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September 12, 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

Re: CMS-5527-P: Medicare program; Specialty Care Models to Improve Quality Care and Reduce Expenditures, 84 Fed. Reg. 34478 (July 18, 2019)

Dear Administrator Verma:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to comment on the proposed Medicare radiation oncology (RO) model. ACS CAN, the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society, supports evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem. ACS CAN empowers advocates across the country to make their voices heard and influence evidence-based public policy change as well as legislative and regulatory solutions that will reduce the cancer burden.

Approximately 1.7 million new cancer cases are expected to be diagnosed in 2019.[1] Many of these new patients will likely be enrolled in the Medicare program since age is one of the most important risk factors for cancer. Therefore, changes to the way cancer is treated in the Medicare program will have a direct impact on those beneficiaries who will be diagnosed with the disease this year.

ACS CAN commends CMS for its emphasis on improving the quality of care for Medicare beneficiaries with cancer through the new payment model while at the same time reducing program spending. It is critical that improved patient care be the central goal of new payment or delivery models and any cost savings should be the result of improved patient care. To that end, our comments on the proposed rule focus specifically on how the proposed RO model could affect cancer patients undergoing radiation treatment and what changes could further enhance the model for patients.

Beneficiary Protections

ACS CAN appreciates the attention the proposed rule pays to ensuring that beneficiaries participating in the RO model will receive the best possible care. However, we believe the proposed rule can be improved to provide additional protections to beneficiaries, as outlined in our letter:

[1] American Cancer Society, *Cancer Facts and Figures* 2019. Atlanta: American Cancer Society; 2019. Available at https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2019/cancer-facts-and-figures-2019.pdf.

Beneficiary Choice: Under the proposed rule physician group practices, hospital outpatient departments and free-standing radiation therapy centers within selected core based statistical areas (CBSAs) would be randomly selected for required participation in the RO model. The proposed rule specifies that beneficiaries remain free to choose any provider they prefer regardless of whether the provider is a participant in the model or not and proposes to codify beneficiary choice.

Allowing beneficiaries the freedom to choose their own provider ensures that cancer patients will be able to seek treatment from the practitioner that best meets their needs. However, the proposal is unclear how beneficiary choice can be guaranteed if all of the providers within a specific CBSA are participating in the RO model. We urge CMS to clarify how beneficiaries will retain their freedom to choose a provider in such instances.

Beneficiary Notification: The proposed rule requires that practitioners notify beneficiaries of their participation in the RO model in writing at the time of a treatment planning session. CMS will provide the notification template which – other than including logos and contact information – providers may not change.

How beneficiaries are informed about their participation in the RO model will greatly influence their perception of the model and their willingness to stay with RO model providers. If a beneficiary with cancer believes that participating in the model will somehow limit his/her access to the best cancer treatment or lessen the quality of their care, they will likely look for a physician outside of the model. Therefore, how the information about the model is presented is critical.

ACS CAN strongly urges CMS to solicit feedback on the proposed templates from patient advocacy organizations. In the past, when information about aligning beneficiaries with Accountable Care Organizations (ACOs) was being crafted, CMS neglected to reach out to patient/beneficiary groups prior to sending out the notices and, unfortunately, the mailings that went to beneficiaries created considerable confusion. Patient advocacy groups have expertise in how to communicate with cancer patients and can provide CMS with invaluable advice on how the information about the RO model should be presented.

Beneficiary Selection and Potential for Discrimination: In order to be eligible to participate in the RO model, beneficiaries would have to have a diagnosis of at least one of the seventeen cancers identified by CMS and receive radiation therapy services from a participating provider in one of the selected CBSAs. To prevent model participants from "cherry-picking" a beneficiary with a better prognosis, or what the proposal refers to as "lemon-dropping" beneficiaries with comorbidities, RO participants will be required to take all "at-risk" beneficiaries who otherwise would qualify for the program.

ACS CAN applauds CMS's goal of ensuring that all eligible Medicare cancer patients could participate in the program. At the same time, we urge CMS to specify how it will ensure that RO model participants comply with these requirements. Specifically, we ask that CMS detail how it will monitor beneficiary enrollees, how it will identify potential patterns that indicate providers have either "cherry-picked" or "lemon-dropped" and specify what course of action CMS will take if it is discovered that certain beneficiaries have been discriminated against.

Coverage of Part A and B Services: The proposed rule requires that RO model participants continue to make medically necessary covered services available to beneficiaries to the extent required by law. The proposed rule defines "medically necessary" services as reasonable and necessary for the diagnosis and treatment of an injury or to improve the functioning of a malformed body part. It also defines "covered services" to mean the scope of health care benefits described in sections 1812 (Part A) and 1832 (Part B) of the Social Security Act. ACS CAN believes that beneficiaries participating in the RO model must have access to the same range of benefits as other Medicare beneficiaries.

Beneficiary Data: CMS proposes to collect quality, clinical, and administrative data and would share with RO model participants certain de-identified patient data. CMS would further establish requirements for the public release of de-identified patient data.

ACS CAN strongly urges CMS to ensure that the data collection and sharing process is fully transparent and that beneficiaries are informed, before agreeing to participate in the RO model, that de-identified data will be collected and specifically how it will be used by CMS and the RO participants.

Beneficiary Appeal Rights: The proposed rule also specifies that beneficiaries who are participating in the RO model would retain their full Medicare appeal rights. CMS states that beneficiaries should not lose the right to appeal claims for Medicare items and services solely because the beneficiary's provider or supplier is participating in the RO model.

ACS CAN supports this provision of the rule. It is imperative that beneficiaries in the RO model have the same rights as other Medicare beneficiaries to appeal any coverage decision they believe is unfounded.

Description Model Materials and Activities

CMS is proposing to prohibit RO model participants from using or distributing descriptive materials such as ads, brochures, letters, web sites, etc. that are "materially inaccurate or misleading" to prevent marketing efforts that could mislead or confuse beneficiaries. Further, CMS reserves the right to review descriptive materials for accuracy.

We applaud CMS for its intent to protect beneficiaries from misleading or fraudulent information. However, because of the potential for confusion resulting from misleading marketing materials ACS CAN believes it is in the best interest of beneficiaries, CMS, and the RO model if CMS reviews all marketing materials from RO participants prior to the materials being made available to beneficiaries. A random sampling for review after the materials have already been sent to beneficiaries is inadequate. CMS has considerable experience in reviewing marketing materials before they are distributed.

CMS requested specific input on whether is should include a disclaimer on materials indicating that CMS prohibits misleading information. We strongly agree with including a disclaimer and also suggest the inclusion of contact information for beneficiaries to use if they suspect the information provided is inaccurate.

Quality of Measures and Model Evaluations

CMS proposes the use of four quality measures for evaluating the RO models. Three of the measures – a plan of care for pain, screening for depression, and advance care plans – are National Quality Forum (NQF) endorsed process measures. CMS will also use the CAHPS Cancer Care Survey to collect information from beneficiaries. CMS states that by plan year three it will propose a set of patient experience measures based on the CAHPS Cancer Care Survey.

While the process measures that CMS has proposed are logical, they are – by nature – about process and not the actual delivery of care. For instance, it makes perfect sense for an RO participant to be required to develop a plan for care of patient pain. But equally important is whether this plan is implemented, and patient pain alleviated. In the absence of outcomes measures, patient experience measures are a good indicator of whether and how changes being implemented in the model are actually achieving CMS's stated goal of improving quality. We appreciate the use of the CAHPS survey, but we urge CMS to accelerate the development of actual patient experience measures for use in the RO model.

In the RO model description, CMS outlines its plans to monitor RO participants for compliance with model requirements including through site visits and medical record audits. ACS CAN also supports CMS interviews with beneficiaries and caregivers to ascertain their treatment experience through the model. These interviews could provide valuable, real-time perspectives on the experience of patients.

As part of the RO model evaluation, CMS proposes to assess the impact of the model based on several factors including whether patient experience of care improved. We also suggest that CMS consider assessing whether patient outcomes improved as well. Understanding that cancer is a serious condition, changes in the way care is delivered to cancer patients, improvements in the quality of care that is delivered, and the inclusion of patients in decisions can have a profound impact on the treatment outcomes and should be included as part of the evaluation.

Conclusion

ACS CAN appreciates the opportunity to offer comments on the proposed rule for the RO model. We support improving the delivery of care for cancer patients and look forward to working with CMS on the model. We urge you to actively engage cancer patient advocates in the final design and implementation of the RO model to help ensure its success. Please feel free to contact Kirsten Sloan, Vice President for Policy at Kirsten.Sloan@cancer.org with any questions about our comments.

Sincerely,

Lisa A. Lacasse, MBA
President