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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

Re: Oncology Care First Model: Informal Request for Information (November 1, 2019)

Dear Administrator Verma:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to comment on the informal request for information (RFI) regarding a potential Oncology Care First (OCF) 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 and the Innovation Center for its emphasis on improving the quality of care for Medicare beneficiaries with cancer while at the same time reducing program spending. This emphasis is clear in the implementation of CMS' current Oncology Care Model (OCM). As CMS looks to its next model, it is critical that improved patient care be the central goal, and any cost savings should be the result of improved patient care. To that end, we offer the following comments to the RFI. We also offer our cancer expertise and technical assistance to you and to potential and eventual participants in the model, and we would welcome the opportunity to discuss this in more detail.

Eligible Beneficiaries

CMS proposes to use a Monthly Population Payment (MPP) intended to cover the costs of management and administration services. A participating OCF practice will receive this payment based on the number of qualifying beneficiaries to whom it provides services. CMS proposes the definition of an eligible beneficiary as "all Medicare FFS beneficiaries…who receive an E&M [Evaluation & Management] service at the OCF PGP [Physician Group Practice] with a cancer or cancer-related diagnosis designated on the Medicare claim."[2] As CMS notes in the RFI, this is a broader population of beneficiaries than in OCM, which limits the model to beneficiaries who receive chemotherapy during six-month windows.

ACS CAN supports including all patients with cancer or a cancer-related diagnosis in the group of assigned beneficiaries in the MPP. While chemotherapy is a common and important cancer treatment, not all cancer patients receive it. Furthermore, a cancer patient's need for the services the MPP is designed to support is not necessarily limited to the 6 months after he or she initiates chemotherapy, as applicable. For example, many patients have surgery before they begin chemotherapy, and would benefit from patient navigation services and the cost-sharing estimates required as part of the MPP. Broadening the group of assigned beneficiaries in this way will more comprehensively compensate PGPs for the services they provide to their cancer patients. It will allow more cancer patients to benefit from management and administration services – particularly the Enhanced Services PGPs are required to provide under the model.

It would be useful for CMS to more clearly define what it means by "cancer-related diagnosis." We encourage CMS to provide this clarity and examples in the final rule.

We also note that under the proposed definition of beneficiaries eligible for the MPP piece of the model, PGP participants might have an incentive to delay transitioning cancer survivors back to primary care – because continuing to care for such survivors would result in higher MPPs. While some cancer survivors need to remain under the care of their oncologist, others might be better served in primary care. ACS CAN encourages CMS to monitor this carefully – perhaps by tracking how many new patients the PGPs are serving – and include information about this in its evaluations of the new model.

Care Transformation

CMS states that the potential OCF model would require PGP participants to implement seven care transformation services for all assigned OCF beneficiaries:

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]
3. Document a care plan for beneficiaries that contains the 13 components of the Institute of Medicine's Care Management Plan;
4. Treat beneficiaries with therapies consistent with nationally recognized clinical guidelines;
5. Use Certified Electronic Health Record Technology as specified in regulation;
6. Utilize data for continuous quality improvement; and
7. Gradually implement electronic patient-reported outcomes (ePROs).

The first six of these activities are currently required in OCM. The seventh requirement, ePROs, would be new to the OCF model, and CMS states this addition is "intended to enhance care coordination."[4]

ACS CAN has supported the OCM's inclusion of care transformation practices from the beginning of that model. We believe that for patients, the requirement to provide these services is one of the most impactful elements of the model. We agree with CMS' statement that these activities "continue to be critical for high-quality care," and its wish to "continue supporting and building on the practice transformation work from OCM participants." We strongly encourage CMS to continue to include these requirements in the OCF model.

Patient Navigation

ACS CAN is particularly supportive of the requirement that PGP participants provide the core functions of patient navigation. For individuals with chronic conditions like cancer, trying to coordinate services

while juggling treatment and employment and/or family obligations adds an additional layer of stress that can negatively impact the outcome of their care.

Evidence continues to build that patient navigation leads to better outcomes for patients, system efficiencies, and a significant return-on-investment. Navigated patients are: more likely to initiate treatment within 30-60 days from diagnosis,[5,6] have increased adherence to recommended cancer screening[7,8,9] and cancer care,[10] increased smoking cessation,[11] improved quality of life[12] and increased patient satisfaction.[13] Studies have also shown that patient navigation decreases hospital readmission among older high risk, safety-net patients;[14] and decreases emergency department and admissions among patients with advanced cancer.[15]

The American Cancer Society (ACS) has a long history of working to help cancer patients by training and supporting patient navigators. The ACS Patient Navigator Program, which began in 2005, is a community-based support program designed to eliminate barriers to early diagnosis and treatment of cancer. This program offers individualized assistance to patients, families and caregivers from diagnosis through survivorship. There are 60 American Cancer Society Patient Navigators currently working in public and private health care institutions across the country. In 2018, these patient navigators reached over 39,000 patients and caregivers, approximately 53 percent of whom are classified as medically underserved.

For all these reasons, ACS and ACS CAN are clearly invested in giving more cancer patients access to patient navigators. We are pleased to see that the patient navigation requirement will continue in the potential OCF model, but we also encourage CMS to consider ways to use this requirement to build on the successes of OCM – instead of just carrying over the same requirement.

The evaluation of the OCM for performance period one[16] – the only evaluative information available currently – showed that OCM practices are incorporating patient navigation services. However, provision of specific services like arrangements for transportation or language translation is not universal; and some OCM practices do not employ dedicated navigators. The report also notes that some practices "rely at least in part on nurse navigators at an affiliated or neighboring hospital where the patient had initial surgery."[17] The report authors also state that "two independent practices increased their patient navigation/care coordination staff for OCM,"[18] implying that other OCM practices did *not* increase their patient navigation staff for the model. While these results show some promising steps to improving patient outcomes through patient navigation, ACS CAN urges CMS to continue to improve patient navigation efforts and carefully monitor the results. We also urge you to work with patient advocacy groups with expertise in patient navigation programs, including the ACS and ACS CAN.

While we recognize the importance of OCF PGP participants having flexibility in implementing the patient navigation requirement, we encourage CMS to make the following changes to the requirement and its implementation:

- **Provide more comprehensive information about patient navigation to PGP applicants and eventual participants.** The RFI links to the description of an inactive National Cancer Institute demonstration project to define "core functions of patient navigation"[19] – and does not make clear which elements of this web page, if any, are actually required. We urge CMS to instead list the patient navigation services it expects PGP participants to provide to patients – while allowing the practices the flexibility to determine how to provide the services. In determining

the list of required patient navigation services, we encourage CMS to consult with national experts and relevant stakeholders, including the National Navigation Roundtable.[20]

- **Clarify that PGP participants must designate patient navigators on staff.** Participants should not be relying on other providers or organizations outside of the model to provide these services to their patients (unless they are specifically contracting with outside organizations to guarantee provision of navigation services to OCF beneficiaries) and requiring such staff designations will also encourage practices to fully incorporate these services into their workflow. CMS could continue to give PGP participants the flexibility to determine which types of staff they designate as navigators, and whether to have staff devoted full-time to this function, or to have part of multiple staff-persons' time designated towards patient navigation.
- **Require specific data to be collected and reported regarding how PGP participants are implementing the patient navigation requirement.** We encourage CMS to hold practices accountable for this requirement through its evaluation process, including asking practices which patient navigation functions it is providing, which and how many staff are designated as navigators, and how this function is incorporated into patient workflow. This will not only hold practices accountable for this requirement, but also provide valuable information to the public and to other practices who want to incorporate patient navigation.
- **Continue to provide technical assistance and educational opportunities.** In July 2017, ACS staff presented on a webinar for OCM participants regarding patient navigation. We would be happy to discuss further opportunities like this with CMS. Additionally, we encourage CMS to provide ongoing resources aimed at improving the quality of patient navigation provided at PGP participants – including a mechanism that would allow designated navigators in each practice to communicate with each other.

Potential Payment Methodology

CMS specifies that "under the OCF Model, beneficiary cost sharing would continue to be the same as under FFS [fee-for-service], as it would absent the Model."[21]

One of the goals of the OCF Model is to generate cost-savings for the Medicare program, and therefore indirectly taxpayers. The model is also structured to financially benefit the providers. However, in this note CMS explicitly states that the patient will not be sharing in any of these cost-savings. ACS CAN understands the challenges in modifying patient cost-sharing in this case, but we do encourage CMS to consider ways to allow the beneficiary to share in the cost-savings generated by the model. At the least, we encourage CMS to include in its evaluation an analysis of how beneficiary cost-sharing is aligned – or misaligned – with the services beneficiaries are receiving under the model.

Quality Strategy

CMS states in the RFI that it "anticipates that the OCF Model Quality Measure Set could be the same as the measures currently used in OCM." It was unclear the extent to which there has been an evaluation of the measure set in the OCM and whether the current measures proved adequate. We urge this kind of evaluation before the measure set is used for the OCF model.

Conclusion

ACS CAN appreciates the opportunity to offer comments on the informal RFI for the Oncology Care First 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 OCF model to help ensure its success. Please feel free to contact Jennifer Hoque at Jennifer.Hoque@cancer.org with any questions about our comments, or to schedule a discussion with the American Cancer Society and ACS CAN experts.

Sincerely,

Lisa A. Lacasse, MBA
President

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[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.

[2] Centers for Medicare and Medicaid. Oncology Care First Model: Informal Request for Information. November 1, 2019. https://innovation.cms.gov/Files/x/ocf-informalrfi.pdf. See pg. 3.

[3] CMS includes this footnote: "Please refer to this link for more information about patient navigation: https://www.cancer.gov/about-nci/organization/crchd/disparities-research/pnrp#PNRP-Overview."

[4] Centers for Medicare and Medicaid. Oncology Care First Model: Informal Request for Information. November 1, 2019. https://innovation.cms.gov/Files/x/ocf-informalrfi.pdf. See pg. 6.

[5] Freund et al., "Impact of Patient Navigation on Timely Cancer Care: The Patient Navigation Research Program." Journal of the National Cancer Institute 106, no. 6 (June 2014): dju115, https://doi.org/10.1093/jnci/dju115.

[6] Ramirez et al., "Reducing Time-to-Treatment in Underserved Latinas with Breast Cancer: The Six Cities Study." *Cancer* 120, no. 5 (March 1, 2014): 752–60, https://doi.org/10.1002/cncr.28450.

[7] Nasar U Ahmed et al., "Randomized Controlled Trial of Mammography Intervention in Insured Very Low-Income Women.," Cancer Epidemiology, Biomarkers & Prevention: A Publication of the American Association for Cancer Research, Cosponsored by the American Society of Preventive Oncology 19, no. 7 (July 2010): 1790–98, https://doi.org/10.1158/1055-9965.EPI-10-0141.

[8] Taylor et al., "A Randomized Controlled Trial of Interventions to Promote Cervical Cancer Screening among Chinese Women in North America."

[9] Karen E Lasser et al., "Colorectal Cancer Screening among Ethnically Diverse, Low-Income Patients: A Randomized Controlled Trial.," Archives of Internal Medicine 171, no. 10 (May 23, 2011): 906–12, https://doi.org/10.1001/archinternmed.2011.201.

[10] Naomi Y Ko et al., "Can Patient Navigation Improve Receipt of Recommended Breast Cancer Care? Evidence from the National Patient Navigation Research Program.," Journal of Clinical Oncology: Official Journal of the American Society of Clinical Oncology 32, no. 25 (September 1, 2014): 2758–64, https://doi.

[11] Karen E. Lasser et al., "Effect of Patient Navigation and Financial Incentives on Smoking Cessation Among Primary Care Patients at an Urban Safety-Net Hospital," JAMA Internal Medicine 177, no. 12 (December 1, 2017): 1798, https://doi.org/10.1001/jamainternmed.2017.4372.

[12] Janine Giese-Davis et al., "Peer-Counseling for Women Newly Diagnosed with Breast Cancer: A Randomized Community/Research Collaboration Trial.," Cancer 122, no. 15 (August 1, 2016): 2408–17, https://doi.org/10.1002/cncr.30036.
[13] Pascal Jean-Pierre et al., "Satisfaction with Cancer Care among Underserved Racial-Ethnic Minorities and Lower-Income Patients Receiving Patient Navigation," Cancer 122, no. 7 (April 1, 2016): 1060–67, https://doi.org/10.1002/cncr.29902.
[14] Richard B Balaban et al., "A Patient Navigator Intervention to Reduce Hospital Readmissions among High-Risk Safety-Net Patients: A Randomized Controlled Trial.," Journal of General Internal Medicine 30, no. 7 (July 2015): 907–15, https://doi.org/10.1007/s11606-015-3185-x.
[15] Kvale EA Rocque GB, Williams CP, Jones MI, Kenzik KM, Williams GR, AzueroA, Jackson BE, Halilova KI, Meneses K, Taylor RA, Partridge E, Pisu M, "Healthcare Utilization, Medicare Spending, and Sources of Patient Distress Identified during Implementation of a Lay Navigation Program for Older Patients with Breast Cancer," Breast Cancer Res Treat 167, no. 1 (2018): 215–23, https://doi.org/10.1007/s10549-017-4498-8.
[16] Abt Associates. Evaluation of the Oncology Care Model: Performance Period One. December 2018. https://innovation.cms.gov/Files/reports/ocm-secondannualeval-pp1.pdf
[17] Ibid. See pg. 63.
[18] Ibid.
[19] https://www.cancer.gov/about-nci/organization/crchd/disparities-research/pnrp#PNRP-Overview
[20] See https://navigationroundtable.org/
[21] Abt Associates. See pg. 6.