November 20, 2017

The Honorable Amy Bassano, MA  
Acting Director  
Centers for Medicare and Medicaid Innovation  
7500 Security Boulevard  
Baltimore, MD 21244

RE: Centers for Medicare and Medicaid Innovation (CMMI) Innovation New Direction: Request for Information

Dear Director Bassano:

On behalf of the Cancer Support Community (CSC), an international nonprofit organization that provides support, education, and hope to cancer patients, survivors, and their loved ones, we appreciate the opportunity to respond to the request for comments regarding the Centers for Medicare and Medicaid Services: Innovation Center New Direction. As the largest direct provider of social and emotional support services for people impacted by cancer, and the largest nonprofit employer of psychosocial oncology professionals in the United States, CSC has a unique understanding of the cancer patient experience. Each year, CSC serves more than one million people affected by cancer through its network of 44 licensed affiliates, more than 120 satellite locations, and a dynamic online community of individuals receiving social support services. Overall, we deliver more than $40 million in free, personalized services each year to individuals and families affected by cancer nationwide and internationally.

Additionally, CSC is home to the Research and Training Institute—the only entity of its kind focused solely on the experiences of cancer patients and their loved ones, as well as the Cancer Policy Institute which focuses on advocacy activities to ensure that patients have access to timely, affordable, high-quality, comprehensive care. This combination of direct services, research, and policy uniquely positions CSC to provide feedback on the future direction of the Center for Medicare and Medicaid Innovation (CMMI).

We are pleased to be provided the opportunity to weigh in on the next iteration of CMMI initiatives and respectfully submit the following comments as you seek to advance best practices, lower health care costs, and enhance patient outcomes:

1. Guiding Principles or Focus Areas
We agree that high-quality health care for patients should be the ultimate goal of any CMMI initiative. Innovation can often be spurred when providers are allowed to make choices that work best for them and produce positive outcomes in the best interests of their patients. However, there must be a balance between “burdensome requirements and unnecessary regulations” and
evidence-based metrics and models which ensure that the highest standard of patient care is provided. Further, competition that is based on quality, outcomes, and costs does not go far enough to fully support and integrate patients as equal partners in their care. There are many other factors which patients consider when making treatment decisions including financial, emotional, social, logistical, and legal considerations, among others. It is vital that CMMI fully and continuously engage patients throughout model development, implementation, and evaluation to determine if the health care system is meeting their needs—and those needs must be defined by the patient.

Our health care system should be tailored to the unique values, goals, and preferences of patients. This should be evidenced through measures and metrics that are created, implemented, and evaluated with patients as equal partners as well as reimbursement systems that are flexible to reflect patient-defined outcomes. For example, some cancer patients may value a cure above all else—and our measures and funding mechanisms should reflect that choice. Meanwhile, other patients may value quality versus quantity of life, and in turn, a model that meets the needs of that patient would look different.

“Patient-centered care” has long been a buzzword and a perfunctory checkbox versus meaningful engagement with the most important player in the health care system—the patient. As noted in this RFI, patients, families, and caregivers should be able to take ownership of their health and have the flexibility and information to make choices as they seek care. However, they must be equipped with the tools to ensure that they can make informed decisions that are right for them. This must include education materials at appropriate reading levels and preferred languages, translation and interpretation services if necessary, and health care teams that are trained in providing culturally sensitive and appropriate care. This also must include transparency around the full range of costs associated with treatment and care such as those related to pharmaceuticals, facilities, professional health care services, insurance-related costs, etc. Patients should feel comfortable engaging in a shared decision making process with their health care team and ultimately selecting services that best fit their needs and values.

Further, as CMMI charts the future course for the agency, CSC supports voluntary, small scale testing that is specific to targeted populations. However, it is critical that ongoing work and lessons learned are incorporated into any new model designs or direction. For example, the Oncology Care Model was launched in 2016 and participating practices are currently awaiting data that they can use to inform their future participation. These data will be critical to understanding the impact of the OCM on both practices and patients. CMMI outcomes and evaluation data must be made available as quickly as possible and on an ongoing basis. However, there must also be ample time to conduct robust analyses on practice-generated data as well as patient experience feedback. The CSC RTI is currently undertaking a study to examine the full patient experience within OCM practices versus non-OCM practices. It will be key to the future of the program to understand if the model not only resulted in cost savings but allowed patients to take ownership of their care and work with their provider to achieve optimal outcomes—as they define them.
2. Model Designs

Mental and Behavioral Health

CSC applauds CMMI for outlining mental and behavioral health as a specific area for model testing. The opioid epidemic has brought these issues to the forefront of national consciousness and policy analysis, however psychosocial health issues are inherent in the lives of all Americans, whether personally or with a loved one. Further, when patients are diagnosed with a disease such as cancer, they may be faced with psychosocial challenges they have never before experienced ranging from worry about the future to feeling lonely or isolated and concern about finances, among many others (Buzaglo et al., 2016). Our current health care system is not keeping pace with the demand for these services. A 2016 CSC study found that 71 percent of cancer patients did not receive social or emotional support services. Patients reported that although they felt like they needed the following services, they were unable to access them: general support services (45%), treatment for side effects (39%), eating and nutrition counseling (38%), financial counseling (29%), and mental health counseling (26%). Across all insurance types, patients felt that availability, coverage, and high cost were the reasons why they did not receive these services. Recently, Nipp et al. (2017) found that hospitalized patients with advanced cancer experience many physical and psychological symptoms and that those patients with a higher burden of these symptoms have longer hospital stays and a greater risk for unplanned hospital readmissions. CSC found in a 2017 study that nearly half of all caregivers of cancer patients experience substantial anxiety and elevated fatigue. They expressed a desire for more information about the patient’s condition and assistance managing personal stress, available financial resources, and navigation the health care system.

It is clear that a robust approach to the full range of biopsychosocial health concerns is vital to patients. As the Institute of Medicine (2008) has noted, “It is not possible to deliver good-quality cancer care without using existing approaches, tools, and resources to address patients’ psychosocial health needs.” Further, the National Comprehensive Cancer Network and the American College of Surgeons recognize that addressing psychosocial distress is an integral part of providing comprehensive care to people with cancer. Most recently, the Food and Drug Administration Reauthorization Act (FDARA) of 2017 included language that revised the definition of “patient experience data” to not only include physical but also psychosocial impacts of a “condition, therapy, or clinical investigation.” This is the first statutory acknowledgment of the need to include psychosocial impacts as equally important components of the patient experience. CSC stands ready to assist CMMI as you move forward with model creation that includes mental and behavioral health provisions, which have been proven to be key components to overall health and wellbeing.


Any future CMMI models should be created with the patient at the center of the design. Enhanced patient outcomes—including physical, psychosocial, financial, legal, social, and logistical among others—should be key outcomes driving each model. A diverse body of patients...
should be involved in every step of model design, implementation, and evaluation based on a specific set of standards that provide transparent guidelines for engagement. Any patient or caregiver who wishes to be involved with CMMI should be given ample opportunities to do so. Likewise, patients should be equal partners in their day-to-day care within the practice in which they receive treatment. There should be a patient and family advisory panel in place for each demonstration/model as well as a patient and family advisory panel at each practice helping to guide processes, interventions, and policies that impact patients. Further, the public should be given the opportunity to engage with CMMI through advisory panels and comment periods as well as the opportunity to view evaluation data and results.

Finally, CMMI models must be voluntary and small scale in nature. Mandatory programs, such as the 2016 Part B demonstration project, that would create blanket requirements for providers and practices are inherently not in the best interests of patients as they don’t take into account the unique circumstances posed by characteristics of specific communities. Further, any proposed models should enhance patient access to care and not limit it by restricting the ability of providers to serve patients. Finally, there should be ample time for CMS to test any proposed model, analyze results from both practices and patients, make appropriate adjustments based on this evaluation, and incrementally scale the model to broader populations.

4. Options beyond FFS and MA

Physician Specialty Models
As noted above, the Oncology Care Model (OCM) launched in 2016 and providers are currently awaiting data to determine continued participation. We hope that CMMI will utilize outcomes and evaluation data as well as external findings such as those that CSC will be gathering, to determine if the OCM is achieving its stated goals. Further, those goals should be adjusted as necessary to focus predominantly on access to high-quality patient care and meeting needs as defined by the patient.

The OCM needs to be fully evaluated before elements are disseminated further. Specifically outlined in this proposal is the concept of prepayment. In disease states such as oncology, where patients often receive personalized care based on the unique nature of their disease, a movement towards pre-payment or capitation could put patients at-risk of not receiving the full range of services that they need.

Prescription Drug Models
The era of precision and personalized medicine will require innovative payment structures. Value based contracting (VBC) is a structure that deserves robust testing to determine feasibility for a range of therapies. VBCs should be voluntary to determine goodness of fit for particular therapies before widespread adoption. As noted throughout these comments, however, the patient must be at the center of any VBC arrangement. Endpoints that are incorporated into the value assessments must be driven predominantly by what the patient values, not simply clinical endpoints such as survival or progression-free survival. In a 2015 CSC study of metastatic breast cancer patients, only 5 percent felt that value in care could be defined in an economic exchange context and nearly 40 percent felt that valuable care meant care of a personal value, including time with their physician, quality of life, and engagement in a shared decision making process. Patients should have access to information about VBCs and provided an opportunity to ask
questions and seek assistance to understand their role within these new systems. Finally, regulatory reforms (such as those pertaining to off-label communications, anti-kickback statutes, and government best price guarantees) must be explored to determine how patients will ultimately benefit from VBCs.

**Medicaid-focused Models**

As evidenced by our comments throughout this letter, our focus is centered on the needs, values, and wellbeing of patients. This takes on an additional layer of importance when we are focusing on patients with limited incomes and those from underserved communities. Medicaid-focused models must be specifically tailored to ensure that the voices of historically underrepresented and vulnerable patients have an opportunity to engage in model design, implementation, and evaluation. State-based and local innovations offer opportunities to alter model design to fit the unique needs of patients within defined communities. As noted above, it is vital to offer information at appropriate reading levels and preferred languages. Translation or interpretation services should be readily available and members of the health care team should be trained to provide culturally appropriate and sensitive care.

Additionally, models that focus on dually-eligible beneficiaries will also be vital as these nearly 12 million individuals experience some of the most complex health challenges and often have costly health care needs (Kaiser Family Foundation, n.d.). It is critical that the goals of the Medicare-Medicaid Coordination Office are realized and CMMI can help to ensure that the two programs work together effectively to improve care and lower costs, simplify processes, eliminate regulatory conflicts and cost-shifting between the two programs, and ensure full access to seamless, high-quality care for beneficiaries (Medicaid, n.d.).

Further, Medicaid-focused models should never limit access or reduce care to patients in need. As evidenced by some proposed state Medicaid 1115 waivers initiatives that would close formularies, impose work requirements, or restrict eligibility or enrollment, various stakeholders define innovation and progress differently. It is our position, as a patient advocacy organization, that many of these approaches would harm patients most in need. CMMI should find innovative new ways to truly serve patients most in need, enhance their care experiences, and act in their best interests.

**Medicare Advantage (MA) Innovation Models**

MA Innovation Models should be created and tested to ensure access to high-quality, affordable, timely, comprehensive care to Medicare beneficiaries. Expansion of the MA Value-Based Insurance Design (VBID) model should occur on a voluntary basis. Although we are not opposed to additional flexibility in MA plans, these plans should still be required to cover Part B drugs in the same way that they are covered in Medicare fee-for-service plans.

5. **Beneficiary Engagement in Model Development**
It is critical that beneficiaries are meaningfully engaged in model development from initial planning to implementation and evaluation. Patients should be included on all advisory panels and processes should be in place to solicit and incorporate their feedback in meaningful ways. Their input on quality measures should be a driving force behind implementation and should carry significant weight in the evaluation of practice results.

In Section 1115A of the ACA, the law calls for the evaluation of payment models against “patient-centeredness criteria,” however these criteria have not been made public by CMMI. These criteria should be strongly influenced by patients and caregivers, and made available for public comment before consistent use and implementation. Likewise, meaningful criteria for shared decision making tools and processes should be incorporated into all new models developed by CMMI.

Patients may define “value” very differently than other stakeholders in the health care system. Patient definitions of value are not influential drivers in our health care system which often is determined by therapies and interventions that are seen simply as the best quality at the lowest cost. Patient-reported outcomes have historically been considered unreliable or invalid which has meant a health care system that lacks the voice of the most important stakeholders. As such, CSC is currently developing a validated tool to measure what patients value throughout their cancer care experience. It will be critical for CMMI to utilize tools such as this one to better define and encourage widespread utilization of patient experience data.

6. Payment Waivers
As noted above, government authority to waive specific regulations or safeguards can bring both innovation and risk. It is critical that any payment waivers promulgated by CMMI ensure that the patient is protected and that the model preserves or enhances quality of care to beneficiaries. As our health care system moves away from fee-for-service and towards a value- or outcomes-based care system, it must do so with the patient as a full member of the care team. Innovative payment methodologies should incentive coordinated care at various sites as well as with different health care professionals working in partnership to best serve the patient. This should include eliminating unnecessary burdens for patients. In a 2016 study, CSC found that over half of cancer patients have been told that their prescribed treatment would require prior authorization and 37% were told that a medical test required prior approval, delaying access to needed care. Additionally, 14% of patients were subjected to step therapy requirements and 53% of those patients had to wait 7 to 30 days to receive the originally prescribed medication. Approximately 8.5% decided not to take any medication as a result of these practices. In this study, Medicaid patients were the most likely to experience care delivery delays. Payer processes that delay access to patients dealing with potentially deadly diseases such as cancer must be addressed.

7. Additional Comments

Safeguards
The creation and implementation of various models brings with it the potential for innovation, as well as inherent risk. As such, safeguards must be in place to protect patients. First, patients must be alerted, in language they can understand and process, of the potential to enroll (and not automatic enrollment) in a CMMI demonstration. They must be given ample opportunities to understand the goals of the demonstration, ask questions about their enrollment in the
demonstration, seek assistance while enrolled in the demonstration, and if they choose not to enroll in the demonstration, they must be offered other high-quality, comprehensive, affordable options for their health care needs. Further, patients deserve access to transparent information regarding demonstrations including information about clinical pathways and financial incentives and the potential for those incentives to drive clinical decision making. If they do not agree with their provider’s recommend course of treatment, they should be able to make individual decisions that fit their unique needs and if necessary engage in a rapid appeals process. Patients should also have access to decision support tools that fit their needs. These decision support tools should be created with tremendous input from patients and caregivers, evaluated on an ongoing basis by patients and caregivers, and updated as necessary when new information becomes available.

Within any demonstration or model, patients should not be subjected to coverage or care decisions based on assessments that include cost-effectiveness or quality adjusted life years (QALYs). Banned by the Americans with Disabilities Act (ADA), these types of assessments can limit access to treatments, particularly for people living with disabilities. An example of this included the proposed Part B Demonstration Project that called for the government to make value determinations based on comparative effectiveness and cost effectiveness analyses. This proposal was not meaningfully information by patient input and ultimately was strongly opposed by many in the health care community.

**Authority**
The authority of CMMI to create, implement, and ultimately spread models should occur in a stepwise approach. All findings should be disseminated and commented upon publicly, and widespread implementation should only occur once stakeholders have had ample time to understand, comment, and meaningfully engage in the process and once consequences of the model are well understood. There should be no unanticipated, mandatory demonstrations and Congress should be an active partner in the overall goals of CMMI, ultimately providing oversight to ensure access, affordability, and high quality health care.

**Transparency**
As a government agency, CMMI should operate transparently. As such, we ask that our comments in response to this RFI, and the comments of all interested stakeholders, are published online, without edits, and in perpetuity so that the health care community has access to the full range of feedback.

In closing, we appreciate the opportunity to respond to the RFI regarding the future direction of CMMI. The Center should be a leading voice in innovative new ways to best serve patients across the nation. As our comments reflect, any actions taken by CMMI should put the patient at the forefront, protecting and promoting their access to affordable, timely, high-quality, comprehensive health care. As our health care system continues to evolve, this goal is more
critical than ever before. Please feel free to contact me at 202.650.5382 or linda@cancersupportcommunity.org if you have questions or if we can serve as a resource to your work.

Sincerely,

Linda House, MSM, BSN, RN
President
Cancer Support Community Global Headquarters

References


