Executive Summary

The health care system is moving to models that seek to pay for value. In January 2015, the U.S. Department of Health and Human Services (HHS) accelerated the movement towards value-based payments by setting a goal to shift 50 percent of Medicare fee-for-service payments to alternative payment models (APMs) by 2018.1 The Center for Medicare and Medicaid Innovation (CMMI) within the Centers for Medicare and Medicaid Services (CMS) is playing a significant role in advancing value-based or alternative payment models. In addition, many State health agencies and private payers are exploring similar changes. However, CMMI and other payers lack sound procedures and standards for patient-centeredness. Patient-centered approaches to value-based payment are needed to ensure that new payment models support value that matters to patients. To get it right, patient engagement is essential.

Under its current process, CMMI lacks the mechanisms to ensure new payment models are consistently developed and tested in ways that are transparent, that actively engage various stakeholders and that support patient-centered care. CMMI has been inconsistent in engaging patients in model development and testing, and this has prompted concerns from the patient community about several recent CMMI model tests. These CMMI proposals; which require participation on large scale (therefore enhancing the risk to patients), fail to include patient safeguards, and would come between patients and their doctors to impose one-size-fits all medicine; are irreconcilable with a patient-centered approach to value-based care.

The Partnership to Improve Patient Care (PIPC) was founded on principles of patient-centeredness that cannot be achieved without engaging patients and people with disabilities. PIPC is now working to make sure the patient voice is heard in three key areas that are defining health care value: value-based payment, value assessment frameworks, and research on comparative value. With respect to value-based payment, patients must have a seat at the table as these models are developed and tested. A more consistent strategy for engaging patients would yield small, controlled model tests that effectively engage and protect patients and incorporate a patient-centered perspective on value.

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As part of its “Patient Voices, Patient Value” Initiative, PIPC is offering a roadmap for consistent patient engagement in the CMMI model design and testing process. This roadmap draws on best practices employed by CMMI in the development of earlier model tests, as well as best practices for patient engagement that have demonstrated success at the Patient Centered Outcomes Research Institute (PCORI), Food and Drug Administration (FDA), and Office of the National Coordinator for Health Information Technology (ONC). Specifically, PIPC recommends:

1. Improve oversight of CMMI by creating a Patient Advisory Panel to ensure patient-centeredness in the agency’s work.
2. Require CMMI to follow a consistent process to seek input from patients and caregivers both early in the development of new demonstrations and throughout the implementation and evaluation process.
3. Improve the transparency of model test designs and evaluation results.

Given the complexity of the patient population, and that patient perspectives differ on an individual level, it is important that CMMI increase patient involvement to best understand this stakeholder groups’ unique perspectives on their individual needs, preferences, and care choices to align new payment models with care that patients value. Increasing the level of patient participation throughout the model development process will improve the impact of value-based payment models by yielding tests that put patient safety, care needs, and preferences first.
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Part One
Overview of CMMI’s Stakeholder Engagement Process

CMMI was created to test innovative payment and delivery system models that maintain or improve the quality and affordability of care in Medicare, Medicaid, and the Children’s Health Insurance Program (CHIP). If models are successful and meet certain criteria with respect to their impact on quality of care, spending, and patient access, they may be expanded. Section 1115A of the statute notes that CMMI should “consult representatives of relevant Federal agencies, and clinical and analytical experts with expertise in medicine and health care management” when developing and testing such models. Furthermore, it asserts that CMMI should use tactics such as open door forums or other mechanisms to solicit input from relevant stakeholders, and calls for evaluating CMMI demonstrations against patient-centered criteria.

This paper evaluates how CMMI is incorporating stakeholders, and specifically patients, into the development, testing, and implementation of these models. This includes examples of CMMI models where CMMI actively engaging stakeholders as well as models that fall short of this goal. In addition, we look to organizations outside of CMMI, such as PCORI and the FDA’s Patient Focused Drug Development (PFDD) Initiative, which offer best practices for increasing transparency and stakeholder participation. Our assessment is based on the following six engagement strategies:

1) Engaging with stakeholders early in the process
2) Holding public meetings
3) Developing standards or guidelines for public engagement
4) Creating advisory panels or workgroups
5) Making information readily available to public
6) Formal comment opportunities

Overall, CMMI has been inconsistent in the way that it engages with stakeholders. Despite requirements to increase stakeholder engagement, CMMI has not implemented a structured approach for involving stakeholders throughout the process of model development and testing. On several occasions, CMMI has taken sufficient measures to engage stakeholders using a number of the six engagement strategies outlined above. However, many CMMI programs lack sufficient stakeholder engagement and transparency. Below we outline examples of where CMMI has appropriately incorporated a variety of the six engagement strategies. In particular, we highlight areas where CMMI specifically integrates the patient-perspective into its approach for model development.

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3 Ibid.
Part Two

Case Studies: CMMI Stakeholder Engagement

#1: Comprehensive Primary Care (CPC) Initiative. The CPC, first announced in 2011 is a voluntary four-year multi-payer initiative designed to strengthen primary care. CMMI utilized a number of engagement strategies in the development and testing of the CPC Initiative.

#2: Holding public meetings. In each CPC region, CMS and other payers hold regular in-person and virtual meetings typically on a monthly basis to discuss the program. At the meetings, payers discuss and share CPC program updates, practice learning activities, approaches to data sharing, as well as ideas for engaging providers, consumers, and other stakeholders. By 2013, all CPC regions integrated a variety of stakeholders such as providers, consumers, and employers into the payer meetings. Payers and stakeholders in New York replaced all of the payer-only meetings with multi-stakeholder meetings. As a result, the payers and stakeholders noted that this approach helped to break down silos, created a cohesive group, and encouraged active participation. CMMI asserts that these meetings help to develop and improve relationships, while building trust and ensuring that a variety of perspectives are incorporated into the model.

#4: Creating advisory panels or workgroups. During the first year of the CPC program, many practices opted for conducting patient surveys as a means of understanding patients' perspectives and improving care experiences. Based on the success of the patient surveys, CMMI encouraged more model participants to establish patient and family advisory councils with the aim of providing a patient-perspective on quality improvement efforts. The advisory councils encourage practices to engage directly with patients and hear firsthand about their experiences. The councils have helped to raise the importance of addressing the needs and concerns of patients that otherwise might be a lower priority for practice staff. For example, one practice council emphasized the negative experiences that patients were having with long waiting periods. The advisory council offered a solution in which practice staff would engage with and provide updates to patients who waited for over fifteen minutes past their scheduled appointment time. Another helpful recommendation was to post a sign at the checkout table reading, “Ask for a List of Your Medications,” to remind patients to ask for this valuable piece of paperwork to effectively track their medications and to share with different providers. The council also offered a solution to reduce the frustration associated with “phone tag.” Council members suggested that a patient's

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6 Ibid.
emergency call be forwarded directly to the care managers if that patient’s nurse is unavailable.7

#5: Making information readily available to public. CPC model evaluation results are regularly made available to the public. In its evaluation reports, CMMI directly solicits and feedback from model participants that is then published on the CMMI website. Evaluation reports provide critical insight into how the model is working. For example, CPC evaluation reports have provided insight into the value of patient advisory panels to CPC participants and have also identified barriers to their use that can inform future efforts. 8

#6: Formal comment opportunities. CMMI has provided several opportunities for submission of formal comments on CPC since its initial implementation. In 2015, CMMI issued a Request for Information (RFI) to solicit input on Advanced Primary Care Initiatives that might build on the CPC model. In the 2016 Medicare Physician Fee Schedule Proposed Rule, CMS provided an opportunity for formal comments on potential expansion of CPC. Formal comment opportunities offer a platform for a broad range of stakeholders, including patients, to document and share ideas, experiences, and concerns.

Oncology Care Model (OCM). OCM is a voluntary CMMI program that tests care management incentives and bundled payments for physician practices administering chemotherapy.9 OCM was developed over a period of 2 years and reflects an intensive stakeholder engagement effort by CMMI. CMMI employed the following strategies in the development of OCM.

- #1 Engaging with stakeholders early in the process. CMMI provided multiple opportunities for input into the OCM before the model reached the Request for Applications (RFA) stage. This included release of the Specialty Care Models RFI as well as a comment opportunity on a preliminary design paper for the model.

- #4: Creating advisory panels or workgroups. CMMI convened a technical expert panel (TEP) to assess and vet design elements for the OCM. This group encompassed physicians, payers, and most importantly, patient advocates and met in November 2013.10

- #5: Making information readily available to public. As CMMI designed and implemented the OCM, it regularly communicated information about the model to the public. As CMMI developed and refined the model design, it released the TEP proceedings, an initial model design report, as well as the results of a model simulation to communicate the evolution of the model design to the public. Following implementation, CMMI also released a detailed methodology document describing its procedures for calculating performance-based

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8 Ibid.
9 Oncology Care Model. CMS. Available at: https://innovation.cms.gov/initiatives/oncology-care/. Accessed on October 21, 2016.
payments under the model.

- **#6. Formal comment opportunities.** In addition to the Specialty Care models RFI referenced above, CMMI published and sought comment on a preliminary design document and incorporated feedback received through formal comments into its final RFA.
Part Three

CMII Programs that Require Improvement in Engagement and Transparency

Despite the progress that CMII has made in incorporating the design elements for effective stakeholder engagement into some of its programs, a number of CMII programs feature limited stakeholder involvement and transparency. CMII has now released three proposals for mandatory models that failed to appropriately involve stakeholders or incorporate the patient perspective from the outset.

One such model is Comprehensive Care for Joint Replacement (CJR). The aim of CJR is to test bundled payments for hip and knee replacements. CJR represents CMII’s first mandatory model and requires participation across all hospitals in one of every five U.S. metropolitan areas – encompassing many hospitals that chose not to participate and bear risk in previous voluntary models testing bundled payments (i.e., Bundled Payments for Care Improvement Initiative). Despite CJR being a mandatory model, CMII did not involve patients or other stakeholders in the initial formation of the proposal. Similar to CJR, in July 2016, CMS released the Advancing Care Coordination through Episode Payment Models Episode Payment Models Rule as a proposed mandatory program that introduces bundled payments for cardiac care. This proposed rule was also developed without prior input from stakeholders and, as a result, contained elements that were concerning to patients and providers from a clinical perspective. A final example is the Part B Drug Payment Model that was proposed in 2016 as a mandatory model to test an alternative drug payment design. The proposal called for the government to make centralized value determinations based on comparative effectiveness and cost-effectiveness analyses.

In all three cases, stakeholders had an opportunity to provide input through the formal rulemaking process; however, the initial proposed rule was drafted with no patient or stakeholder engagement or even awareness. A notice of proposed rulemaking has already undergone multiple levels of agency review and so allows only limited opportunity to shift the course of proposed programs. As a result, it provides an insufficient forum for meaningful patient engagement. Patient engagement must occur early in the model design process to positively shape the direction of CMII proposals.

The lack of stakeholder engagement and the absence of transparency from the initial stages of drafting many of these rules has led to widespread stakeholder and bipartisan congressional

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12 42 CFR Parts 510 and 512. Medicare Program; Advancing Care Coordination Through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model (CJR). CMS. Available at: https://innovation.cms.gov/Files/x/advancing-care-coordination-nprm.pdf. Accessed on October 21, 2016.
opposition. This stands in stark contrast to earlier CMMI proposals like the CPC and OCM, where stakeholders – including patients feel invested in the model designs and committed to their success.
Part Four
Organizations Outside of CMMI with Effective Stakeholder Engagement

Looking beyond CMMI offers valuable examples and productive practices for engaging stakeholders and incorporating the patient perspective. The organizations outlined below display a combination of the engagement strategies that CMMI has not yet applied consistently, in addition to examples of other promising practices that could be adopted by CMMI. Some organizations use unique techniques that CMMI isn’t currently utilizing, such as developing guidelines for public engagement. CMMI has the opportunity to enhance its approaches to program development and testing based on modeling its practices after the creative elements used in the positive approaches illustrated by other organizations below.

Patient-Centered Outcomes Research Institute’s (PCORI) Research Topic Selection
PCORI was established by congress in 2010 with the aim to “improve the quality and relevance of evidence available to help patients, caregivers, clinicians, employers, insurers, and policy makers make informed health decisions.”14 PCORI utilizes various stakeholder engagement strategies to provide funding for research studies related to comparative clinical effectiveness research (CER) that specifically seek to engage patients.

- **#1: Engaging with stakeholders early in the process.** PCORI encourages stakeholder engagement prior to the initiation of any research study. For example, PCORI provides a formal set of methodological standards and requirements associated with patient-centeredness and engagement that applicants use to best integrate patients into their study design. In addition, patients and other stakeholders participate on panels that review and select research proposals.15

- **#2: Holding public meetings.** PCORI holds monthly Board of Governor’s Meetings that are open to the public. During each meeting, the board reviews and approves new research funding awards and discusses other relevant agenda items. The meetings are all held using a teleconference/webinar system to facilitate broad participation.16

- **#3: Developing standards or guidelines for public engagement.** Any application for PCORI funding is required to include an Engagement Plan specifying methods to engage

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patients and other stakeholders in the design, execution, and dissemination of research.\textsuperscript{17} To guide applicants in actively considering stakeholder engagement in their research proposals, PCORI developed an Engagement Rubric that applicants can consult when developing their Engagement Plans. Applicants consult an Engagement Rubric developed by PCORI to provide guidance on how to incorporate patients and other stakeholders into the study design. The rubric underscores PCORI's Methodology Standards for patient-centeredness and Patient-Centered Outcomes Research (PCOR) Engagement Principles. Applicants are encouraged to demonstrate how they will incorporate the six PCOR Engagement Principles (reciprocal relationships, co-learning, partnerships, transparency, honesty, and trust) into their research plans.\textsuperscript{18}

- **#4: Creating advisory panels or workgroups.** PCORI encourages stakeholder participation through membership on Advisory Panels and through stakeholder roundtables on priority topics (comprised of practicing and research clinicians, patients, and experts in scientific and health services research and delivery), to review and select applications for funding.\textsuperscript{19}

PCORI’s consistent approach to engaging patients has been highly successful. For example, PCORI effectively engaged patients in a recent study researching the best methods for teaching patients how to think differently and cope more effectively with chronic pain. The patient representatives on the advisory board helped to define target population groups, develop questionnaires for patient assessments, and improve the adapted treatment. In addition, the patients on the advisory board provided the applicant with valuable input on the application that eventually led to full funding for the study. The patient participants and community partners who participate in the research board began to take on new, unexpected roles in promoting the study findings through interviews, presentations, and advocacy efforts.\textsuperscript{20}

*Food and Drug Administration’s (FDA) Patient-Focused Drug Development (PFDD) Initiative*

In 2012, the FDA reauthorized the Prescription Drug User Fee Act (PDUFA) V, which included a PFDD initiative to emphasize the importance of incorporating the patient perspective into the agency’s benefit-risk assessment of new therapies. This initiative is designed to solicit the patient perspective on specific disease conditions and currently available therapies.\textsuperscript{21}

- **#2: Holding public meetings.** Under PDUFA V (FY 2013 – FY 2017), the FDA committed to hold public meetings covering at least 20 disease areas. Since only some disease areas are chosen by the FDA for PFDD meetings, the agency also encourages patient organizations to

\textsuperscript{17} Ibid.
\textsuperscript{18} Engagement Rubric for Applicants. PCORI. June 6, 2016. Available at: http://www.pcori.org/sites/default/files/Engagement-
\textsuperscript{19} How We Select Research Topic. PCORI. May 4, 2014. Available at: http://www.pcori.org/research-results/how-we-select-research-
\textsuperscript{20} Enlisting the Brain in the Fight against Pain. PCORI. October 2016. Available at: http://www.pcori.org/research-in-action/enlisting-
hold externally-led PFDD meetings and share meeting deliverables with the FDA. Patient stakeholders may provide input at the public meetings or share their perspectives through comment submissions to the public dockets.  

- **#5: Making information readily available to public.** After each meeting, the FDA produces public reports entitled “The Voice of the Patient” that summarize the patient and patient representative input for each disease area.  

**Meaningful Use Federal Advisory Committees**

The 2009 American Recovery and Reinvestment Act (ARRA) authorized CMS to provide a reimbursement incentive for physicians and hospital providers who successfully demonstrate “meaningful use” of electronic health records (EHRs). This led to the development of a three-stage EHR Incentive Program.

- **#2: Holding public meetings.** The Office of the National Coordinator for Health Information Technology (ONC) actively solicited input throughout the development of the program from both government agencies and the public in the form of open dialogue, public forums, and written comments.

- **#4: Creating advisory panels or workgroups.** Two federal advisory committees governed under the Federal Advisory Committees Act (FACA) significantly improved the level of stakeholder participation in the development of requirements for the EHR Incentive Program. The HIT Policy Committee and HIT Standards Committee were established to make recommendations to HHS on the new program. Stakeholders are nominated to participate on the committees and industry organizations and consumer organizations can request to participate in the selection of committee members to represent their interests. The open FACA meetings and extensive materials library on the program website provided an opportunity to publicly debate and offer feedback on policies for “meaningful use” and directly influence the direction of eventual CMS rules for the program. The multi-stakeholder composition of the FACAs also ensures representation of diverse perspectives in these conversations.

- **#6: Formal comment opportunities.** CMS used the FACA process as well as several RFI’s to solicit input on program rules for meaningful use prior to initiating the formal

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26 Current Advisory Committee Federal Register Request for Nominations Notices. FDA. Available at: [http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/CommitteeMembership/ucm446874.htm](http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/CommitteeMembership/ucm446874.htm). Accessed on November 30, 2016.

27 Ibid.
rulemaking process.\textsuperscript{28}

Part Five

Conclusion

As CMMI continues to play a larger role in advancing value-based care, and given that CMMI can use its authority to expand the duration and scope of models being tested, it is imperative that CMMI programs are designed, tested, and implemented in a way that drives towards better value for patients. CMMI has not consistently applied procedures and standards for stakeholder engagement and incorporating patient-centeredness, to the detriment of achieving this goal.

Engaging the patient community is a complex task and will require more than the notice and comment process that are traditionally used by regulatory agencies. However, a more structured process for patient engagement that leverages CMMI’s own best practices along with creative methods employed by organizations such as PCORI and the FDA’s PFDD Initiative will ensure that the patient perspective is well represented in CMMI model tests and improve their likelihood of success.

**Recommended Roadmap**

Based on the practices for stakeholder engagement outlined above, PIPC recommends a roadmap to consistently and effectively engage with stakeholders and advance patient-centered approaches to value-based payment:

1. **Improve oversight of CMMI by creating a Patient Advisory Panel to ensure patient-centeredness in the agency’s work.** CMMI lacks mechanisms to ensure new payment models are consistently developed and evaluated in ways that protect patients and support patient-centered care. In order to ensure APMs are aligned with care that patients value, CMMI’s work should be informed by a Patient Advisory Panel that is tasked with:
   
   o Creating criteria for patient-centeredness per CMMI’s statutory guidance;  
   o Advising on the infrastructure needed for meaningful patient engagement;  
   o Identifying deficits in care that could be addressed by new model tests;  
   o Determining patient-centered quality measures; safeguards; and techniques for shared decision-making;  
   o Assessing CMMI model designs against criteria for patient-centeredness; and  
   o Making recommendations with respect to the impact of model expansions on quality and access to care for patients.

2. **Require CMMI to follow a consistent process to seek input from patients and caregivers in the development of new demonstrations and throughout the implementation and evaluation process.** CMMI should establish and consistently apply a clear process for seeking input from patients, caregivers and other stakeholders early in the
process of developing and testing new APMs. This process should include:

- A mechanism for patients and advocates to proactively propose new model designs and model elements to CMMI;
- Improved advanced communication about CMMI’s work plan for new model tests;
- Formal opportunities for early input into potential model tests (e.g., through an RFIs and/or a design concept paper); and
- A mechanism for regular engagement with patients throughout the implementation process.

3. **Improve the transparency of model test designs and evaluation results.** CMMI should clearly communicate information about its model test designs and their implications for patients. This includes more transparency in:

- The requirements for patient engagement and evidence-based decision-making, such as those relied on by Accountable Care Organizations;
- The measures, particularly measures of patient outcomes and patient centeredness, that are relied upon to evaluate models;
- Model evaluation findings with respect to quality and access to care; and
- Options for patients in CMMI model tests to opt out or seek assistance when they are subject to a CMMI test (e.g., appeals mechanisms, CMMI ombudsman).

To achieve the goals of a value-based health care system, we must prioritize patient care needs and preferences. Targeted reforms to improve CMMI’s patient engagement strategy will ensure that CMMI model designs support patient centeredness and achieve better outcomes that matter to patients.