COLLEGE of AMERICAN PATHOLOGISTS

August 26, 2025

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

Dear Assistant Secretary Keane:

On behalf of the members of the College of American Pathologists (CAP), congratulations on becoming Assistant Secretary for Technology Policy and National Coordinator for Health Information Technology. 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. 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.

We look forward to working with you in promoting the adoption of health information technology and the promotion of nationwide, standards-based health information exchange to improve health care. As the Trump Administration looks to reduce regulatory burden, create efficiencies with the federal government, and improve our nation’s health, the CAP has expertise and resources to help the government achieve these goals. The CAP seeks to have a meeting with you to discuss ways in which we can leverage our expertise to enhance the nation’s health care system by addressing key Health Information Technology (HIT) issues. These include:

1. Interoperability
2. Information Blocking
3. Artificial Intelligence (AI)

CAP HIT Priorities

1. Interoperability

The benefits of interoperability include wider availability of clinical data at the point of patient care, reduction of redundant or repeated testing, elimination of result interpretation errors leading to unnecessary treatment or patient harm, and reduction in costs of system implementation and maintenance. To that end, the CAP supports the use of consistent, open (i.e., nonproprietary) standards to satisfy data exchange or data

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provision requirements, including public health and other federal/state/municipal reporting. 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 collaborating with the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP) to promote interoperability while avoiding potential unintended consequences and patient harm.

The CAP promotes the use of standards in the laboratory ecosystem through initiatives such as the FDA Systemic Harmonization and Interoperability Enhancement of Laboratory Data (SHIELD). We have also worked with leading industry partners to develop the electronic CAP Cancer Protocols to both provide standardized data sets and to enable the synoptic gathering of data within the laboratory information system (LIS) or as a standalone application. Many LIS vendors have integrated the CAP electronic Cancer Protocols into their AP-LIS software products.[1][2]

2. Information Blocking

The CAP supports patient access to test results but is concerned with immediate release of results to patients without clinician input. Immediate release without medical context can hinder care coordination and cause undue confusion and distress. The CAP urges a blanket exception to the Information Blocking Rule—which was established in ASTP's 2020 final rule *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program* (85 FR 25642)—to allow for the opportunity for involved clinicians to create an integrated response before patient communication for the best care coordination.

Additionally, the CAP supports seamless and straightforward integration between LISs, hospitals, and other stakeholders such as clinical data registries. Currently, hospitals and LIS vendors often refuse to share data with pathologists and clinical data registries or charge exorbitant fees to access data. Hospitals and EHR vendors should not prevent physicians from accessing data generated within their practices for use in quality improvement, reporting, and research purposes. The CAP encourages ASTP to continue collaborating with the Centers for Medicare and Medicaid Services (CMS) and other relevant stakeholders ensuring data flows freely. We suggest that ASTP work to increase incentives for hospitals to share data. Finally, as a last resort for clinicians who are being entirely denied access to their data, we suggest ASTP and CMS work with stakeholders to streamline the information blocking claim system.

3. Artificial Intelligence (AI)

AI may present both significant opportunities and substantial, evolving challenges for the field of pathology and has the potential to affect the way pathologists practice medicine.

[1] https://www.cap.org/protocols-and-guidelines/electronic-cancer-protocols

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Pathologists are critical thought leaders with special expertise in laboratory operation and have responsibility for the selection, analytic verification or validation, clinical validation, integration, and performance monitoring of laboratory tests. The expansion of pathologists' responsibilities to include AI constitutes an important new element in pathologists' role as Clinical Laboratory Improvement Amendments (CLIA) laboratory directors and section directors. The CAP supports and encourages the professional and critical role of pathologists in the development, implementation, and maintenance of AI systems within the laboratory.

The CAP has advocated to the Administration in several ways to advance the Administration's AI priorities:

- Ensure that federal regulations on AI are reasonable and not overly burdensome from a laboratory perspective, prioritize patient safety, ensure clinical validity, allow innovation, and preserve the role of pathologists as physicians and advocates for patients.
- Ensure any new regulatory requirements are not duplicative with existing regulations and do not infringe on the practice of medicine.
- Recognize the leadership role that pathologists must have in the selection, configuration, deployment, application, and monitoring of AI systems involved in the pre-analytical, analytical and post-analytical phases of laboratory workflow.

Conclusion

We appreciate your considerations of these priority items and look forward to meeting with you to build a strong partnership as we advance America's health. Please contact Helena Duncan, Senior Director of Quality and Healthcare Policy (hduncan@cap.org, 202-354-7131) to schedule a meeting to discuss any additional questions.

Sincerely,

Donald S. Karcher, MD, FCAP
President, College of American Pathologists

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