



COLLEGE of AMERICAN PATHOLOGISTS

February 25, 2026

The Honorable Thomas Keane, MD, MBA
Assistant Secretary for Technology Policy and Office of the National Coordinator for Health
Information Technology
U.S. Department of Health and Human Services
330 C St SW
Floor 7
Washington, DC 20201

**Re: RIN 0955-AA09 – Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory
Actions to Unleash Prosperity [Docket No. HHS-ONC-2025-0005]**

Submitted via Electronic Submission to www.regulations.gov

Dear Assistant Secretary Keane,

The College of American Pathologists (CAP) appreciates the opportunity to comment on the *Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions to Unleash Prosperity (HTI-5) Proposed Rule*, issued by the Assistant Secretary for Technology Policy (ASTP). 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. As physicians specializing in the diagnosis of disease through laboratory methods, pathologists deliver high quality diagnostic services to patients and other physicians. The pathologist's diagnosis and value are recognized throughout the care continuum and many patient encounters. For almost 80 years, the CAP has been the advocate for pathologists, patients, and the public when it comes to improving laboratory quality and assuring that patients receive the right test, at the right time, and with the right result.

The CAP supports the goals of ASTP's HTI-5 Proposed Rule, which are to (1) reduce burden on health IT developers by streamlining the ONC Health IT Certification Program by removing redundant requirements; (2) update the information blocking regulations to better promote electronic health information access, exchange, and use so that patients' access to their data is not blocked; and (3) advance a new foundation of artificial intelligence (AI)-enabled interoperability solutions. However, the CAP has concerns with two aspects of the proposed rule, which we will focus our comments on:

1. Decision Support Interventions (III.A.2.e)
2. Information Blocking (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. Decision Support Interventions (III.A.2.e)

The CAP prioritizes patient safety in the development and responsible implementation of AI in pathology. Pathologists must have full information to build trust in the health IT systems that they are deploying in the laboratory setting. Consequently, the CAP urges HHS to maintain requirements for transparent information from AI developers regarding source attribute support, access, and modification and intervention risk management for predictive decision support interventions (DSIs), which include AI algorithms in ASTP's Health IT Certification Program.¹ ASTP is proposing in the HTI-5 proposed rule to rescind these informational requirements. However, as the CAP noted in 2023,² these informational requirements help guide pathologists in their responsibilities to assess AI systems. Specifically, these informational requirements help provide transparent information to pathologists to help them understand the development, deployment, and configuration of AI technology. This information helps pathologists apply their knowledge of laboratory testing in the implementation of AI-enabled devices in the laboratory, including ethical considerations, patient safety issues, risks, workflow, and other challenges. The information included in these requirements is important to promote trust in AI algorithms and encourage adoption and use of AI in pathology and laboratory medicine. Moreover, repealing these requirements would increase the risk of waste, fraud, and abuse proliferating in the healthcare system, as their repeal will make it more difficult for physicians to assess whether specific AI models are trustworthy.

2. Information Blocking (IV)

The CAP supports patient access to test results but is concerned with immediate release of pathology and laboratory results to patients prior to clinician review. Immediate release without medical context can hinder care coordination and cause undue patient confusion and distress. For example, some test results are not indicative of cancer but contain technical biomarker findings that may appear alarming when viewed without context. A patient undergoing a diagnostic workup for a benign condition may receive an automatically released laboratory or pathology report indicating "*markedly elevated CA-125*" or "*positive p16 overexpression.*" While such biomarkers can be associated with malignancy, they are frequently elevated in non-cancerous conditions such as endometriosis, inflammation, or reactive conditions. Without clinician interpretation, the patient may incorrectly conclude that they have cancer, leading to significant emotional distress and unnecessary downstream testing or consultations. This scenario illustrates the real-world challenges created by automatic, immediate release of complex interpretive results without clinical context. Moreover, even when there is a positive cancer diagnosis, the clinical implications of a cancer diagnosis vary tremendously. For example, the clinical implications of a diagnosis of a skin basal cell carcinoma and malignant melanoma are quite different. Without proper context discussed with a physician, a patient may experience undue stress.

¹ These requirements are in § 170.315(b)(11)(iv), (v), and (vi).

² <https://documents.cap.org/documents/CAP-HTI-1-Comment-Letter.pdf>.



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It is for this reason that the CAP supports patient access to test results but is concerned with immediate release of pathology and laboratory results to patients prior to clinician review. The CAP urges a blanket exception to the Information Blocking Rule³ to allow for the opportunity for involved clinicians to create an integrated response before the release of pathology and laboratory results for the best care coordination and so physicians can provide medical context and help patients manage their responses.

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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.

Sincerely,
College of American Pathologists

³ Which was established in ASTP's 2020 final rule *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program*