



## AcademyHealth Responds to Centers for Medicare & Medicaid Services Request for Information: New Directions for the Innovation Center

AcademyHealth appreciates this opportunity to provide comment on future directions for the Center for Medicare & Medicaid Services Innovation Center (CMMI) and applauds the Center for its continued efforts to address healthcare quality, outcomes and costs through the development, deployment and evaluation of evidence-based program models.

As the nonpartisan, professional home for more than 4,000 health services researchers, policy analysts, practitioners, and organizations, AcademyHealth is deeply committed to work that helps us understand and improve care for individuals, strengthen the performance of the health system, and enable better health outcomes for more people, at greater value. Our input on future directions for CMMI is informed by the experience of our members and offered in service to our mission to support the production and use of evidence to improve health and the performance of the health system.

### Guiding principles for Expanded Opportunities for Participation in Advanced APMs

AcademyHealth applauds CMS for recognizing and supporting the importance of evidence for decision-making as well as encouraging integration of the best available research into the development and evaluation of various models and initiatives.

While the guiding principles as proposed cover an appropriate range of choice, competition and patient-centered designs, AcademyHealth also encourages CMMI to think beyond economic models to examine other aspects of motivation and incentives, such as professionalism, social determinants, unintended consequences, and ethics. In addition, we suggest that the guiding principles should prioritize models that drive the generation of new, actionable knowledge.

Another important principle which is embedded, but for which additional clarification and commitment would be valuable, is the commitment to transparent, end-user engaged model design, large-scale tests of change, and evaluation. In support of that aim, the evaluation and improvement of the methods used.

In the development and testing of any new model or innovation, researchers evaluate the impact and relative risks and benefits of one or more interventions (or lack of intervention). AcademyHealth is



concerned by the absence of an explicit ethical framework to guide this work and protect its human subjects. One such framework is presented by Faden et al in “An Ethics Framework for a Learning Health Care System: A Departure from Traditional Research Ethics and Clinical Ethics” available in [the January 2013 Hastings Report](#). We further encourage CMS to add a principle that clearly outlines its expectation for model designs for which the benefits outweigh the risks for the beneficiary population and further suggest that Institutional Review Board (IRB) approval be required for evaluation efforts under the Innovation Center, a requirement that is not consistently applied in current grants and contracts.

### Are there any other comments or suggestions related to the future direction of the Innovation Center?

AcademyHealth appreciates the scope and definition of models to be considered. In our consideration of the future direction of the Innovation Center, we identify three areas for attention that could beneficially impact the work of CMMI across each of the stated areas of focus and accelerate learning and health system improvement, maximizing the value realized from the Federal investment in innovation and evaluation. These include placing additional emphasis on a learning health system model and adaptive designs, additional investment in evaluation and improvement methods and increased transparency and dissemination of models and evaluations.

#### *Learning and Adaptation*

AcademyHealth encourages CMMI to engage a learning health system approach at the earliest phases of model design to consider the system impact of various designs across a range of community and market contexts, the infrastructure necessary to collect and analyze appropriate and useful data, and the means to produce evidence more quickly. Such an approach is further improved by the use of evaluation designs and methods (such as adaptive designs) that facilitate rapid evaluation and mid-course corrections. Opportunities also exist to align this effort with the [recommendations](#) of the Commission on Evidence-Based Policymaking and resulting, proposed [legislation](#) from Speaker Ryan and Senator Murray. The recommendations focus on improving availability of and access to rigorous evidence by leveraging data and information from routine government programs in order to inform policymaking while at the same time ensuring privacy protections.

#### *Evaluation and Improvement Methods*

Across the domains outlined for future directions, the evaluation of complex interventions (as recently summarized [here](#)) requires the use of the most rigorous methods, and additional investment in these methods is encouraged. Further, we suggest that mixed methods approaches that leverage quantitative and qualitative evidence are critical to harvesting the full range of contextual knowledge from model implementation. Such approaches go beyond determining if a model was ‘effective’ in achieving certain



outcomes to understanding why and how a model was effective, or not, under which circumstances and for which populations.

#### *Oversight, Transparency and Dissemination*

A final recommendation pertains to the oversight, transparency and pace of dissemination. CMMI has a responsibility for ensuring that program model evaluations are conducted ethically, use sound methods, and are financially efficient. However, AcademyHealth would point out that too often, this oversight responsibility has resulted in overly burdensome processes with multiple layers of approval before even the simplest of steps can be executed by contracted evaluators. This not only results in wasted resources, driving up the cost of evaluations, it also slows down the evaluation itself, something we can ill afford at a time of such rapid, complex changes in our healthcare marketplace.

In order to ensure knowledge is produced to advance the public good, support a learning health system, and realize the full benefits of the federal investment in the Innovation Center, additional attention is needed to ensure that model design and evaluation is transparent and broadly disseminated in a timely manner. As a first step, AcademyHealth encourages CMMI to faithfully ensure evaluation designs are made public as early as possible, as required in regulation. We also encourage CMMI to increase transparency around the performance measures used in alternative payment plans, in effect allowing research and health system leaders to understand the performance of the measures being used. To support transparency and replicability, we encourage CMMI to explore options for making data and code available in a way that recognizes the contributions of researchers and gives appropriate credit for original work.

Importantly, we encourage CMMI to support scale and spread of innovation by removing unnecessary barriers to the release of independent evaluation findings. Too often research and evaluation results produced from innovations and evaluations are delayed for months if not years, redacted or otherwise modified in ways that make broader learning from the experience impossible. Releasing evaluation designs and facilitating access to data and code will address this issue in part, but additional action is required to assess current clearance and contracting policies within CMMI to facilitate rapid dissemination. In particular, AcademyHealth members have experienced barriers to their ability to present findings at AcademyHealth and other professional conferences, an important dissemination opportunity for CMMI. Finally, we encourage CMMI to leverage its investments by regularly compiling and summarizing lessons to date, for release to the public in a timely manner, to ensure that innovation efforts can spur additional learning on what works to improve quality, efficiency and delivery in the private sector.



Thank you for the opportunity to submit these comments. We look forward to working with you as you consider future directions for CMMI as well as the principles and priorities that will help to ensure lessons from these models can be efficiently captured, disseminated and implemented to improve patient outcomes and maximize the value of health care.