October 21, 2020

Mr. Steven Posnack, MS, MHS, Deputy National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology (ONC)
U.S. Department of Health and Human Services
330 C St SW
Floor 7
Washington, DC 20201

Submitted electronically via e-mail

Dear Mr. Posnack,

The American Society of Clinical Oncology (ASCO), MITRE, and the mCODE™ Initiative Collaborators¹ are pleased to submit a proposal for new data elements to be added to the US Core Data for Interoperability (USCDI). While we have utilized the USCDI ONC New Data Element and Class (ONDEC) submission system as required, we wished to also highlight our submission to you and provide additional information regarding the breadth of our membership, and current pilot activities. We feel it is important to begin this discussion as CMS is already considering data elements in oncology, as evidenced by the recent Radiation Oncology RFI released by the Center for Medicare and Medicaid Innovation.

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mCODE™ Initiative Collaborators

The mCODE (“Minimal Common Oncology Data Elements” - a focused set of data elements selected based on their broad applicability to cancer patients and survivors) Initiative is governed by the mCODE Executive Committee, a group of public and private entities who have voluntarily come together to further mCODE adoption. Members include The Alliance for Clinical Trials in Oncology Foundation; the American Society of Clinical Oncology (ASCO) and its nonprofit subsidiary, CancerLinQ LLC; The MITRE Corporation; The American Society for Radiation Oncology (ASTRO); and the Society of Surgical Oncology. A larger standing group, the mCODE Council, provides thought leadership for mCODE, advises the Executive Committee, sponsors use cases, and promotes mCODE adoption. The Council also consults on new and amended data elements and use cases for the mCODE core data specification and its extensions. The Council currently consists of over 20 groups and includes medical societies such as the American Society of Hematology (ASH) and the College of American Pathology (CAP), health information technology developers such as Varian and Epic, and health system and government entities such as Intermountain Healthcare, Mount Sinai Health System, and the National Cancer Institute (NCI).

Ongoing Implementation Pilots to Test mCODE

Many organizations are collaborating on pilots to enable, test, and advance mCODE use. Several of these activities are being coordinated through the CodeX HL7 FHIR Accelerator:

¹ Available at https://mcodeinitiative.org/collaborators/
• ICAREdata™ study: The mCODE team is working with the Alliance for Clinical Trials in Oncology on the Integrating Clinical Trials and Real-World Endpoints (ICARE) data project. ICAREdata aims to demonstrate that mCODE-based real-world data can drive more efficient clinical research by incorporating the data for a broader population of patients while maintaining the same quality as traditional clinical trials.

• Integrated Trial Matching for Cancer Patients and Providers: The American Cancer Society Cancer Action Network (ACS CAN), The MITRE Corporation, TrialScope, Cancer Insights, and Breastcancertrials.org are working to leverage mCODE to improve capability for patients to find clinical trials for which they may be eligible. The goal is to demonstrate the ability of a trial matching service to receive an mCODE record, analyze the record to make matches, and then present the matches back to the patient or provider.

• Cancer Registry Reporting: Several CodeX members are working to enable low-burden, mCODE-centered reporting of cancer data from cancer centers to registries that are aggregating data for different reasons. The goal is to demonstrate that information can be reported from the clinical site to the designated cancer registry, in a low-burden and semantically interoperable way, allowing a patient’s status and outcomes to be tracked as that patient’s therapy progresses.

mCODE Data Elements Selected for Submission to USCDI

In the US, an estimated 16.9 million individuals with a history of cancer were alive on January 1, 2019; by January 1, 2030, it is estimated that the population of cancer survivors will increase to more than 22.1 million due to the growth and aging of the population alone.2 In 2020 there will be an estimated 1.8 million new cancer cases diagnosed and 606,520 cancer deaths in the United States.3 For this population of patients and survivors it is critical that their medical records reflect at least the minimum amount of data required to enhance care coordination and to highlight previous diagnoses of cancer and, given long-term treatment effects, therapies received.

mCODE is 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. mCODE elements were developed by a collaboration of oncology experts. 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. For this initial submission to the ONDEC, the Collaboration is submitting elements that have both reached consensus within the oncology and HL7 communities and are also applicable to disease areas beyond oncology.

Data Classes and elements submitted include:

• Patient
  o Date of Death/Deceased - Indicates if the individual is deceased or not at the time the data is reported

• Problem

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Disease Trend - clinician's overall judgment on the current trend of a condition, e.g., whether it is stable, worsening (progressing), or improving (responding)

Disease Stage / Staging System – A disease-specific set of categories, based on etiology, pathophysiology and severity used to cluster clinically homogeneous patients to inform treatment options

- Assessment and Plan of Treatment
  - Functional Status (examples include ECOG and Karnofsky) - Tools used to measure a patient’s functional status and used to compare the effectiveness of or patient’s ability to tolerate different therapies.
  - Treatment Change - Documents the reason for changes to the plan of treatment plan

- Procedures/Medications
  - Treatment Intent - The purpose of a treatment, or the desired effect or outcome resulting from the treatment (i.e. curative vs. palliative).

**Radiation Oncology Model Clinical Data Elements and mCODE**

Adoption of mCode into USCDI could help to support CMS priorities such as the Center for Medicare and Medicaid Innovation’s (CMMI) Radiation Oncology (RO) mandatory payment model. CMMI is requiring the collection of certain specific “clinical data elements” (CDEs) from participants in the RO model scheduled to begin in January, 2021. Incorporation of standard cancer data classes and elements into the USCDI and certified EHRs by ONC could ultimately help CMS to standardize data collection and decrease reporting burden, benefiting both patients and providers.

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ASCO thanks ONC for the opportunity to submit to ONC these data elements for consideration for use in the USCDI and thanks the agency for its time and attention. If you have any questions or need further information, please contact Andre C. Quina at MITRE (aquina@mitre.org) or Karen Hagerty at ASCO (karen.hagerty@asco.org).

Sincerely,

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