PMC
PERSONALIZED MEDICINE COALITION
Celebrating 10 Years

April 10, 2014

Patrick Conway, MD
Chief Medical Officer
Deputy Administrator for Innovation and Quality
Centers for Medicare & Medicaid Services (CMS)
Center for Medicare and Medicaid Innovation (CMMI)
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Baltimore, MD 21244

Sent via email: SpecialtyCareModels@cms.hhs.gov

RE: Request for Information: Specialty Practitioner Payment Model Opportunities

Dear Dr. Conway:

On behalf of the Personalized Medicine Coalition (PMC), I am pleased to submit comments on the Centers for Medicare & Medicaid Services (CMS), Center for Medicare and Medicaid Innovation (CMMI), Request for Information (RFI) on Specialty Practitioner Payment Models.

While payment models meant to promote coordination and integrated care could incentivize personalized medicine, we are concerned that, if improperly designed, such models will set payment based on current standards of care and therefore discourage advances in medicine.

After explaining the importance of sustaining growth in personalized medicine and the impact that payment models might have on this growth, we suggest that CMS:

- *Proceed only after a thorough evaluation of new models;*
- *Avoid models that hold health care in a "one-size-fits-all" paradigm;*
- *Account for the long-term benefits of personalized medicine;*
- *Ensure transparency; and*
- *Include mechanisms to support adoption of advances in personalized medicine.*

Personalized medicine uses diagnostic tools to identify specific biological markers, often genetic, that help assess which medical treatments and procedures will work best for each patient. By combining this information with an individual's medical history and circumstances, personalized medicine allows doctors and patients to develop cost-saving, targeted prevention and treatment plans. Personalized medicine therefore has the potential to optimize delivery and dosing of treatments so patients

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can receive the most benefit with the least amount of risk, eliminating the difficulties of the "trial-and-error" process many patients endure to obtain the correct diagnosis and treatment for their condition.

PMC is an education and advocacy organization that promotes the understanding and adoption of personalized medicine to benefit patients and the health care system. We represent more than 225 academic, patient, provider, and payer organizations, as well as drug and diagnostic manufacturers and clinical laboratories. Given the hopes and desires of the patient and health care stakeholder communities united in PMC, the Coalition has a keen interest in CMMI's forward-looking activities.

In previous communications with CMS, PMC has explained that poorly developed or vetted policies negatively impact the improvement of health care. We repeat here our hope that CMS will avoid putting in place policies, or, in this case, specialty models, that unintentionally impede the continued developments in personalized medicine and associated improvements in health care.

The Importance of Sustaining Progress 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, preempt its progression, target treatments, and increase the overall efficiency and effectiveness of the health care system.

These advances have already impacted the way we treat patients. Melanomas are now characterized as BRAF-positive or –negative. In addition, non-small cell lung cancer can be categorized as EGFR- or ALK-positive, and can be treated with the targeted drug most likely to improve the patient's health. From only 13 personalized medicine products in 2006 to more than 70 in 2012, patients, physicians, and manufacturers are appreciating the heterogeneity of disease and are working together to develop personalized solutions that improve patient care and reduce overall health care costs.

In order to sustain this evolution and support continued biomedical innovations, Medicare and private payers should establish a path toward evaluating the clinical and economic utility of personalized medicine. Proposals that impose blunt payment cuts or rigid clinical or cost-effectiveness standards create significant barriers to the development of the innovative drugs and diagnostics that drive quality improvements in health care and are the hallmark of personalized medicine. To support these important advances, payment policy and models 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 bring value to the health system.

Align Emerging Payment Models with the Principles of Personalized Medicine

As the health care system shifts away from fragmented payment structures and toward a much more integrated system that rewards value, alternative payment models (APMs) are being proposed as mechanisms to drive greater value in health care while avoiding blunt price controls or coverage restrictions. While APMs, which are meant to promote coordination and integrated care, could incentivize personalized medicine, we are concerned that, if improperly designed, such models will set payment based on current standards of care and therefore discourage advances in medicine.

It is essential that APMs are designed in ways that allow physicians to tailor care based on an individual's genetics and other factors, and that they support the adoption of novel targeted therapies and the diagnostics that guide them. Accordingly, these models must include sufficient incentives to augment clinical care quality, not just cost control; ensure that patients have access to and are aware of all their diagnostic and treatment options; and accommodate innovation that improves patient outcomes and quality of life. As APMs continue to be developed, it is imperative that they are aligned with the principles of personalized medicine and biomedical innovation.

Policy Considerations for Sustaining Personalized Medicine in Innovative Payment and Service Delivery Models

Proceed cautiously, using evidence-based APM designs

While the evidence-base is expanding, many new payment models are still largely untested. It is important to move forward carefully and in ways that enable policymakers and stakeholders to understand the impact of various approaches on cost, quality, patient care, and innovation.

Avoid models that hold health care in a "one-size-fits-all" paradigm

APMs, such as models that base payment on narrowly defined treatment pathways or episode-based payment bundles, may restrict treatment choices based on implicit assumptions of equivalent effectiveness. This is very concerning. Personalized medicine targets care based on an understanding of what will work for whom. Policies like those referenced above likely fail to recognize the benefits of personalized medicine and its ability to tailor treatments to patients based on their individual characteristics. They would instead impose "one-size-fits-all" treatment options that both undermine patients' abilities to access targeted and personalized care that is specific to their circumstances and preferences and also restrict providers' abilities to tailor care to the individual patient. Finally, they will prevent the health care system from benefiting from the efficiencies that will be derived from a personalized approach to health care.

Account for the long-term benefits of personalized medicine

CMMI should consider which diseases or conditions to include in any future demonstrations through the lens of whether existing quality and cost measures are able to capture the realities of how the disease is treated. Especially in the case of chronic and complex diseases, personalized medicine offers significant short- and long-term benefits. Thus, it is important that APMs not dis-incentivize interventions that may raise short-term costs but yield greater clinical/cost value over time. While APMs create incentives based on short-term budget cycles, the benefits of personalized medicine advances are likely to become evident over a longer time horizon. PMC believes that policies should promote improved care management throughout the continuum of care. Payment models that incorporate the principles of personalized medicine will allow physicians to individualize treatment plans for patients both through the early diagnosis of disease and through targeted treatments meant to optimize clinical outcomes. These models could also prevent unnecessary hospitalizations and care and reduce long-term costs.

Ensure transparency

As stated above, PMC supports new payment models that deliver high-quality, efficient, patient-centered care through appropriate and applicable alternative payment models. However, while these models hold potential to improve quality and reduce costs, there are inherent challenges and concerns regarding their ability to address patient-centered needs. Therefore, it is essential that any potential

demonstration using APMs be developed, implemented, and evaluated through open and transparent processes. These include 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 these demonstrations on the quality of patient care and the ability of demonstration projects to promote advances in personalized medicine.

Include mechanisms to support adoption of advances in personalized medicine
Advances in the science of personalized medicine are leading to important advances in diagnosis and treatment of cancer as well as many other burdensome and life-threatening diseases. Because personalized medicine is rapidly changing health care, APMs with payment incentives that do not accommodate novel technologies 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.

Conclusion

New payment models must be carefully considered, and evidence to support them must be robust, or we might yet entrench ourselves into our current medical model that is built on trial-and-error medicine.

If you have any questions about these comments, please contact Amy M. Miller, Ph.D., at 202-589-1769 or via e-mail at amiller@personalizedmedicinecoaltion.org.

Sincerely yours,

Edward Abrahams
President