



November 20, 2017

Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: Innovation Center New Direction  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Sent electronically

**Re: Centers for Medicare & Medicaid Services: Innovation Center  
New Directions Request for Information**

Dear Administrator Verma:

The Personalized Medicine Coalition (PMC) appreciates the opportunity to submit comments regarding the Centers for Medicare & Medicaid Services (CMS) Innovation Center New Directions Request for Information (RFI).

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. Our interest in the RFI pertains to how the concepts therein can support personalized medicine. Our comments focus specifically on CMS' proposed guiding principles for the Innovation Center, the direction of future payment and delivery model development, and program improvements to allow for broad stakeholder involvement in the design of care models and their implementation so that they can best serve patients.

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 in order to provide the right treatment in the right dose to the right patient at the right time.

Personalized medicine is helping shift the patient and provider experience away from trial-and-error and toward a more streamlined process for making clinical decisions, which will lead to improved patient outcomes, a reduction in unnecessary treatment

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costs, and better patient and provider satisfaction, particularly for chronic conditions that disproportionately affect Medicare beneficiaries. PMC's 240 members, which include representatives from all health care sectors, are leading the way in personalized medicine and recommend that patients who may benefit from the approach undergo appropriate testing and tailored treatment as soon as possible during their clinical experiences.

### **Statement of Neutrality**

Many of PMC's members will present their own responses to 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 RFI or related issues.

### **Support for CMS Guiding Principles for the Innovation Center**

As you know, the Innovation Center was created by Congress to develop, test, and implement new payment and delivery models. In an attempt to meet the previous administration's ambitious target of tying 30 percent of all Medicare fee-for-service payments to alternative payment models (APMs) by the end of 2016 and 50 percent of payments by 2018, CMS and Congress invited and imposed new, large, national, mandatory payment and delivery models through the Innovation Center that appeared to be more focused on reducing cost than improving the outcomes that matter to patients. They were difficult to implement. Fortunately, many stakeholders continue to unite around the promise of a systemic shift that allows them to provide value-driven care that is measured by improved patient outcomes.

In that context, we commend CMS for re-examining the direction of the Innovation Center. It is our hope that the relationships forged since the Center's inception and the lessons learned from early attempts at aligning outcomes with payment can be leveraged by CMS to achieve its goal of promoting affordable, accessible health care that puts patients first. We believe that personalized medicine has the potential to help CMS deliver on this goal if it focuses on maximizing individual patient outcomes, if new models are fully evaluated before large-scale implementation, if payment is not rooted in current standard of care, and if physicians have the flexibility to tailor care based on a patient's genetics and other factors.

In previous communications with CMS, PMC has explained that poorly developed or vetted policies negatively impact the improvement of health care. The guiding principles laid out in the RFI provide reasonable assurance that the Innovation Center plans to proceed at a more measured pace with an eye toward increased transparency and broader participation in value-based model design and testing. Such an approach will create a context in which policies that unintentionally impede continued developments in personalized medicine can be avoided.

### **Recommendations to Ensure Future Payment Models Foster Adoption of Personalized Medicine**

Advances in personalized medicine have noticeably impacted the way we treat patients. Melanomas are now characterized as BRAF-positive or –negative. 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 a patient’s health. Most Americans with breast cancer now benefit from targeted treatments. We expect future advancements to improve treatment in other disease states, as they have for cancer. In 2015 alone, 28 percent of the U.S. Food and Drug Administration’s novel new drug approvals were personalized medicines.

In order to sustain this rapid 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 can drive quality improvements in health care and accelerate progress in personalized medicine. To support a more effective and efficient health system, payment 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 deliver value to the health system.

As health care shifts away from fragmented payment structures and toward a more integrated system that rewards value, APMs should be mechanisms to drive value while avoiding price controls or coverage restrictions. APMs are meant to promote coordination and integrated care, but depending on their design, such models can discourage advances in personalized medicine by setting payment based on current standards of care, narrowly defined arbitrary treatment pathways, or episode-based payment bundles. Models like these restrict treatment choices based on implicit assumptions of equivalent effectiveness and impose “one-size-fits-all” treatment approaches that can undermine a patient’s ability to access targeted care.

Patient-centered medical homes are models that focus on an individual patient, relying on a team of providers and the patient to manage care. The role of personalized medicine in the medical home setting is still evolving, but there are models, such as the Patient-Centered Oncology Medical Home, that appear to have at least a modest impact on the utilization of personalized medicine because of the role diagnostics play in determining the initiation of payment and the assumption of responsibility for delivering comprehensive, coordinated, accessible, safe quality care. As part of the Innovation Center’s new direction, PMC recommends testing of new models that reflect the realities of how disease is treated and incentivize care accordingly. In the case of chronic and complex diseases, personalized medicine offers significant short- and long-term benefits, but a proper model in this context must include comprehensive and accurate quality measures so as not to disincentivize the use of diagnostics and treatments that may raise short-term costs but yield greater clinical/cost value over time.

In *Paying for Personalized Medicine: How Alternative Payment Models Could Help or Hinder the Field*, PMC highlighted that the greatest barrier in determining the true value of personalized medicine is the lack of pharmacoeconomic data needed to create an evidence base of benefits versus costs. The Coalition found that for providers participating in APMs, it is difficult to expend the resources necessary to assess the value of various personalized medicines in the face of higher costs for new technologies. Without rapid learning systems that can extract clinically meaningful information and apply it to modify clinical practice guidelines in real-time, providers are unlikely to utilize new technologies — and that could jeopardize their cost savings targets. Adaptable

models utilizing electronic medical records and real-time data sharing that integrates generalized knowledge from external sources, patient experiences, genomic information, and treatment history could counter this challenge. The Department of Veterans Affairs Point-of-Care Precision Oncology Program might serve as a model for rapid data sharing that creates an evidence base to quickly inform treatment decisions.

In health care systems where personalized medicine has already been integrated, patient-centeredness and empowerment were a critical component to success. Patient-centeredness is also an attribute of the patient-centered medical home. Personal decisions about health care are rarely straightforward, but patients who engage in shared decision-making with their clinicians are more satisfied, more engaged in their care, and more likely to follow the agreed-upon treatment plan, which can ultimately lead to improved health.

The National Quality Forum (NQF) Partners for Shared Decision-Making Action Team issued a national call to action for all individuals and organizations that provide, receive, pay for, and make policies for health care to embrace and integrate shared decision making into clinical practice as a standard of person-centered care. This action team included 20 leaders representing a diverse range of perspectives and areas of expertise, including consumer advocates, nurses, home health providers, clinicians, and health systems. These experts released an [action brief](#) identifying key barriers and solutions to advance shared decision making as a standard of care. CMS is reimbursing health care providers and facilities for engaging in shared decision-making with patients experiencing preference-sensitive conditions in two pilot models. Because shared decision-making has the potential to improve patient experience, engagement, and value, PMC encourages the inclusion of and reimbursement for shared decision-making practices that are consistent with the principles and standards articulated by the National Quality Partners Shared Decision-Making Action Team in additional models tested by the Innovation Center. In addition, there is the need for more rapid endorsement of shared decision-making performance measures to drive quality improvement and accountability programs, accreditation, certification, payment, and public reporting. Beneficiaries derive a direct benefit from shared decision-making and tools are improved by their involvement.

NQF convened an expert panel to develop guidance on national standards for the certification of high-quality, evidence-based, and unbiased patient decision aids, which clinicians can use when selecting decision aids. The expert panel's recommendations are contained in the [report](#), "National Standards for the Certification of Patient Decision Aids." Importantly, the panel recognized that the criteria for certifying decision aids about diagnostic testing should be different from the criteria used to certify decision aids regarding treatment options. While PMC does not have a position on the adoption of national certification standards for shared decision aids, PMC believes that the criteria identified in this report – and their distinction between diagnostics and treatments – bears consideration in CMS' policymaking around developing CMMI models that would explore shared decision-making as an intervention. Those criteria include, without limitation, that the patient decision aid provides a balanced presentation of options, is based on a rigorous and documented evidence synthesis method, provides information about the evidence sources used, provides key outcome probabilities that communicate risk, and includes information about the funding sources and potentially competing interests and/or policy.

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 (PROs) evaluate a patient experience from his/her perspective and provide 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 states where no other clinical outcome measures currently exist. 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. PMC believes that the inclusion and refinement of PROs should continue to be a part of new models tested by the Innovation Center.

### **Recommended Program Improvements to Allow Broad Stakeholder Engagement and Transparency**

The RFI states that the Guiding Principles will direct how the Innovation Center will approach new model design. The principles will not only impact the future of the Innovation Center, but also the future of health care. For this reason, PMC supports CMS codifying the principles in rulemaking. This step would add to their durability and establish a level of predictability for stakeholders to conform to if they are interested in developing or participating in care models.

The RFI further requests feedback on how CMS can engage beneficiaries in the development of new and existing care models. PMC believes that the Innovation Center has significant additional opportunities to test new models that empower patients and consumers with current data, support the shift to personalized medicine, and reduce overall health care costs. However, the process for accepting and considering these types of specific proposals requires clarification. We recommend the development of a transparent comment process for each of the opportunities related to new model development, piloting, or refinement. CMS should provide an opportunity for public comment on each model and CMS should publish comments received.

Finally, the Physician-Focused Payment Model Technical Advisory Committee (PTAC) was created to provide comments and recommendations on physician-focused payment model proposals. Since the guiding principles in the RFI focus to an equal extent on the involvement of providers and public stakeholders from a broad range of organizations across the country in the design and evaluation of care models, PMC encourages CMS to specify the role the PTAC will have in considering a proposal that may not come exclusively from physicians. Further, PMC encourages CMS to make the review process for PTAC recommendations more efficient and better aligned with Congressional intent.


### **Conclusion**

In summary, PMC recognizes and appreciates CMS' efforts to chart a new direction for the Innovation Center. The Coalition supports the stated guiding principles for this transition, and recommends that:

1. Future payment and delivery models evaluated by the Innovation Center foster the adoption of personalized medicine.
2. Program improvements are instituted under the Innovation Center's new direction to allow transparency that fosters broad stakeholder engagement.

Thank you for considering our comments on the Innovation Center's New Directions RFI. PMC looks forward to working with you as new models of care are developed to deliver affordable, accessible health care to patients. If you have any questions about the content of this letter, please contact me at 202-589-1769 or [cbens@personalizedmedicinecoalition.org](mailto:cbens@personalizedmedicinecoalition.org).

Sincerely yours,



Cynthia A. Bens  
Vice President, Public Policy

CC: Amy Bassano, M.A., Acting Deputy Administrator for Innovation and Quality & Acting Director, Center for Medicare and Medicaid Innovation (CMMI), Centers for Medicare & Medicaid Services

Arrah Tabe-Bedward, J.D., M.S., Deputy Director, Center for Medicare and Medicaid Innovation (CMMI), Centers for Medicare & Medicaid Services

Steven Farmer, M.D., Ph.D., Senior Advisor and Medical Officer, Center for Medicare and Medicaid Innovation (CMMI), Centers for Medicare & Medicaid Services