COLLEGE of AMERICAN PATHOLOGISTS

March 16, 2026

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

Re: Request for Information: Diagnostic Imaging Interoperability Standards and Certification (RIN 0955-AA11)

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 Request for Information (RFI) *Diagnostic Imaging Interoperability Standards and Certification* issued by the Assistant Secretary for Technology Policy (ASTP)/Office of the National Coordinator for Health Information Technology (ONC). ASTP's RFI seeks input from the public regarding the potential adoption of diagnostic imaging technical standards and certification criteria for health information technology (IT) under the ONC Health IT Certification Program to better enable the access, exchange, and use of diagnostic images by health care providers and patients. 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 have a long track record of delivering high quality diagnostic services to patients and other physicians.

The CAP believes the ASTP's goal of promoting exchange of diagnostic images is not currently applicable to pathology. Pathology involves diagnostic testing of a biospecimen provided by the patient, consisting of tissue, cells, and/or fluid. The pathology diagnostic process does not begin with an image, as with specialties such as radiology. The biospecimen is processed and a glass slide or less frequently a digitized image thereof together with relevant data are interpreted by a pathologist. Based on the analysis of the slide or digitized image together with relevant data, pathologists convey diagnostic information through the pathology report, which serves as the clinical deliverable to the ordering clinician and the patient. The ordering clinician and patient review the pathology report and generally do not reexamine the images. Accordingly, while pathology images may be created and used for diagnosis or pathologist-to-pathologist consultation, they are not routinely required by ordering clinicians or patients for clinical decision-making; the report conveys the diagnostic interpretation. Pathologists do not typically send the physical biospecimen (e.g. microscopic slides) without a report to either the clinician or the patient. Consequently, ASTP's goal of promoting the exchange of diagnostic images is not currently applicable to the practice of pathology.

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Pathologists will often prepare glass slides of the biospecimen to conduct a variety of types of analyses. Although creating digital whole slide images of the glass slides can facilitate easier transfer to reference labs for consultations, creation of the glass slide is a necessary starting point. Indeed, the glass slide remains the source of truth. Pathologists and laboratories must confirm diagnostic accuracy and equivalence of whole slide imaging systems with glass slides and digital microscopy systems before they can use these systems for diagnostic purposes.[1]

Digital pathology—which involves acquiring, managing, and interpreting pathology information from digitized glass slides—is not yet the standard of care; national adoption remains limited. Adoption has been slow due to significant infrastructure demands, including the cost of scanners, digital storage space, high-performance computing, and related health IT systems. The CAP collected data in its 2025 Practice Leaders Survey that indicated that only 15% of practices reported ever using digital pathology to arrive at a primary diagnosis. Even among these 15% of practices, fewer than half of the practices make most diagnoses digitally. Evidence indicates adoption varies significantly by practice setting, with academic medical centers and reference laboratories more likely to digitize slides.

However, even when whole slide images are used, the pathologist conveys the diagnosis through the pathology report, not sending the image to the clinician to interpret. Although some institutions display digital images of microscopic slides within the electronic health record system (EHR) for reference, all routine clinical workflows in pathology still rely on the report rather than clinician or patient review of the images themselves. For these reasons, it is exceedingly rare for patients to access the images that pathologists may use to arrive at a diagnosis or for ordering clinicians to request the images. Patients generally access the pathology report, not the underlying images, and ordering clinicians rarely need to consult a pathology image to obtain diagnostic information beyond what is already contained in the report.

To encourage further adoption of digital pathology, the CAP recommends federal policies that increase investment in digital infrastructure and workforce training. Pathologists need additional resources to support these efforts given a range of cost pressures, including laboratory reagents, increasing administrative burdens, staff salaries, office rent, and essential technology without commensurate increases in reimbursement.

The CAP is working with stakeholder organizations and technology companies to promote interoperability in digital pathology through use of the DICOM® (Digital Imaging and Communications in Medicine) standard. DICOM holds promise to ensure interoperable digital pathology in the long run by moving toward a standard and away from proprietary approaches. While use of DICOM for pathology is still in the early stages, adoption is steadily increasing, with leading academic centers already implementing it and a significant rise in vendor participation in DICOM

[1] Evans AJ, Brown RW, Bui MM, et al. “Validating Whole Slide Imaging Systems for Diagnostic Purposes in Pathology Guideline Update From the College of American Pathologists in Collaboration With the American Society for Clinical Pathology and the Association for Pathology Informatics” *Archives of Pathology & Laboratory Medicine* 146.4 (2022): 440-450. DOI: 10.5858/arpa.2020-0723-CP.

interoperability testing events. To this end, the CAP is playing a leadership role in a DICOM working group (WG-26) designed to support and develop the DICOM standard for pathology.[2]

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We would appreciate an opportunity to meet with ASTP to discuss the applicability of this RFI for pathology and laboratory medicine, as well as the ways that we can work together. Thank you for the opportunity to submit these comments. Questions can be directed to Han Tran at htran@cap.org.

Sincerely,
College of American Pathologists

[2] https://www.dicomstandard.org/activity/wgs/wg-26.

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