September 16, 2019

Seema Verma, Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS – 5527-P
P.O. Box 8013
Baltimore, MD 21244-1850

Re: Medicare Program: Specialty Care Models to Improve Quality of Care and Reduce Expenditures; CMS-5527-P

Dear Administrator Verma,

On behalf of the Cancer Support Community (CSC), an international nonprofit organization that provides support, education, and hope to people impacted by cancer, we appreciate the opportunity to submit the following comments in response to the proposed rule to implement a Radiation Oncology (RO) Model under section 1115A of the Social Security Act.

CSC applauds the Centers for Medicare and Medicaid Services (CMS) and the Innovation Center for its efforts to develop a prospective, 90-day episode based payment method to physician group practices (PGPs), hospital outpatient departments (HOPD), and freestanding radiation therapy centers for radiotherapy (RT). The proposed RO Model seeks to preserve or enhance the quality of care furnished to beneficiaries while reducing program spending through enhanced financial accountability for model participants. As with any proposed policy change, the RO Model’s potential implications for patients is at the center of CSC’s comments. With this consideration being paramount, CSC wishes to express its overall support for the goals of the proposed RO Model, subject to specific areas of concern expressed below.

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 over 45 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 Support Community research.
Experience Registry, various publications and peer-reviewed studies on distress screening, and the psychosocial impact of cancer, and cancer survivorship. This combination of direct services and research uniquely positions CSC to provide valuable patient and evidence-informed feedback to CMS.

Background
CMS supports its selection of radiotherapy as an appropriate test subject to further efforts to improve cancer care for Medicare beneficiaries and reduce Medicare expenditures, in part, because radiotherapy is a common treatment impacting nearly two thirds of all cancer patients. The proposed RO Model would replace fee-for-service (FFS) RT payments. CMS notes that a FFS RT payment structure has the potential to lead some providers and suppliers to order increased volume of services to receive higher payments and to detract from investing in improved quality or better care coordination. The bundled prospective payments in the proposed rule would apply to 17 specific cancers and run for five years (currently slated to begin on January 1, 2020 and run through December 31, 2024), with payments being divided into a Professional Component (PC) for services that can only be provided by a physician and a Technical Component (TC) for services not rendered by a physician. However, depending on the circumstance, a provider could potentially receive payment under both PC and TC, referred to as a dual participant in the proposed rule.

Section III.C.8 - Quality
Section III.C.8 of the proposed RO Model, “quality,” is at the heart of the issues CSC deems of critical importance to patients. CSC believes the four quality measures proposed in this section will enhance the quality of care patients receive during RT therapy. CSC supports the proposed rule’s connection of these quality measures to payment as set forth in the calculation of such payments in Section III.C.8.f. The four identified quality measures proposed in the RO Model are:

1. Oncology: Medical and Radiation - Plan of Care for Pain – NQF #0383; CMS Quality ID #144
2. Preventive Care and Screening: Screening for Depression and Follow-Up Plan – NQF #0418; CMS Quality ID #134
3. Advance Care Plan – NQF #0326; CMS Quality ID #047
4. Treatment Summary Communication – Radiation Oncology

Pain is the most common symptom in cancer, occurring in approximately one quarter of patients with newly diagnosed malignancies, one third of patients undergoing treatment, and three quarters of patients with advanced disease. The proposed RO Model assesses “whether a plan of care for pain has been documented for patients reporting pain, and aims to improve attention to pain management and requires a plan of care for cancer patients who report having pain to allow for individualized treatment.” CSC believes the inclusion of this assessment will improve the quality of patient care.

The second Quality Measure proposed in the RO Model, Preventive Care and Screening: Screening for Depression and Follow-Up Plan, is a process measure that assesses the “percentage of patients screened for clinical depression with an age-appropriate, standardized tool and who
have had a follow-up care plan documented in the medical record.” CMS supports including the depression screening and follow-up plan in the RO Model noting that some of the side effects of RT have been identified as having a detrimental effect on a patient’s quality of life and could potentially impact the patient beyond physical discomfort or pain. CSC strongly agrees, but urges CMS to broaden this quality measure to include screening for distress (e.g. anxiety, stress, social isolation) as well as for depression. An investigation which documented the magnitude of anxiety patients experienced in response to one particular stressful form of radiation treatment reported that, “[p]erhaps the most obvious clinical outcome from this investigation was the description of the stressful nature of this radiation treatment for gynecological patients.” The results of another clinical trial which tested the hypothesis that a psychological intervention can reduce emotional distress, improve health behaviors and dose-intensity, and enhance immune responses, 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.” Depressed cancer patients incur significantly higher health care charges across multiple cost categories including ambulatory care, emergency department visits, and hospital visits. Patients with depression also have lower rates of treatment adherence. Follow-up care in addition to screening is essential. Patients who have the full range of their needs assessed and met are more likely to maintain enrollment in a study, adhere to treatment, and ultimately experience improved outcomes – as they define them. Studies have shown that breast cancer patients engaged in social and emotional interventions had significant psychological and physiological benefits over those who do not, including survival advantages (1.5 years), reduced risk of recurrence (45%), as well as decreases in anxiety, and fewer symptoms and toxicities from cancer treatment.

Advance Care Plan, the third Quality Measure included in the proposed RO Model, describes the percentage of patients aged 65 years and older that have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan. Advanced care planning has been associated with lower rates of ventilation, resuscitation, intensive care unit admission, earlier hospice enrollment, and decreased cost of care at the end of life. CSC applauds CMS for including advance care planning as a Quality Measure in the proposed RO Model and agrees with CMS’s assertion that it is essential that a patient’s wishes regarding medical treatment are established as much as possible prior to incapacity.

The fourth and final Quality Measurement, Proposed Treatment Summary Communication – Radiation Oncology, is included to improve communication from RT services to the physicians providing continuing care and to the patient within one month of completing treatment. As explained by CMS, this Quality Measure assesses care coordination and communication between providers during transitions of cancer care treatment and recovery – both essential to quality care. Promoting effective care coordination among different cancer treatment providers, as well as ensuring timely and transparent communication between providers, and between providers and patients, is a necessary element to quality patient care.

**Proposed CAHPS Cancer Care Survey for Radiation Therapy**
In addition to the four Quality Measures set forth above, CMS proposes to include a CAHPS Cancer Care Survey for Radiation Therapy, the results of which would subsequently be used as the basis to propose a set of patient experience measures.\textsuperscript{xvii} As noted in the proposed RO Model, variations of the CAHPS survey are widely used measures of patient satisfaction and experience of care and are responsive to the increasing shift toward incorporation of patient experience into quality measurement and pay-for-performance programs.\textsuperscript{xviii} Patients’ experiences living with, treating, and/or managing their disease provides crucial information not otherwise captured through the clinical process. The importance of patient experience data is particularly elevated with regard to collecting and including the psychosocial impact of a disease. Recognition of the importance of patient experience data and psychosocial impact is evidenced in the 21\textsuperscript{st} Century Cures Act which provides “patient experience data” includes data that –

1. Are collected by any persons (including patients, family members and caregivers of patients, patient advocacy organizations, disease research foundations, researchers, and drug manufacturers); and

2. Are intended to provide information about patients’ experiences with a disease or condition, including –
   A. The impact (including physical and psychological impacts) of such disease or condition, or a related therapy or clinical investigation on patients’ lives; and
   B. Patient preferences with respect to treatment of such disease or condition.\textsuperscript{xx}

Patient input not only informs the clinical context and provides insight to frame the assessment of benefits and risks, but it can also serve as a direct source of evidence for use in clinical studies in investigational therapies and to assist shared decision making between provider and patient. CSC strongly supports including patient experience measures in the proposed RO Model, and urges its incorporation before PY 3 as currently proposed.

**Proposed Clinical Data Collection**

CSC repeatedly promotes the importance of collecting patient experience data in addition to clinical data to provide quality cancer care to all patients. As discussed in detail above, we applaud the four Quality Measures included in the proposed RO Model, as well as the proposed CAHPS Cancer Care Survey. CSC wants to take this opportunity to support the Proposed Clinical Data Collection requirements included in Section III.C.8.e of the proposed RO Model. This would require professional participants and dual participants to report basic clinical information not available in claims or captured in the proposed Quality Measures, such as cancer stage, disease involvement, treatment intent, and specific treatment plan information.\textsuperscript{xx} The required collection of quality measures and clinical data will afford patients the opportunity to receive the highest level of quality care.

**Areas of Concern and Need for Guardrails**

On July 15, 2018, CSC and Friends of the Cancer Policy Institute provided comments on the HHS *Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*. Included in those comments are guiding principles we asked Secretary Azar to utilize as policy changes are made in an effort to curb drug pricing. The guiding principles set forth in those comments are included below. We believe these are equally applicable to CSC’s position on the proposed RO Model.

These guiding principles are:
1. Policy changes should be considered in a broad context which places patients at the center. It is vital to understand the implications that each policy change will have on the health care system and in the lives of individual patients.

2. We urge HHS to pursue efforts to rein in drug pricing in concert with initiatives that address affordability and stability in the health care marketplace more broadly. We urge the Administration to revisit and halt any regulations and policies that are rolling back consumer protections under the ACA, including Medicaid, which were improving affordability and access for Americans.

3. Policy changes should be transparent to all stakeholders.

4. Policy changes should improve patient access to appropriate therapies.

5. Policy changes should improve affordability for patients.

6. Policy changes should be accompanied with information to help patients understand the potential impact to them. Such information should be provided in language they can understand and process.

7. Patients should be given ample opportunity and time to understand policy changes, ask questions, and seek assistance necessary to maintain access to care.

8. Decision support tools should be provided to patients. These 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.

Notwithstanding CSC’s overall support for the proposed RO Model due in large part to the proposed quality measures, we need to express concern and reservation in connection with some of the proposed provisions which CSC believes may conflict with our guiding principles above.

Keeping true to CSC’s guiding principle that all policy changes should place patients at the center, we ask CMS to include language that clearly defines what and how CMS will do to monitor regularly, and in real time, the effect the RO Model will have on beneficiaries. Specifically, well-developed and meaningful guardrails need to be included in the RO Model that address the following issues: 1) what is CMS’s oversight, 2) how will CMS 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 CMS take to mitigate any adverse impact on beneficiaries.

While CSC appreciates the proposal to require professional participants and dual participants to notify RO beneficiaries of the beneficiary’s inclusion in the model through a standardized written notice, CSC expresses general concern for the mandatory nature and the breadth of the proposed RO Model (capturing approximately 40% of eligible radiation therapy episodes), for both patients and RT providers and suppliers. As currently designed, beneficiaries who need RT
services living within a covered geographic area who do not want to participate in the RO Model would be forced to travel (often significant distances) to obtain care – resulting in tremendous burden, financially and otherwise, for patients already confronting a serious medical condition. Patients living in rural America would be disparately impacted by the mandatory requirement of the proposed rule. CSC urges CMS to provide patients with a mechanism to opt-out of the RO Model.

CSC appreciates the attention to detail CMS committed to the proposed RO Model. However, a consideration accompanying this detail is the need for ample time for patients to be informed of the proposed rule and to ask questions regarding its potential implications on their care. Not unrelated, providers of RT must also be provided adequate time to understand and prepare for the requirements in order to ensure they are ready to provide quality care to their patients.

The design of the payment model under the proposed RO Model groups together different modalities for specific cancer types, often with variable costs, into a single payment that reflects average treatment costs. Beneficiaries receiving RT services in the proposed RO Model will continue to pay 20% coinsurance. While the payment model may result in cost savings to some beneficiaries, the grouping of the different modalities into a single payment may, depending on the services received, result in some beneficiaries’ cost-sharing increasing under the proposed RO Model. With beneficiaries having no ability to opt out if living in the designated geographic area, CSC urges CMS to adopt measures to off-set any cost-sharing increases incurred by beneficiaries in the RO Model. As expressed in the 5th guiding principle set forth above, policy changes should improve affordability for patients. Under no circumstances should beneficiaries bear the burden of assuming greater cost in order to reduce Medicare program spending.

CSC asks CMS to ensure that the proposed payments to PC, TC, and dual participants are sufficient to adequately compensate providers for their services to ensure that beneficiaries receiving RT services under the RO Model receive the same quality of care as beneficiaries not included in the proposed RO Model. Consideration should expand beyond direct payment and include such factors as the ability to purchase new and/or innovative technologies that may become available during the timeframe under the proposed RO Model.

The RO Model makes reference to patient navigators in its discussion of the Oncology Care Model. However, CSC notes the absence of provisions calling for the inclusion of patient navigators within the RO Model itself. The episodic nature of radiation oncology, generally, coupled with the potential number of provider touchpoints for patients in the RO Model – physician group practices (PGPs), hospital outpatient departments (HOPD), and freestanding radiation therapy centers for radiotherapy (RT) – augments the importance of patient navigators in ensuring effective continuum of care for patients receiving RT. Poor coordination of care during periods of transition can lead to poor patient quality of life, increased utilization of emergency department services and hospital readmission rates, duplicated tests, and medication errors. Navigators play pivotal roles in recognizing the stages of transition, identifying patients at highest risk for gaps in care and providing logistical support, empowering patients by education about anticipated events throughout the trajectory of care, and facilitating communication among providers and between patients and providers to result in better
continuum of care overall. CSC voices its strong recommendation to include a prominent role for patient navigators in the RO Model.

**Conclusion**
CSC appreciates the opportunity to provide our comments on the proposed RO Model. We appreciate issues that matter to patients being incorporated into the proposed RO Model. However, we ask that CMS please give serious consideration to finding methods to address the areas of concern to patients that CSC has identified. We would be happy to serve as resource to CMS in connection with the proposed RO Model moving forward. I may be reached at efranklin@cancersupportcommunity.org.

Sincerely,

Elizabeth Franklin, MSW
Executive Director, Cancer Policy Institute

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1 Federal Register, Vol. 84, No. 138, Thursday, July 18, 2019, Proposed Rules, Section III.B.1, Page 34490.


