COLLEGE of AMERICAN PATHOLOGISTS

June 20, 2023

Micky Tripathi
National Coordinator
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

Subject: RIN 0955-AA03 – Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing

Submitted via Electronic Submission to www.regulations.gov

Dear Dr. Tripathi:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the Office of the National Coordinator for Health Information Technology's (ONC) Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule. 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 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.

The CAP supports the overall objectives of the HTI-1 proposed rule—to advance interoperability, improve transparency, enhance health IT certification, reduce burden and costs, and support the access, exchange, and use of electronic health information. The CAP—a leader in promoting the use of standards in the laboratory ecosystem through initiatives such as the FDA Systemic Harmonization and Interoperability Enhancement of Laboratory Data (SHIELD) and the CAP Cancer Protocols[1]—

[1] 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. For more information on the CAP Cancer Protocols,

College of American Pathologists
1001 G Street, NW, Suite 425W
Washington, DC 20001
202-354-7100

appreciates the importance of interoperability in the health information technology (HIT) ecosystem and applauds the ONC's work on this issue. The COVID-19 pandemic has shown the need for standardized data reporting so officials can access comprehensive and nearly real-time data to inform decision making in their response during public health emergencies.

Nevertheless, the promotion of interoperability, if done improperly, poses the risk of unintended regulatory consequences and patient harm. This is especially true in the complex pathology and laboratory ecosystem. Indeed, standards need to first mature for them to work safely in the laboratory. The CAP is dedicated to helping the ONC to mature the standards and to avoid unintended consequences and patient harm. We will consequently focus our comments on the following provisions included in the proposed rule:

1. Laboratory Data Interoperability Request for Information (Section III.G.1)
2. The United States Core Data for Interoperability Standard (USCDI) v3 (Section III.C.1)
3. Decision Support Interventions and Predictive Models (Section III.C.5)
4. Patient Requested Restrictions Certification Criterion (Section III.C.10)
5. Information Blocking Enhancements (Defined Terms and Exceptions) (Sections IV.A and IV.B)
6. Health IT Capabilities for Data Segmentation and User/Patient Access—Request for Information (Section IV.C.3)

The CAP always stands willing to work with government agencies, industry, pathologists, and other stakeholders to support high quality laboratory operations and medical care.

1. Laboratory Data Interoperability Request for Information (Section III.G.1)

The ONC has issued a request for information concerning laboratory data interoperability. The ONC seeks public comment on the use of health IT standards by clinical laboratories, use of such standards by laboratories and their effect on the interoperability of laboratory data with public health systems, including any challenges. The ONC also seeks comment on whether ONC should adopt additional standards and laboratory-related certification criteria as part of the ONC Health IT Certification Program.

Because the laboratory ecosystem is uniquely broad and complex, certification of Laboratory Information Systems (LIS) is consequently not currently feasible. Specifically, existing standards are not currently sufficient to capture the

please see the following resources: https://www.cap.org/protocols-and-guidelines/cancer-reporting-tools/cancer-protocols; https://ascopubs.org/doi/full/10.1200/CCI.18.00104.

complexity of the laboratory systems.[2] As one example of this, studies have shown that with the Logical Observation Identifiers Names and Codes (LOINC) standard[3]—which has existed for over 25 years—there is inconsistent LOINC code selection for common laboratory tests across an array of laboratory settings; such inconsistency may of course pose risks to patient safety.[4] In addition, the use of LOINC does not guarantee seamless interoperability of laboratory test names and codes in electronic interface messages between different information systems[5]; although LOINC has potential utility in expressing test type, patients will be harmed if LOINC is used to indicate clinical interoperability of results. Similarly, although the relatively new Fast Healthcare Interoperability Resources (FHIR) standard is developing rapidly, it is not yet ready to cover the full set of laboratory use cases. Indeed, moving to FHIR-based laboratory data exchange would be costly in that it would require replacement of existing interfaces. If standardization is needed immediately, a well-defined strategy making use of Health Level 7 (HL7) v2 Laboratory Order and Result Interface (LOI/LRI) implementation guides would be preferable to a hybrid HL7 v2/FHIR strategy because of simplicity.[6] HL7 LOI/LRI have well-specified field content and incorporate existing terminology standards such as SNOMED CT, Unified Code for Units of Measure (UCUM), and additional well-defined value sets, and could solve many existing incompatibility problems while reusing substantial portions of existing interface code without requiring a complete replacement of interfaces. Some additional work needs to be done to extend the test result data model so that it can safely indicate which results are clinically interoperable; the ONC should support this work and the minor extension of standards required to accommodate it. Moreover, there need to be safeguards to ensure correct implementation/utilization of existing standards, quality assurance mechanisms and data quality measurement.

It is essential that the CAP and other professional societies within the laboratory ecosystem be the ones to develop a solution that balances of the goal of interoperability with the constraints of clinical laboratories while ensuring that patient safety is not compromised. This will minimize the risk of unintended regulatory consequences and patient harm. It is also worth noting that although LIS certification is currently infeasible;

[2] Data standards are in use widely for laboratory data transmission. However, their main interoperability problem is that the content of the defined data elements is not fully standardized.
[3] LOINC requires special consideration. This coding system was originally designed to indicate the type of observation (ie, general type of lab test). It does not provide enough information about a particular test result to determine whether that result is comparable to another result of the same general type. There are two problems that occur with LOINC as it is commonly used. The first is that LOINC codes are often incorrectly assigned because there are a large number of tests from different manufacturers and they can differ in a variety of ways so that code assignment is complex. Various aids to code assignment may improve this problem. The second problem is that LOINC is commonly used incorrectly in deployed systems to determine whether results are clinically comparable. This is an incorrect use of LOINC because specific tests of a similar general type (with the same LOINC code) may have different units, reference ranges, or performance characteristics, and their results may not be directly comparable unless the tests are standardized. This problem cannot be fixed within the LOINC terminology because it is outside of LOINC's design scope. Additional data elements must be added to the result data model to reliably indicate clinical comparability. Either of these LOINC problems, incorrect code assignment or incorrect use, can and do yield erroneous clinical decisions resulting in serious patient harm. Because of this, the use of LOINC must be carefully considered and, if it is used, effective safeguards against both problems need to be in place.
[4] https://meridian.allenpress.com/aplm/article/144/5/586/427465/A-Survey-of-LOINC-Code-Selection-Practices-Among.
[5] https://meridian.allenpress.com/aplm/article/144/2/229/433652/Logical-Observation-Identifiers-Names-and-Codes.
[6] The HL7 LOI/LRI (Laboratory Order and Result Interface implementation guides) are well-specified and similar to the semi-standards that are in use.

certification—which has disadvantages related to cost, flexibility, and usability—is only a means to an end and is not the exclusive pathway to interoperability.

The CAP emphasizes that regulatory efforts to promote interoperability may have unintended consequences—such as imposing costs and burdens on laboratories—that may be unsustainable for smaller laboratories. Realizing consistent interoperability principles in the laboratory will require a thoughtful cost containment strategy. Any future LIS certification must minimize costs, burdens, and risks on laboratories. For example, if an LIS vendor requires healthcare organizations to pay for the required upgrade of the LIS to a certification-compliant version, then LIS certification will, by default, be an unfunded mandate. Providing funding to laboratories and/or LIS vendors to offset the costs of certification would promote compliance and ease the burden. It also bears emphasis that cost containment efforts will incentivize the updating of LIS interfaces—it would be easier to incentivize such updates with a lower cost and effort barrier and might be accomplished through a desire to improve performance and avoid certification with its potential negative effects. Moreover, if interfaces do not need to be fully replaced (which would be the case for a strategy making use of HL7 LOI/LRI), conversion to standardized content could be done incrementally, by profile, which would spread the cost and effort over time to minimize disruption.

In the very last question in the laboratory data interoperability RFI, the ONC requested information on whether there are any other steps that ONC and HHS should consider taking to advance laboratory interoperability.

The CAP appreciates the importance of advancing laboratory data interoperability and that such advancement is a multifaceted project. The CAP also appreciates that many components of laboratory data will need to be interoperable, and that these components include order identification, laboratory test identification, laboratory test reference ranges, result units, time collected, time received, time reported, and clinical comparability of result values. The CAP—as a leader in promoting standardization of laboratory data—stands willing to collaborate with the ONC every step of the way to ensure that the aforementioned laboratory data elements are interoperable while also avoiding unintended regulatory consequences and patient harm. As part of the solution to laboratory data interoperability, the CAP would like to promote its work on the FHIR standard. **Specifically, the CAP has created FHIR profiles that have been vetted in the pathology space that will help the ONC achieve its goal of advancing interoperability: Structured Data Capture (SDC) on FHIR,[7] and FHIR – Cancer Pathology Data Sharing (FCPDS).[8]**

SDC on FHIR

[7] https://build.fhir.org/ig/HL7/ihe-sdc-ecc-on-fhir/.
[8] http://build.fhir.org/ig/HL7/cancer-reporting/.

The SDC on FHIR profile enables implementers to transmit data from the CAP electronic Cancer Protocols (eCPs)[9] using FHIR resources, which are based on Integrating the Healthcare Enterprise (IHE) SDC.[10] SDC provides an infrastructure for capturing, exchanging, and using patient data within EHR systems for clinical research, adverse event reporting and public health reporting. The CAP has worked on SDC on FHIR with the Centers for Disease Control and Prevention (CDC), the North American Association of Central Cancer Registries (NAACCR), Lantana, MITRE and CodeX.

FHIR - Cancer Pathology Data Sharing (FCPDS)

The FHIR - Cancer Pathology Data Sharing (FCPDS) implementation guide (IG) documents best practices for transmitting pathology data as FHIR resource bundles and distributing them to the Central Cancer Registry (CCR) via two pathways: LIS to CCR via an EHR intermediary, and from LIS to CCR directly. FCPDS promotes structured data collection and exchange of cancer pathology data, provides the data model, defined data items and their corresponding code and value sets. It also specifies the collection and exchange of data specific to a cancer pathology synoptic report for public health reporting. FCPDS is derived from NAACCR Vol V,[11] which is widely used and derived from ELR (Electronic Laboratory Reporting from HL7 v 2.5, which is also widely used).

2. The United States Core Data for Interoperability Standard (USCDI) v3 (Section III.C.1)

The ONC proposes to adopt the third version of the United States Core Data for Interoperability (USCDI) as the new baseline for ONC Health IT Certification. Although USCDI v3 is imperfect, the CAP supports the transition from USCDI v1 to USCDI v3 as the baseline to support the use, promotion, and advancement of the USCDI in the health information technology (HIT) ecosystem. The CAP understands that the USCDI is a work in progress. Although some of the vocabulary standards in USCDI v3 have issues, we hope to see the ONC keep evolving the USCDI in ways that improve interoperability while also protecting patient safety and avoiding unintended regulatory consequences. Data sharing through widely accepted standards is critical to ensure that health information is available and comprehensible across care settings for use in patient care, public health, and emergency (e.g., pandemic) preparedness and response. For broader sharing of electronic health information, the USCDI is critical to establishing foundational standards to support patient care. In its participation in the USCDI development process,

[9] The CAP 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. Most anatomic pathology AP-LIS vendors offer a CAP electronic Cancer Protocols synoptic module for reporting on surgical cancer resections and selected biopsies. For more information on the CAP electronic Cancer Protocols, please see https://www.cap.org/protocols-and-guidelines/electronic-cancer-protocols.

[10] https://wiki.ihe.net/index.php/Structured_Data_Capture; see also https://documents.cap.org/documents/sdc-system-manual-v1-0.pdf.

[11] https://www.naaccr.org/wp-content/uploads/2020/07/NAACCR-Vol-V_Revised_20200720.pdf.

the CAP has advocated for the USCDI to align with CLIA Test Report requirements in the Clinical Laboratory Improvement Amendments (CLIA) of 1988.[12] CLIA requirements are mandated for clinical laboratories, and those elements should consequently be the basis for developing a foundation for the standardized sharing and reporting of laboratory information to support patient care.[13] Aligning the USCDI with CLIA requirements will support interoperability by building on existing standards and patterns of use while avoiding contradictory or duplicative reporting requirements.

Although USCDI v3 does not align with CLIA, it is an improvement over USCDI v1, and the CAP consequently supports the ONC's proposal to set USCDI v3 as the new baseline for ONC Health IT Certification. However, if finalized as is, USCDI v4 would be preferable to USCDI v3 as the ONC's baseline, as USCDI v4 is more closely aligned with CLIA Test Report requirements. Specifically, the draft version of USCDI v4 has the following data elements that align with CLIA Test Report Requirements: Facility Identifier (aligns with name and address of laboratory location), Test (aligns with test performed), Specimen Source Site (aligns with Specimen Source), Values/Results (aligns with the test result), Result Unit of Measure (aligns with the units of measurement or interpretation), and Specimen Condition and Disposition (aligns with any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability). The CAP urges the ONC to align future versions of USCDI even more with CLIA Test Report requirements.

3. Decision Support Interventions and Predictive Models (Section III.C.5)

In section III.C.5 of the HTI-1 proposed rule, the ONC proposes to revise the existing Clinical Decision Support (CDS) criterion[14] to reflect an array of contemporary and emerging software functionalities that aid user decision-making in health care, including artificial intelligence (AI) and machine learning (ML). This criterion is intended to provide users and the public greater information, available in a consistent manner, on whether

[12] See https://www.healthit.gov/isa/sites/isa/files/2022-09/CAP%20USCDI%20v4%20Comments.pdf and https://www.healthit.gov/isa/sites/isa/files/2023-04/CAP%20USCDI%20v4%20Final%20Comments%202023_0.pdf.

[13] CLIA's test report requirements (42 CFR § 493.1291(c)) are as follows:

1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number.
2) The name and address of the laboratory location where the test was performed.
3) The test report date.
4) The test performed.
5) Specimen source, when appropriate.
6) The test result and, if applicable, the units of measurement or interpretation, or both.
7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

[14] § 170.315(a)(9). The initial requirements for this criterion, which was known as the Clinical Decision Support (CDS) criterion, were intended to ensure that Health IT Modules support broad categories of CDS while being agnostic toward the intended use of the CDS beyond drug-drug and drug-allergy interaction checks. This criterion as revised is now meant to apply to Predictive Decision Support Interventions (DSI)—defined as technology intended to support decision-making based on algorithms or models that derive relationships from training or example data and then are used to produce an output or outputs related to, but not limited to, prediction, classification, recommendation, evaluation, or analysis.

such software functionalities—which include AI, ML, and Natural Language Processing (NLP)—are fair, appropriate, valid, effective, and safe (FAVES).

The CAP supports transparency and explainability in AI/ML devices. Developers must implement an open system that describes updates and modifications as they occur to patients and clinicians.[15] When the test set data are available and not in violation of any Protected Health Information (PHI) rules and policies, transparency must also include the test sets used in the model as available information, which this criterion includes.[16] When the raw test set data is not able to be made available, a well described test set would be acceptable.

This criterion will also help pathologists in their AI-related responsibilities, which will constitute an important part of pathologists' role as CLIA-laboratory directors and section directors. Specifically, the criterion will help pathologists' engagement in the development, deployment, and configuration of AI technology and will ensure that the pathologists' unique knowledge of laboratory testing, including ethical considerations, patient safety issues, risks, workflow, and other challenges, are incorporated into AI systems. The CAP prioritizes patient safety and clinical utility in development and responsible implementation of AI in pathology, which transparency and explainability would promote.

The CAP consequently supports this updated criterion and requests that the ONC provide examples that would assure the public on how the ONC's FAVES framework would be determined based on the information required in this criterion.

4. Patient Requested Restrictions Certification Criterion (Section III.C.10)

The ONC is proposing that for any data expressed in the standard in the USCDI,[17] a health IT developer must enable a user to flag whether such data needs to be restricted from being subsequently used or disclosed and prevent any data flagged from being included in a use or disclosure. The ONC is also proposing to modify the Privacy and Security Framework[18] to add the proposed new "patient requested restrictions" criterion and to require it by January 1, 2026 (or 24 months after the effective date of a final rule),[19] and to add a paragraph[20] stating patients (and their authorized representatives) must be able to use an internet-based method to request a restriction to be applied to any data expressed in the USCDI.

[15] https://documents.cap.org/documents/cap-comments-to-fda-ai-framework.pdf.
[16] The CAP would also like to iterate that PHI must be protected if it is included in the test sets used to train AI/ML algorithms.
[17] § 170.213.
[18] § 170.550(h).
[19] The section modified would be § 170.550(h).
[20] The section modified would be § 170.315(e)(1).

The CAP supports these proposals. Patient portals and EHR/LIS systems may have difficulty segmenting patient data. Specifically, some patient portals or similar apps may be incapable of suppressing blocked reports in accordance with a patient's wishes. There are complex situations that patient portals cannot handle: most patient portals are limited in their ability to display or hide or restrict result views for a particular patient based on certain patient or situational criteria. For example, some states may require that all sexually transmitted infection results and pregnancy tests can only be shown to the adolescent between the ages of 13 and 18. Some patient portals do not have the flexibility to hide some results from those who have proxy access while showing them to the patient. Some portals also cannot toggle displaying vs. not displaying results in a portal based on the patient's age or presence of proxy access into the account. For example, a sexually transmitted infection result, if hidden from patients 0-17 years of age, would also be hidden from that same patient when they become an adult with no proxy access. Other portals which block results based on state law do not have the capability to allow a physician to release a result to the portal even after legally required counseling has occurred.

Moreover, some LIS/EHR systems do not adequately handle the concept of preliminary reports, addended reports, or amended reports. This could cause premature release of non-validated results to a portal in violation of a patient's wishes. Very few LISs or EHRs use sufficient coding for noting whether results are preliminary versus final. It is not clear that EHRs are set to exclude results with an HL7 result status of "preliminary" from a patient portal or other result distribution system. Patient portals might show preliminary results due to this issue, and this could be very harmful to patients. In addition, patient portals have difficulty navigating conflicting state and federal reporting requirements, especially in the context of special rules for pediatric patients. The work required to make these changes in current installed systems would be significant and, in some cases, technically infeasible. Indeed, sometimes organizational or state policy may require sending out all a patient's health information regardless of the patient's wishes and regardless of the health IT products' capabilities.

To improve the problems that LIS/EHR/portals have with segmenting patient data—which this criterion is designed to do—the CAP supports the ONC's proposals in this section of the HTI-1 proposed rule.

5. Information Blocking Enhancements (Defined Terms and Exceptions) (Sections IV.A and IV.B)

The CAP does not oppose the information blocking enhancements proposed by the ONC. The CAP supports ONC's broad aim of patients having access to their health information, including laboratory and pathology reports. However, providing patients with direct and immediate access to laboratory and pathology reports has very real barriers, challenges, and potential safety issues. The HTI-1 proposed rule does not

do enough to mitigate ONC's information blocking regulations in this regard.

The CAP requests that the ONC reduce potential patient harm and improve care coordination by allowing some limited blanket delays for specific kinds of tests. Some CAP members have expressed concerns about psychological harm caused by the immediate release of distressing reports. Pathologists are most concerned about the myriad of situations in which automatic release of final reports to a patient portal can have disastrous psychological and practical consequences, and case-by-case implementation of an exception is impractical or unworkable. Specifically, patients may already have accessed results before a physician realizes that the result may be harmful to the patient and/or the patient's family, particularly when the diagnosis or result produced by a pathologist, or the laboratory was not anticipated.

We do not believe it is ONC's goal for patients to receive uncoordinated, confusing information. The CAP urges ONC to consider allowing a delay for the opportunity for involved clinicians to create an integrated response before patient communication for the best care coordination. We are not suggesting this is necessary for all test results, but rather, those that are complex, could be misconstrued without proper context, require counseling and the like should be allowed to have blanket delay of release.

The burden of asking ordering physicians to anticipate, on a patient-by-patient basis, each result that could possibly result in harm to a patient if it is released immediately to a patient is too high. Indeed, the regulations create an unnecessary burden on pathologists and patient care physicians by requiring them to anticipate and attempt to mitigate (by multiple methods) harms that are enabled purely by the regulations. Put differently, it is not practical to identify cases for exceptions in real time, and there are a limited number of problematic case types that can be predicted and set up ahead of time appropriately if there is adequate flexibility. It is also worth noting that the regulations do not provide detailed mitigation strategies, so these responses will probably vary by locale in confusing ways.

The CAP urges the ONC to allow for blanket exceptions to the information blocking rule until such that the EHR vendors' patient portals can accommodate the various state laws, forms and formats surrounding this and other result release issues.

6. Health IT Capabilities for Data Segmentation and User/Patient Access—Request for Information (Section IV.C.3)

The ONC has issued a request for information relating to health IT capabilities for data segmentation and user/patient access. The ONC seeks public comment on what steps ONC might consider taking to improve the availability and accessibility of solutions supporting health care providers' and other information blocking actors' efforts to honor

patients' expressed preferences regarding their electronic heath information (EHI), comment related to the capabilities of health IT products to segment data and support health care providers (and actors) in sharing information consistent with patient preferences and all laws applicable to the creation, collection, access, exchange, use and disclosure of EHI, comment on experiences with the availability and utility of certified health IT products' capabilities to segment data in use cases including but not limited to the illustrative examples above, comment on how greater consistency in provider documentation practices could enhance the feasibility of technical segmentation solutions, and comment on barriers to technical feasibility presented by local, state, and federal regulations.

With respect to the state of data segmentation and user/patient access in health IT, the CAP would like to reiterate that some patient portals or similar apps may be incapable of suppressing blocked reports in accordance with a patient's wishes. To improve the availability and accessibility of solutions supporting health care providers' and other information blocking actors' efforts to honor patients' expressed preferences regarding their EHI, the CAP would also like to reiterate ONC can help by allowing some blanket delays for specific kinds of tests.

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Thank you for the opportunity to submit these comments. The CAP looks forward to working with ONC. Please direct questions on these comments to Han Tran at htran@cap.org.

College of American Pathologists
1001 G Street, NW, Suite 425W
Washington, DC 20001
202-354-7100