October 19, 2020

Christina Ritter, Director
Center for Medicare and Medicaid Innovation
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Innovation for High-Value Radiotherapy: An Informal Request for Information on Radiation Oncology Model Clinical Data Elements (CDEs) from the Center for Medicare and Medicaid Innovation

Submitted electronically via e-mail to RadiationTherapy@cms.hhs.gov*

Dear Director Ritter,

I am pleased to submit these comments on behalf of the Association for Clinical Oncology (ASCO) in response to the Center for Medicare and Medicaid Innovation's (CMMI) *Informal Request for Information on Radiation Oncology Model Clinical Data Elements (CDEs)*.

ASCO is a national organization representing nearly 45,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. We are also dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practices for the prevention, diagnosis, and treatment of cancer are available to all Americans.

ASCO previously submitted comments[1] on CMMI's proposed rule,[2] Specialty Care Models to Improve Quality of Care and Reduce Expenditures, in which we urged CMMI to consider use of the mCODE® data elements and classes in the Radiation Oncology (RO) model to assist model participants in complying with reporting requirements. In this letter we provide brief comments on CMMI's proposed clinical data elements (CDEs) in the finalized RO model and put forth a proposal that would lessen provider burden and enhance the interoperability

[1] Joint ASCO/CancerLinQ LLC letter to CMMI dated September 16, 2019. Available at https://beta.regulations.gov/comment/CMS-2019-0101-0277
[2] Available at https://www.federalregister.gov/documents/2019/07/18/2019-14902/medicare-program-specialty-care-models-to-improve-quality-of-care-and-reduce-expenditures

of electronic health records (EHRs) for the millions of cancer patients and survivors who often receive care from a variety of specialists and primary care providers across the health care spectrum.

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The Center for Medicare & Medicaid Services' (CMS') Innovation Center finalized the Radiation Oncology (RO) Model on September 29, 2020. The RO Model policies and regulations were included in the *Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures Final Rule*[3] and CMMI is seeking additional feedback specifically on the clinical data elements the agency will collect as part of the model through this informal RFI.

CMMI states that it is collecting these CDEs in an effort to shepherd the development of new outcome measures in radiation oncology, explore opportunities to inform pricing for episodes in the RO Model, and inform monitoring of care quality during the RO Model. CMMI further states that The Innovation Center aims to minimize data collection burden for RO participants to the extent possible, consistent with the CMS Administrator's Patients over Paperwork initiative that aims to reduce unnecessary burden. At this time, CMMI will only consider removal of CDEs for Performance Year 1 of the RO model.

ASCO has previously objected[4] to the implementation timeline of the RO model as we believe it is untenable for practices and providers to ramp up for such major changes in such a compressed timeline and during a pandemic that continues to impact medical practice across the country. If CMS insists on moving forward with this still-flawed mandatory model in such rapid fashion the agency should at the very least minimize the reporting burden on providers forced to participate.

First, the agency should minimize or remove completely from reporting requirements those CDEs that require manual reporting and focus on collecting CDEs that exist in structured fields and lend themselves to more automated reporting. Second, the agency should work with the Office of the National Coordinator for Health Information Technology (ONC) to adopt the mCODE data elements and classes we are proposing[5] to ONC for incorporation into the US Core Data Elements for Interoperability (USCDI; the set of data elements and classes selected for use in certified EHRs, a process overseen by ONC and finalized in the *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program* final rule).[6] The adoption of mCODE data elements would streamline

[3] Available at https://www.federalregister.gov/documents/2020/09/29/2020-20907/medicare-program-specialty-care-models-to-improve-quality-of-care-and-reduce-expenditures
[4] Letter to Sec. Azar and Administrator Verma dated October 2, 2020, joined by ASCO and other stakeholders. Available at https://www.astro.org/ASTRO/media/ASTRO/News%20and%20Publications/PDFs/ROModel_SignOn_letter.pdf
[5] To be submitted to ONC through ONDEC week of October 19, 2020
[6] Available at https://www.federalregister.gov/documents/2020/05/01/2020-07419/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification

data reporting under the RO model and provide tangible benefits to the broader oncology community, as described below.

mCODE elements are developed by a collaboration of oncology experts and consist of the minimal common oncology data elements that should be represented in EHRs. They are a focused set of data elements selected based on their broad applicability to cancer patients and survivors and to support a variety of cancer care and research applications across a variety of cancer types. As a Health Level 7 (HL7) Standard for Trial Use, these elements were refined with broad input and review through the ballot. Finally, the mCODE elements are currently being tested through a variety of implementation use cases managed through the CodeX HL7 FHIR Accelerator.

The mCODE elements we are proposing for adoption in the USCDI include overlap with CDEs that CMMI proposes to collect in the RO model (e.g. performance status, treatment intent). Given CMS' oft-stated desire to reduce provider burden, increase interoperability, and streamline reporting requirements, the opportunity here is clear. Incorporation of mCODE data classes and elements into the USCDI and certified EHRs by ONC would help CMS achieve these goals in the oncology space, decrease reporting burden specifically in a CMMI payment model, and benefit both patients and providers. We urge CMMI to work with ONC and CMS' Office of Burden Reduction and Health Informatics to realize the real-world advantages that adoption of these mCODE data classes and elements would provide.

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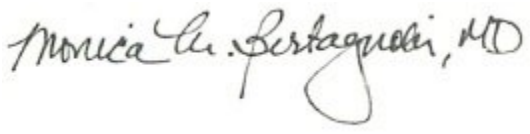
We thank CMS and CMMI for the opportunity to submit these comments and would be pleased to make our experts available to you to further discuss how adoption of mCODE would benefit this demonstration model specifically and high quality patient care in the oncology sphere more broadly. For any questions or for additional information, please contact Karen Hagerty (karen.hagerty@asco.org).

Sincerely,



Monica Bertagnolli, MD, FACS, FASCO
Chair of the Board
Association for Clinical Oncology