities to support shared decision making at the patient level and flexibility for physicians to tailor care to the individual patient.

When evaluating the care provided to a patient, it is important that his or her perspective and opinion is at the center of the evaluation. Patient-reported outcome measures are survey questions that evaluate a patient from his/her perspective, providing invaluable information about his/her health maintenance, progress, or lack thereof. We believe these measures have the potential to provide insight into patient treatment and outcome achievement in disease

[4] ACA §3506, adding §936 of the Public Health Service Act

states where no other clinical outcome measures currently exist. Use of outcome measures, including patient-reported outcomes like functional status and quality of life, can serve as counterweights to measures aimed at cost of care in order to more accurately depict the value of an intervention.

Ensure transparency in the development and implementation of the Oncology Care Model.

PMC supports new payment models that deliver high-quality, efficient, patient-centered care. However, even when models can improve quality and reduce costs, there are inherent challenges and concerns regarding their ability to address patient-centered needs. Therefore, it is essential that the agency develops, implements, and evaluates the Oncology Care Model through open and transparent processes. Transparency includes active engagement with physicians and patients in the development of these demonstrations; rigorous testing and validation before a demonstration is expanded; and clear standards assessing the impact of demonstrations on the quality of patient care and the ability of demonstration projects to promote advances in personalized medicine.

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PMC has addressed several of these issues in more detail in our recently published paper, *Paying for Personalized Medicine: How Alternative Payment Models Could Help or Hinder the Field*.[5] We hope that you find the overview and citations in the document helpful when considering future program development.

As CMS works to implement the Oncology Care Model, it will be particularly important to ensure that the model supports continued development and adoption of personalized medicine. We would be pleased to discuss our recommendations with CMS in more detail and identify concrete steps PMC can take to support the Oncology Care Model and its goal of achieving higher quality, higher value health care. For more information or to schedule an appointment, please contact Amy Miller, Ph.D., Executive Vice President of PMC, via e-mail at amiller@personalizedmedicinecoalition.org or via phone at (202) 589-1769.

Sincerely yours,

Edward Abrahams

Edward Abrahams
President

[5] *Paying for Personalized Medicine: How Alternative Payment Models Could Help or Hinder the Field*. April 2015. Available from: http://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/paying_for_personalized_medicine.pdf