December 13, 2019

Seema Verma
Administrator
Centers for Medicare and Medicaid Services (CMS) U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

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

VIA Email: OCF@cms.hhs.gov

RE: Centers for Medicare and Medicaid Innovation (CMMI) Oncology Care First Model: Informal Request for Information

Dear Administrator Verma and 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 provide feedback on the Centers for Medicare and Medicaid Innovation (CMMI) Oncology Care First Model (OCF): Informal Request for Information. CSC supports CMMI’s efforts to learn from the OCM and improve the quality of patient care.

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 is committed to representing the patient voice and it is through this lens that these comments are offered. Each year, CSC serves more than one million people affected by cancer through its network of 47 licensed affiliates, more than 170 satellite locations, and a dynamic online community of individuals receiving social support services. Overall, we deliver more than $50 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 (RTI)—the only entity of its kind focused solely on the experiences of cancer patients and their loved ones. The RTI has contributed to the evidence base regarding the cancer patient experience through its Cancer Experience Registry, various publications and peer-reviewed studies on distress screening, and...
the psychosocial impact of cancer, and cancer survivorship. Below we discuss how the robust work of the RTI may be leveraged to transform and improve care.

Finally, the CSC Cancer Policy Institute (CPI) brings together patient advocates and policy experts to ensure that the voices of cancer patients and their loved ones play a central role in federal and state legislative, regulatory, and executive policy making. We work in partnership with patient advocates, the CSC affiliate network and RTI, and numerous allied health care and oncology organizations to work towards a future where 15.5 million cancer survivors have access to comprehensive, high-quality, timely, and affordable medical, social, and emotional care.

This combination of direct services and research uniquely positions CSC to provide valuable patient and evidence-informed feedback to CMMI and CMS. As expressed in our comments below, CSC supports many aspects of the OCF Model, but we also have areas of concern and/or request additional information or guidance.

**Model Goals**
The underlying goal of the OCF Model is to test “whether an innovative approach to prospectively paying for management and drug administration services provided by oncology practitioners, together with a total cost of care accountability, reduces program expenditures while preserving or enhancing the quality of care for Medicare beneficiaries with cancer or a cancer-related diagnosis.” We want to emphasize the critical importance of *preserving or enhancing the quality of care* as an essential and leading component of the OCF Model.

**Building on the Current Oncology Care Model**
CSC applauds CMMI for stating its intent to build upon the lessons learned to date in OCM, which CSC has identified as providing significant improvements in patient care. Through our own study, *Patient Perspectives on the Oncology Care Model*, we have found that patients who are enrolled in an OCM practice versus a non-OCM practice generally expressed greater satisfaction and an overall better experience with their cancer care. We look forward to sharing additional details regarding our study soon. Although we are encouraged by our findings, there remains little to no time allotted between the conclusion of OCM and the commencement of OCF. As such, CSC urges CMMI to continue in-depth analyses, extrapolation, and incorporation of the lessons learned resulting from the OCM to improve the quality of care, patient experience, and outcomes for cancer patients.

**Potential Model Design Elements**

**Model Timing and Duration**
CSC commends the voluntary nature of the OCF Model for both PGP and HOPD participants. However, absent from the informal RFI is any description of how beneficiaries will be notified of their providers’ participation in the OCF Model and what, if any, information will be required to be shared with beneficiaries regarding the implications of the OCF Model on their care. Through our study on *Patient Perspectives on the Oncology Care Model*, we held focus groups at three OCM practices. Participants were largely unaware of their participation in an OCM practice. Although we know patients receive notices regarding the model, we encourage CMMI
to continue to work with patient advocacy organizations like CSC to craft understandable, meaningful, and transparent information for patients. Patients should receive this information at multiple points during their care and should have opportunities to ask questions and seek alternative care if they wish to do so.

Potential Model Beneficiaries - Assigned Beneficiaries Included in the Monthly Population Payment (MPP)
We support CMMI’s decision to broaden the definition of assigned beneficiary included in the Monthly Payment Population (MPP). This expanded definition both increases the population upon which participants’ prospective monthly payments will be calculated and, of particular importance to CSC, increases the population of beneficiaries that will receive the enhanced services required to be delivered in OCF. The OCF Model defines the population of assigned beneficiaries as “all Medicare FFS beneficiaries (that are eligible for Part A and enrolled in Part B with Medicare as his/her primary payer) who receive an E&M service at the OCF Physician Group Practices (PGP) with a cancer or cancer-related diagnosis designated on the Medicare claim.” Notably, this expanded definition would include beneficiaries with cancer who receive chemotherapy, those who receive hormonal therapy only, and those who receive no cancer-related drugs at all. Defining the assigned patient population in a way that is more representative of an oncology practice’s entire patient population is beneficial to ensuring all patients receive the appropriate enhanced care for their diagnosis. CSC supports this distinction with the OCM, which currently limits the Monthly Enhanced Oncology Services payments for beneficiaries who receive chemotherapy.

Multi-Payer Participation
Similar to our support of broadening the definition of assigned beneficiary to instill benefits on a larger population of cancer patients, CSC also supports CMMI’s consideration of the OCF Model being a multi-payer model where commercial payers and state Medicaid agencies would be invited to partner with CMMI via a signed Memorandum of Understanding to align their oncology value-based payment models with the OCF Model. The main goal of multi-payer alignment, as stated by CMMI, would be to promote a consistent approach across payers. Aligning multi-payers would help address the variability of cancer care that is provided to different populations of patients based not on their diagnosis, but, instead the identity of their payer.

Care Transformation
By requiring PGP participants (which includes both community and hospital-based PGPs) to redesign activities to transform care, including providing enhanced services to all assigned beneficiaries, the OCF Model takes a significant step forward in preserving or enhancing the quality of care Medicare beneficiaries receive. CSC appreciates and agrees with CMMI’s acknowledgement on the importance of the seven delineated redesign activities listed under Care Transformation – five of which are Enhanced Services for all OCF assigned beneficiaries described above. CSC believes these activities are integral to providing quality care for all cancer patients. These seven activities are:

1) Offer beneficiaries 24/7 access to a clinician with real-time access to their medical records;
2) Provide the core functions of patient navigation;
3) Document a care plan for beneficiaries that contain the 13 components of the Institute of Medicine’s (IOM) Care Management Plan;
4) Treat beneficiaries with the therapies consistent with nationally recognized clinical guidelines;
5) Use Certified Electronic Health Record Technology (CEHRT) as specified in regulation (42 C.F.R. 414.14155(a));
6) Utilize data for continuous quality improvement; and
7) Gradually implement electronic patient-reported outcomes (ePROs).

CSC would like to emphasize the importance of assessing and meeting the full range of cancer patients’ needs. Cancer research, treatment, and care should attend to the aspects of life that patients define as the most important – family and friends, career, psychological well-being, exercise and nutrition, etc. We believe that by requiring all assigned beneficiaries to receive the five redesign activities identified as Enhanced Services (items 1, 2, 3, 4, and 7 listed above), the OCF Model will build on the OCM and continue to make strides to incorporate the patient experience and preserve or enhance the quality of oncology care.

CMMI proposes as its seventh PGP participant redesign activity, and the fifth and final Enhanced Service, the gradual implementation of ePROs for the intended purpose to enhance care coordination. CMMI includes a statement that information from ePRO systems can be used for monitoring patient symptoms in clinical care and identifying high-risk patients for complications or utilization of emergency services. CMMI also references recent publications that have highlighted the value of ePROs in helping clinicians to stay aware of patients’ clinical status, translating to improved survival outcomes.

CSC supports the collection of ePROs as a participant redesign activity and as an Enhanced Service for assigned beneficiaries for care coordination, patient symptom monitoring, identifying high-risk patients for complications or utilization of emergency services - but we believe the benefit of collecting and using ePROs is illustrative of the importance of consistently and meaningfully seeking robust patient feedback and patient experience data at all points along the cancer care continuum, including clinical studies, investigational therapies, and shared decision making between provider and patient.

Patients’ experiences living with, treating, and/or managing their disease provides crucial information not otherwise captured through the clinical process. Recognition of the importance of patient experience data and psychosocial impact is evidenced in the 21st Century Cures Act. Title III, Section 3001 of the 21st Century Cures Act (Pub. L. 114-255), as amended by section 605 of the Food and Drug Rehabilitation Act of 2017 (Pub. L. 115-52, 131 Stat 1005 §605. In one of the studies referenced by CMMI in its informal RFI, the results showed significant benefits from the collection and use of PROs, including in an area not discussed above, which is quality of life. Specifically, “[s]ignificant benefits in quality of life as well as secondary outcomes of 1-year quality-adjusted survival (mean: 8.7 months in the PRO group vs 8.0 months in the usual care group; \( P = .004 \)), duration of chemotherapy, and emergency department use were found and previously reported” (Basch et al., 2018). The use of PROs in this study resulted
in both reduced expenditures (emergency department use) and preserved or enhanced quality of cancer care (prolonged life and improved quality of life).

In a 2013 Report Brief by the Institute of Medicine, the IOM stated:

“Clinical research that gathers evidence of the benefits and harms of various treatment options is an essential part of a high-quality cancer care system. Patients, in consultation with their care teams, could use this information to make treatment decisions that are consistent with their needs, values, and preferences. Improving the evidence base will require expanding the breadth and depth of data collected on cancer interventions, including more data on older adults and patients with multiple chronic diseases, as well as more data on patient-reported outcomes, patient characteristics, and health behaviors.

The same IOM Report Brief (2013) found that while many electronic health records and cancer registries are already in place, they are not implemented or integrated in a way that creates a true learning system. CSC’s Cancer Experience Registry, which includes over 12,000 individuals, serves as the cornerstone of our research effort and allows us to measure what matters most to patients. CSC is uniquely positioned and stands ready to assist CMMI in identifying meaningful ePRO measures that are valuable to patients, as well as how to incorporate (without undue burden) such information to improve patient care and achieve outcomes patients have identified as important to them.

In addition, we believe that CMMI should provide additional guidance to participants in the OCF Model so that they better understand how to both collect and use ePROs in clinical care to reduce expenditures while preserving or enhancing the quality of cancer care. CSC concurs with the 2013 IOM’s Report Brief that found “HHS should work with professional societies to create and implement a formal long-term strategy for publicly reporting quality measures for cancer care. They should also prioritize, fund, and direct the development of meaningful quality measures for cancer care with a focus on outcome measures, as well as implement the infrastructure for public reporting.

CSC is eager to work with patients, participants, CMMI and other stakeholders to implement and integrate ePROs and patient experience data into care delivery to improve cancer patients’ quality of life and outcomes.

**Potential Payment Methodology**

**Overview**

In its overview of OCF’s potential payment methodology, CMMI states that under the OCF Model, beneficiary cost sharing would continue to be the same as under FFS. CSC encourages CMS to determine if Medicare beneficiaries may share in the savings resulting from Models under which they receive their care. We believe that the financial toxicity cancer imposes on patients demands that steps be taken to enable patients to share in the savings achieved through reduced expenditures which were realized, in part, thanks to their commitment to fulfilling their patient obligations per their care plan and shared decision making with their provider.
Monthly Population Payment (MPP)
CSC notes that CMMI states that it is considering the inclusion of additional services in the MPP, such as imaging or lab services. CSC is open to the possibility of including such services, but we would need to have more information on the potential impact on patients and their care. However, if additional services are considered, we would like to propose that diagnostic testing be included in such discussions.

Quality Strategy
CSC supports the OCF Model tying quality measures to determine the amount of a participants’ Performance-based Payment (PBP). We believe linking quality measures to payment in this manner rightfully elevates the importance of the quality of care in calculating PBP. We particularly appreciate that a participant’s performance on the OCF Quality Measure Set (which CMMI anticipates could be the same as the measures currently used in OCM) will be applied to a participant’s potential PBP, as well as a participant’s potential PBP recoupment. In both instances, participants with a higher performance measure will be rewarded for their commitment to delivering high quality care.

If the current OCM Quality Measure Set is adopted for OCF, CSC urges CMMI to broaden that Quality Measure Set to include screening for distress (e.g. anxiety, stress, social isolation) as well as depression. Currently, the OCM Measure List - OCM-5 – calls for Preventive Care and Screening: Screening for Depression and Follow-Up Plan, but does not include screening and a Follow-Up Plan for distress. Screening for both distress and depression (and providing a Follow-Up Plan for each) achieves OCF’s goal of reducing expenditures while preserving or enhancing the quality of cancer care.

CSC has found that when patients experience distress that interrupts their work, family, or school life, they have an 86% probability of developing a clinical diagnosis of depression (Miller et al., 2014). Depressed cancer patients incur significantly higher health care charges across multiple cost categories including ambulatory care, emergency department visits, and hospital visits (Mausbach, Bos, & Irwin, 2018; Buzaglo et al., 2014) treatment adherence.

Another clinical trial tested the hypothesis that a psychological intervention can reduce emotional distress, improve health behaviors and dose-intensity, and enhance immune responses. Women who were surgically treated for regional breast cancer were randomly assigned to either the intervention group - small patient groups with one session per week for 4 months – or the assessment group only. The monthly sessions included strategies to reduce stress, improve mood, alter health behaviors, and maintain adherence to cancer treatment and care. The results noted “[a]s predicted, patients receiving the intervention showed significant lowering of anxiety, improvements in perceived social support, improved dietary habits, and reduction in smoking.” (Andersen et al., 2004).

Evaluation
CSC asks CMMI to include language in the OCF Model that clearly defines what and how CMMI will monitor regularly, and in real time, the effect of the OCF Model on beneficiaries. Specifically, well-developed and meaningful considerations need to be included in the OCF Model that address the following issues: 1) what is CMMI’s oversight; 2) how will CMMI
ensure patient stakeholder groups have access to the resulting data; 3) how and when will patient advocate groups be able to provide input on what is and is not working from the patient perspective, and 4) what steps will CMMI take to mitigate any adverse impact on beneficiaries.

**Conclusion**

CSC appreciates the opportunity to provide these comments on the OCF Model. We are pleased to see that patients and issues important to ensuring quality cancer care are incorporated throughout the OCF Model. We would be happy to serve as a resource to CMMI as the process to finalize and implement the OCF Model moves forward. I can be reached at efranklin@cancersupportcommunity.org.

Sincerely,

Elizabeth Franklin, MSW
Executive Director, Cancer Policy Institute
Cancer Support Community Headquarters

**References**

21st Century Cures Act (Title III, section 3001, Pub. L. 114-255), as amended by the Food and Drug Rehabilitation Act of 2017 (section 605, Pub. L. 115-52) (FDARA)


survivors. *Quality of Life Research*, 23, 2855-2863. [https://doi.org/10.1007/s11136-014-0742-4](https://doi.org/10.1007/s11136-014-0742-4)