COLLEGE of AMERICAN PATHOLOGISTS

October 3, 2024

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
Floor 7
Washington, DC 20201

Subject: Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (RIN 0955-AA06)

Submitted via Electronic Submission to www.regulations.gov

Dear Assistant Secretary Tripathi:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology's (ASTP) *Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) 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-2 Proposed Rule—to advance interoperability, improve transparency, 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]—appreciates the importance of interoperability in the health information

[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

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technology (HIT) ecosystem and applauds ASTP'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 with respect to pathology and laboratories. The CAP is dedicated to helping ASTP avoid unintended consequences and patient harm. We will focus our comments on the following provisions included in the proposed rule:

1. The United States Core Data for Interoperability Version 4 (USCDI v4) (Section III.B.1)
2. Promotion of the LOI, LRI, and FCPDS Standards (Sections III.B.13.d, III.B.13.e, and III.B.18)
3. Revised Criterion for Encrypt Authentication Credentials (III.B.12)
4. New Standardized API for Public Health Data Exchange (Section III.B.13.f)
5. Multi-Factor Authentication Criterion (Section III.B.17)
6. Minimum Standards Code Sets Updates (Section III.B.5)
7. New Imaging Requirements for Health IT Modules (Section III.B.6)
8. Information Blocking Enhancements (Section IV)

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. The United States Core Data for Interoperability Version 4 (USCDI v4) (Section III.B.1)

ASTP proposes to update the USCDI standard in ASTP's Health IT Certification Program by adding USCDI v4 and establishing an expiration date of January 1, 2028 for USCDI v3 for purposes of the Program. **The CAP supports this proposal. Indeed, the CAP noted in its comments on the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule[2] that USCDI v4 would be preferable to USCDI v3 as ASTP's baseline, as USCDI v4 is more closely aligned with CLIA Test Report requirements in the Clinical Laboratory Improvement Amendments (CLIA) of 1988.** CLIA requirements are mandated for clinical laboratories, and those elements should

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, 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.

[2] https://documents.cap.org/documents/CAP-HTI-1-Comment-Letter.pdf

consequently be the basis for developing a foundation for the standardized sharing and reporting of laboratory information to support patient care.[3] Aligning the USCDI with CLIA requirements supports interoperability by building on existing standards and patterns of use while avoiding contradictory or duplicative reporting requirements. However, while the USCDI v4 adds additional CLIA-required elements, it still does not provide an adequate data model for safe laboratory interoperability and does not address standards for anatomic pathology reports. **Therefore, the CAP supports USCDI v4 only as a temporary step toward useful interoperability.**

2. Promotion of the LOI, LRI, and FCPDS Standards (Sections III.B.13.d, III.B.13.e, and III.B.18)

In several sections of the HTI-2 Proposed Rule,[4] ASTP has added to its Health IT Certification criteria the following standards relevant for pathology and laboratory data:

- HL7 Version 2.5.1 Implementation Guide: Laboratory Orders from EHR, Release 1, STU Release 4 - US Realm (LOI)
- HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface, Release 1 STU Release 4 - US Realm (LRI)
- HL7 FHIR Cancer Pathology Data Sharing, 1.0.0 - STU1 (FCPDS)

The CAP has been favorable to the LOI, LRI, and FCPDS standards in the past, and promoted them in the CAP's HTI-1 comments. **Consequently, the CAP finds the addition of these standards to ASTP's Health IT Certification to be a step in the right direction**. **However, the CAP urges ASTP to proceed cautiously as implementing these standards too quickly may inflict burden on pathologists and laboratories. The CAP emphasizes that expanded funding is necessary for this provision to be implemented effectively.** The CAP will offer further commentary on the LOI, LRI, and FCPDS standards below.

The CAP notes that LOI and LRI are well-developed though non-mandatory standards**.**

[3] 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.

[4] The sections in the HTI-2 Proposed Rule are Health IT Modules Supporting Public Health Data Exchange -- Revised Certification Criteria for Health IT Modules Supporting Public Health Data Exchange (Section III.B.13.d), Health IT Modules Supporting Public Health Data Exchange -- New Certification Criteria for Health IT Modules Supporting Public Health Data Exchange (Section III.B.13.e), and Revised Computerized Provider Order Entry – Laboratory Criterion (Section III.B.18).

However, it is worth noting that because LOI and LRI are based on Version 2.5.1 of the Health Level Seven (HL7) Standard for electronic data exchange, they may not be fully compatible with all Laboratory Information Systems (LIS) and Electronic Health Record Systems (EHRs) in use. The implementation of LOI and LRI would improve laboratory data interoperability at a considerable cost for software and data content updates. **Nevertheless, it is probably feasible to require certified health IT to incorporate LOI/LRI communication capabilities by January 1, 2028 (as currently proposed) if the final rule is adopted by January 1, 2025.** However, if the final rule is delayed, the requirement should be pushed back to maintain the three-year span.

With respect to the use of LOI and LRI for public health reporting,[5] the CAP notes that because the software and data upgrades for clinical interoperability and public health reporting have significant overlap, these two goals must be addressed in a coordinated and integrated way. For example, although the LRI standard can be used for public health reporting, it was initially designed primarily to address the challenge of laboratory reporting to ambulatory primary care providers so ASTP will need to proceed cautiously and make sure that needs are met for both clinical interoperability and public health in a straightforward way. **Support for both laboratories and public health agencies will likely be required**. **Public health reporting requirements should be implemented according to a schedule that accounts for all participants.**

The promotion of the FCPDS standard in the HTI-2 Proposed Rule is promising. However, the FCPDS standard may not be ready yet to be required in regulation by January 1, 2028 (as currently proposed) given current funding for FCPDS testing, training, revising, and implementing across the country. FCPDS is currently undergoing some updates which need to be finalized, tested, and validated. **FCPDS would be the first FHIR pathology implementation guide put into widespread use, so enhanced financial support to laboratories, CAP, the Centers for Disease Control and Prevention (CDC), the North American Association of Central Cancer Registries (NAACCR), and other stakeholder organizations would be essential, as these groups would need to spend considerable effort on the rollout should this provision go into effect as proposed. As an alternative in addition to FCPDS, the CAP would also like to promote the NAACCR Vol. V standard**, which is currently the only widely used public health reporting protocol for cancer pathology. 2028 would be an acceptable date for NAACCR Vol. V implementation, as implementation assistance and testing are available from public health entities such as state central cancer registries and the CDC and allows vendors to adopt a new Vol V interface within a few months. Adding NAACCR Vol V as an

[5] Which is included in the following sections of the HTI-2 Proposed Rule: Health IT Modules Supporting Public Health Data Exchange -- Revised Certification Criteria for Health IT Modules Supporting Public Health Data Exchange (Section III.B.13.d) and Health IT Modules Supporting Public Health Data Exchange -- New Certification Criteria for Health IT Modules Supporting Public Health Data Exchange (Section III.B.13.e).

alternative should ease the burden on laboratories that already implement it, and to allow new laboratories that do not want to or cannot support FHIR to have a more familiar HL7 2.5.1 path for data exchange. This may also be contingent upon future HL7 balloting. **Vendors should not charge laboratories for implementing FCPDS or NAACCR Vol. V, and these interfaces should be part of the core package for laboratory software systems so that laboratory users do not have to spend any extra time or money on their implementations.**

3. Revised Criterion for Encrypt Authentication Credentials (III.B.12)

ASTP proposes that Health IT Modules designed to store authentication credentials must protect the confidentiality and integrity of their stored authentication credentials. **This is desirable and the CAP supports this provision. However, meeting the requirement will have a cost for systems that do not already support it. Consequently, the CAP emphasizes that expanded funding is necessary for this provision to be implemented.**

4. New Standardized API for Public Health Data Exchange (Section III.B.13.f)

ASTP proposes to adopt a new certification criterion that would establish requirements for a standardized HL7 Fast Healthcare Interoperability Resources (FHIR)-based API for public health data exchange. **Although the relatively new 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.

Moreover, the CAP notes that there are aspects of this proposal for the use of FHIR standards that appear at odds with the requirements for LOI/LRI data exchange described above. This provision includes requirements for FHIR capabilities such as FHIR Bulk Data Access and could provide a foundation for additional FHIR capabilities in the future. The focus of this API would presumably be for retrospective bulk data and the LOI/LRI interface noted previously would support prospective case reporting. **The CAP cautions that this API would be a new type of interface for most labs and the FHIR Bulk Data Access capability needs to be evaluated to make sure it meets public health needs (ie, that the critical data elements for public health could be made available within the bulk transfer in an interoperable form).** This API would effectively be a second public health interface, in addition to LOI/LRI for case reporting, and there would be additional expense for its development and maintenance. **It is not clear that moving forward with this API now would provide substantial benefit consistent with its cost, as opposed to rolling this into a future FHIR transition for overall public health reporting.**

5. Multi-Factor Authentication Criterion (Section III.B.17)

ASTP proposes to update the requirements in the “Multi-factor authentication” (MFA) certification criterion in § 170.315(d)(13) to increase support for MFA in certified health

IT without imposing additional requirements on health care providers. **The CAP supports this security improvement with the caveat that implementation in systems currently without it would have a cost. Consequently, the CAP emphasizes that expanded funding is necessary for this provision to be implemented.**

6. Minimum Standards Code Sets Updates (Section III.B.5)

ASTP proposes that newer versions of minimum standards code sets would serve as the baseline for certification and developers of certified health IT would be able to use newer versions of these adopted standards on a voluntary basis. **The CAP supports this update.** In addition, the latest versions of content standards (e.g., CAP Cancer Protocols) and data exchange standards should be used. For the latter, updates should be implemented within a year after the updated standard is officially released by the standard's owner Standards Development Organization (SDO). When several types of releases (e.g., drafts, trial use, etc.) are made at a relatively rapid pace, the SDO or ASTP may need to explicitly indicate a start date for the new version.

7. New Imaging Requirements for Health IT Modules (Section III.B.6)

ASTP proposes to include new certification requirements to support access, exchange, and use of diagnostic images via imaging links, which ASTP is defining to be technical details which enable the electronic viewing or retrieval of one or more images over a network. The requirement is for an accessible link to images and associated narrative without specification of any particular format by January 2028. Pathology images are mentioned as a potential class of images for increased accessibility. **The CAP requests that pathology and clinical laboratory images be excluded from the requirements at this time unless those images are reported to the EHR and used for exchange between hospitals for patient care.** The other image types mentioned in this section, such as radiology types, are generally inherently electronic. In contrast, most pathology cases nationally are not yet captured electronically and installing Whole Slide Imaging (WSI) systems with storage, communication, and viewing infrastructure just to meet this requirement is impractical on a cost and management basis. In the clinical laboratory, images produced as part of the laboratory workflow but not intended for reporting to the EHR (ie, automated urine microscopy and blood smears, flow cytometry, capillary SPEP) do not currently have adequate export, storage, and linkage capabilities for this purpose and should be excluded. If pathology and laboratory images are included in the scope of diagnostic images and pathology is compelled to comply, then it would be burdensome given the state of current systems. In the future, as digital images become part of the routine, pathology diagnostic and reporting workflow, external access to images may become practical.

8. Information Blocking Enhancements (Section IV)

ASTP proposes to update two existing exceptions and establish two new exceptions. These proposals respond to patient, provider, and other communities' concerns about

patient privacy, care access, Electronic Health Information (EHI) sharing preferences, and a balance of certainty and flexibility for actors as they seek to optimize interoperability and sharing of EHI. ASTP's revisions to existing exceptions would expand application of the existing Privacy Exception to further support more actors' practices protecting the privacy of patients' health information and update the existing Infeasibility Exception to offer actors more clarity and more flexibility under certain conditions. Other proposals would also enhance clarity around the codified definitions of certain terms for information blocking purposes Specifically, ASTP has proposed the following new Information Blocking Exceptions:

- The Protecting Care Access Exception would, under specified conditions, cover actors' limiting EHI sharing to reduce a risk of potentially exposing patients, providers, or persons who facilitate care to legal action based on the mere fact that they sought, obtained, provided, or facilitated lawful reproductive health care. The Protecting Care Access Exception would also apply where an actor limits sharing of a patient's EHI potentially related to reproductive health care to protect that patient from potential exposure to legal action.
- The Requestor Preferences Exception would provide actors a framework under which they can be confident they will not be committing information blocking if they agree to a requestor's ask for restrictions on when, under what conditions, and how much EHI is made available to that requestor.

The CAP supports the updated and new exceptions to the Information Blocking Rule. The CAP has previously requested that ASTP reduce potential patient harm and improve care coordination by allowing for greater flexibility and more expansive use of the legal exceptions to the information blocking regulations. Moreover, the CAP would like to reiterate the statement that it made after the U.S. Supreme Court's *Dobbs v. Jackson Women's Health* ruling.[6] The CAP stands with the physician community as it defends the practice of medicine and protects the sanctity of the patient-physician relationship. While it is necessary for laws and regulations to provide proper oversight in our health care system, any statute criminalizing evidence-based medical care provided by physicians represents a harsh and unwarranted intrusion by state governments. In addition, with respect to the Protecting Care Accession Exception, the CAP notes that pathologists should not be compelled to provide speculative information in the absence of conclusive medical evidence, or on matters beyond the purview of pathological examination. **The new exceptions to the Information Blocking Rule are a step in the right direction in terms of protecting patients and providers who seek, obtain, provide, or facilitate lawful reproductive healthcare.**

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[6] https://www.cap.org/member-resources/articles/college-of-american-pathologists-issues-statement-on-dobbs-v-jackson-womens-health-ruling

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

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