COLLEGE of AMERICAN PATHOLOGISTS

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The Honorable Micky Tripathi, PhD, MPP
Assistant Secretary for Technology Policy and National Coordinator for Health IT
Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (ASTP)
U.S. Department of Health and Human Services
330 C St SW
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Washington, DC 20201

Dear National Coordinator Tripathi:

The College of American Pathologists (CAP) appreciates the opportunity to comment to the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (ASTP) on the Cancer Registry use case for the United States Core Data for Interoperability Plus (USCDI+) Cancer. As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide. Pathologists are crucial in providing appropriate laboratory testing and ensuring laboratory quality so that diagnostic testing is safe and accurate. Pathologists are physicians whose timely and accurate diagnoses drive care decisions made by patients, primary care physicians, and surgeons. When other physicians need more information about a patient's disease, they often turn to pathologists who provide specific diagnoses for each patient. The pathologist's diagnosis and value are recognized throughout the care continuum and many patient encounters.

ASTP's USCDI+ Cancer domain contains data elements to advance the development and adoption of a data model for use by the cancer community and promote access to standardized data for research from real-world implementations. The aim of USCDI+ Cancer is to improve underlying data quality issues, mitigate bias, and improve the reproducibility of methods. USCDI+ Cancer's goals are to support adoption and use of interoperable cancer health IT standards and digital health technologies, provide strategic, technical, and regulatory support to advance the development and adoption of cancer specific use cases to more broadly support the cancer community, and to promote health IT alignment for federal partners—such as the Centers for Medicare and Medicaid Services (CMS) and the Food and Drug Administration (FDA)—to establish use-cases that align with real-world data and infrastructure.

The scope of ASTP's Cancer Registry use case—the use case on which we are

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commenting—includes the Surveillance, Epidemiology, and End Results (SEER) program, the Centers for Disease Control and Prevention/National Program of Cancer Registries (CDC/NPCR), state cancer registries, and the North American Association of Central Cancer Registries (NAACCR). Together, these entities play a critical role in understanding the burden of cancer in the US related to cancer incidence, first course of treatment patterns, mortality, and survival. The focus of the Cancer Registry use case is on early incidence reporting. Currently, there are delays in facilities reporting data to central registries, with available data often up to three years behind. The objective of this use case is to enhance the efficiency and timeliness of cancer registry data collection for early incidence reporting by identifying standards (e.g., Fast Healthcare Interoperability Resources (FHIR), Minimal Common Oncology Data Elements (mCODE)) to efficiently extract or collect cancer registry data directly from Electronic Health Records (EHRs) and pathology laboratories at a sufficiently granular level. This data must be interoperable with clinical, public health, and research communities focused on cancer. The Cancer Registry use case is defining the data standards and models needed for identifying and extracting the required incidence data, as well as supporting current data sharing and linkage approaches for cancer registry data via SEER and CDC/NPCR.

ASTP has specifically welcomed public feedback on the USCDI+ Cancer Registry draft data element list for early incidence reporting and integrating the CAP Cancer protocols—which provide guidelines for collecting the essential data elements for complete reporting of malignant tumors and optimal patient care—into ASTP's data element requirements to enhance pathology reporting standards. To maintain the highest quality and consistency in pathology reporting, ASTP, the National Cancer Institute (NCI) and the CDC have noted their strong recommendation that implementers adhere to the CAP Cancer Protocols when meeting pathology reporting requirements. For more than 30 years, the CAP Cancer Protocols have provided structure for consistent and meaningful information that enables health care professionals to manage and study clinical data for improved patient care. Using the CAP Cancer Protocols helps ensure that all pathology reports contain necessary data elements to improve patient care. The synoptic reporting of the CAP Cancer Protocols ensures more accurate reports that communicate findings in a clear, standardized format to clinicians, colleagues, researchers, and other users of the data. The CAP Cancer Protocols are one of the many solutions that can help with cancer registry reporting and standardization, as they contain all the essential diagnostic pathology information for new cancer cases, with mapping also available to standard ICD-O histologic terms and morphology, behavior, and primary site codes as well as unique identifiers for all data elements.

Synoptic reporting, which the CAP Cancer Protocols facilitate, has documented benefits. According to a study in the Journal of Clinical Oncology, the use of structured reporting "improved patient care in those with CRC [colorectal cancer] by providing more complete reports of higher quality, which had significant effects on the delivery of adjuvant therapy

and patient outcomes." The authors also concluded that implementation of structured reporting for CRC "resulted in increased completeness of pathology reports, higher-quality pathology evaluation, and better outcomes for patients."[1] In a separate article in the Archives of Pathology and Laboratory Medicine, "the introduction of a synoptic report dramatically improved the completeness of reporting of rectal cancer among both non-gastrointestinal and GI pathologists."[2]

The CAP Cancer Protocols are available both as free downloadable templates, and in a licensed electronic format that can be incorporated in Laboratory Information Systems (LIS). The CAP's electronic Cancer Protocols (eCPs) enable pathologists to use the CAP Cancer Protocols directly within their laboratory information system (AP-LIS) workflow and to ensure that each report is completed with the necessary required elements. The benefit of the CAP's eCPs include integrating the CAP Cancer Protocols into the pathologist's AP-LIS workflow, supporting and aiding the pathologist in the diagnostic process, standardizing the collection and reporting of cancer patient data, facilitating communication between pathologists, clinicians, and cancer registrars, improving and supporting information exchange and data interoperability, and providing automated access to patient data through work with vendors.

For more information on the CAP Cancer Protocols, please see the following resources: https://www.cap.org/protocols-and-guidelines/cancer-reporting-tools/cancer-protocols; https://www.cap.org/protocols-and-guidelines/cancer-reporting-tools/cancer-protocol-templates. For more information on the CAP electronic Cancer Protocols, please see: https://www.cap.org/protocols-and-guidelines/electronic-cancer-protocols.

The CAP emphasizes that expanded funding is necessary for pathologists and laboratories to properly report the data elements in the Cancer Registry use case of USCDI+ Cancer. This is particularly true if pathologists and laboratories are using the CAP eCPs to meet pathology reporting requirements. In addition, the CAP will provide specific comments in response to some of the questions posed by ASTP:

Data Element Completeness

1. What additional data categories and/or elements should be included?
    - CAP Comment:
        - *Primary Site – Primary Site* describes the code for the primary site of the tumor being reported using either ICD-O-2 or ICD-O-3. The CAP agrees that this data element is necessary and supports its inclusion. However, the primary site of the tumor is not always clear

[1] The Journal of Clinical Oncology study can be found here: https://ascopubs.org/doi/abs/10.1200/CCI.18.00104.
[2] The Archives of Pathology and Laboratory Medicine article can be found here: https://meridian.allenpress.com/aplm/article/135/11/1471/64981/What-Impact-Has-the-Introduction-of-a-Synoptic.

from reports (e.g. simultaneous involvement of the ovary and endometrium by carcinoma when it is not clear if it is endometrial carcinoma metastatic to the ovary or two synchronous primary tumors). There should be a way to properly record such cases through an additional data element.

- The *Ordering Physician* data element describes the care provider who orders a test or procedure. The *Facility Identifier* data element describes the sequence of characters representing a physical place of available services or resources. The CAP finds the *Ordering Physician* data element and *Facility Identifier* data element to be currently insufficient and too vague for laboratories. To mitigate this, the CAP recommends that the USCDI+ Cancer Registry use case dataset contain data elements for pathologist identity (e.g., name, NPI) and laboratory facility identifiers (e.g., name, CLIA identifier). Those data elements would provide specificity to the *Ordering Physician* and *Facility Identifier* data elements, which should probably refer to the ordering facility.

2. What data elements should we remove to create a core, concise list of cancer registry data elements for early incidence reporting?
    - CAP Comments:
        - The *Date of Diagnosis* data element is the date of first determination by a qualified professional of the presence of a problem or condition affecting a patient. The CAP finds this *Date of Diagnosis* data element to be redundant. That is, *Date of Diagnosis* is covered by issue date of the pathology report for the first diagnostic report, and the report issue date or verification date (synonym) is already a data element. However, an explicit data element for pathology report date may be needed.
        - The *Cancer Diagnosis* data element is the cancer-related condition, diagnosis, or reason for seeking medical attention. The CAP finds that the *Cancer Diagnosis* data element to be redundant for laboratories and pathology reports and may conflict with the following data elements: *Histology* (The morphologic and behavioral characteristics of the cancer) and *Behavior Code ICD-O-3* (Code for the behavior of the tumor being reported using ICD-O-3). The *Cancer Diagnosis* data element may be redirected to reflect an ICD-10 code and thus may be unavailable from laboratories.
        - The *Race* data element describes an individual's response to the race question based upon self-identification. The *Ethnicity* data element describes the patient's self-identification as Hispanic/ Latino or Non- Hispanic/ Non-Latino. The *Current Address*

describes the place where a person is located or may be contacted. The *Previous Address* data element describes the prior place where a person may have been located or could have been contacted. The *Diagnostic Imaging Report* describes the interpreted results of imaging tests. The CAP notes that the *Race*, *Ethnicity*, *Current Address*, *Previous Address*, *Diagnostic Imaging Report*, and *Date of Diagnosis* (for existing cancer cases) data elements are difficult for laboratories to collect, as they may not be available to laboratories. Laboratories cannot be required to report on data they do not have. Similarly, some laboratories no longer use ICD-O codes for *Histology*, *Behavior Code ICD-O-3* and *Primary Site*. However, these codes are mapped to the CAP Cancer Protocols data elements and will be available with the planned free open-source data element release later this year.

3. Do cancer registrars consider these data elements clinically significant?
    - CAP Comment:
        - We defer to our cancer registrar colleagues for these comments.

Level of Specificity:

1. Which data elements could significantly impact the efficiency and accuracy of data collection if they were better specified or constrained?
    - CAP Comment:
        - The standardized format of pathology data elements in the CAP Cancer Protocols should be considered the gold standard. For example, the *Primary Site*, *Laterality*, *Histology*, and *Behavior Code ICD-O-3* data elements, among many others, are included in the CAP Cancer Protocols, and the updated ICD-O codes will be available from CAP probably by early 2025. CAP Cancer Protocol-generated pathology report data almost always takes precedence over other data sources if they are in conflict. Exceptions may be made; for example, for outside expert consultation, report amendments, and delayed results (e.g., genomic tests) that modify the original diagnosis and other findings.[3]
        - It is worth noting that some data elements (e.g., *Facility Identifier*, *Pathology Report Number*) may want to permit for multiple entries if more than one facility is involved or if the information appears in more than one report (e.g., cytology & surgical).

[3] See here for access to the CAP Cancer Protocol data elements in human-readable formats: https://www.cap.org/protocols-and-guidelines/cancer-reporting-tools/cancer-protocol-templates.

2. How would the addition of usage notes for data elements provide clarification?
    - CAP Comment:
        - The *Histology*, *Primary Site*, and *Behavior Code ICD-O-3* data elements are not always straightforward, as histologic data collections for some tumors can be complex. In some pathology reports, multiple histologies may be present in the same primary site. Usage notes would help clarify edge cases for histologic data collections.
        - *Diagnostic Confirmation* – The *Diagnostic Confirmation* data element is the code for the best method of diagnostic confirmation of the cancer being reported at any time in the patient's history. The CAP contends that the *Diagnostic Confirmation* data element needs a usage note that includes the answer choices.
        - Usage notes are necessary for ICD-O and other coding. Specifically, ICD-O coding is complex and changes as new versions are released. Also, there are manuals available to assist with registry coding that should be aligned with the data element usage in lab systems.

Integration of Elements Related to Cancer Treatment and Outcomes:

1. What other cancer registry use cases should we consider?
    - CAP Comment: We defer to our cancer registry colleagues for these comments.

Real-Time Reporting:

1. Which specific data elements are crucial for real-time reporting and may pose data quality, timeliness, or other challenges?
    - CAP Comment:
        - Correct and accurate use of the latest version of ICD-O terminology and codes for morphology, behavior, and primary site is crucial.
        - The CAP Cancer Protocols core data elements are critical for determining prognosis and guiding treatment and should eventually be included. Note that CAP updates are released up to 4 times per year, so these data elements can experience considerable changes and are not suited to be copied into secondary locations such as USCDI+ tables.

2. How can we ensure that real-time data reporting meets quality standards and remains usable for clinical, public health, and research purposes?

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- CAP Comment:
    - We recommend using the CAP Cancer Protocols and their associated ICD-O and other code maps, which are updated on a regular basis. We recommend that the most recent maps be applied to the data element unique identifiers at the time of data analysis, not the time of data transmission.
    - We recommend adopting automated methods for ICD-O coding, based on the planned open-source CAP and NAACCR Cancer PathCHART code tables.

Implementation Considerations:

1. Which data elements in USCDI+ Cancer Registry may be hard to record or may create more work, making them less likely to be gathered and shared?
    - CAP Comment:
        - Please see our comments above regarding data elements that may not be present in laboratory systems. Laboratories cannot be required to report on data they do not have.

2. How can we display data elements differently to reduce the amount of documentation needed and to better connect with features in Electronic Health Records (EHR) or similar systems?
    - CAP Comment:
        - The USCDI+ website could, in principle, link to the CAP's visualization tools. Specifically, for data elements in the CAP Cancer Protocols and eCPs, the CAP plans in late 2024 to release open-source visualization tools to view and compare eCP template versions. The tool will allow downloading of eCP spreadsheets containing data elements with unique IDs and mapped codes. We can also provide an eCP XML□HTML conversion tool for simple template viewing in EHRs.

3. What other guidance about appropriate vocabulary criteria or references to information exchange specifications (e.g., HL7) would help map the data elements currently used in your environment to these USCDI+ Cancer Registry data elements?
    - CAP Comment:
        - We recommend using a controlled data capture vocabulary ("interface terminology") at the time of report creation. We also recommend checking the data entries against lists of standardized allowable values. This functionality is already built into the eCPs, but eCPs do not cover all pathology reports/types.
        - CAP Cancer Protocol data are mapped to the Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT) and

ICD-O standards as mentioned above. These maps will be updated on a regular basis, and we plan to support ICD-O-4 mappings after ICD-O-4 is finalized. USCDI+ data elements derived from pathology reports should use those values as well.

* * * * *

Thank you for the opportunity to submit these comments. The CAP looks forward to working with the ASTP and always stands willing to work with government agencies, industry, pathologists, and other stakeholders to support high quality laboratory operations and medical care. Please direct questions on these comments to Han Tran at htran@cap.org.

Appendix:
Exploring the College of American Pathologists Electronic Cancer Checklists: What They Are and What They Can Do for You:
https://meridian.allenpress.com/aplm/article/145/4/392/448764/Exploring-the-College-of-American-Pathologists

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