COLLEGE of AMERICAN PATHOLOGISTS

CLIAC Meeting November 2024

CAP Statement regarding Cybersecurity Requirements in the Clinical Laboratory

The College of American Pathologists (CAP) appreciates the opportunity to provide written comments to the Clinical Laboratory Improvement Advisory Committee (CLIAC). 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.

The CAP strongly supports efforts to protect health data and continuity of care from cybersecurity attacks and understands the need for policy solutions. Cybersecurity attacks can and do affect every entity in the healthcare community. Hospitals, medical practices, laboratories, patients, and private and public payors all must exchange health data with each other to diagnose, treat, and report diseases. This data is critical to patient care, but also very valuable to bad actors should it fall into the wrong hands.

Adding cybersecurity requirements to the CLIA regulations is both an incorrect and insufficient approach. CLIA is intended to regulate the core functions of the clinical laboratory. Regulatory requirements beyond oversight of laboratory certification and testing would be out of scope. Additionally, government agencies such as the Food and Drug Administration (FDA) and the Cybersecurity and Infrastructure Security Agency (CISA) are working to establish regulatory requirements. These would protect individuals, specify the defensive measures that covered entities need to implement, and outline the responsibilities of covered entities in case of cybersecurity attacks. Effective policy to thwart cybersecurity attacks entails an all-of-Health and Human Services, or even all-of-government approach, working in concert with all-of-industry working collectively. These efforts must include funding support for implementation of new security measures and ensure consistency across government agencies' requirements.

Laboratory systems, including Laboratory Information Systems (LIMS), are connected to and a part of wider systems in hospitals. Data is and must continue to be exchanged between ordering physicians, laboratories, patients, and when appropriate, public health authorities and payors. Each of these actors has a role to play in securing health data. Data is not siloed, and cybersecurity solutions should not be, either. Continuing to address cybersecurity in a piecemeal fashion, singling out individual industries or actors, will not increase security of our health data. Effective solutions will entail rules and standards for preventing and addressing cybersecurity incidents developed and implemented by governments working with all stakeholders.

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The CAP requests that CLIA, or CMS more widely, undertake study and discussions with the laboratory community to understand cybersecurity concerns and the gaps that could be addressed with regulatory action.

For laboratories, one of the most significant risks is documenting that they have received orders once systems go down or are unable to be accessed. Some redundancy should be encouraged, while not being too prescriptive. This could entail parallel, or backup systems, involving paper-based orders and records. Any guidance should be system-wide, constructive rather than punitive, and include a timeframe for integrating paper-based records into electronic systems. Federal funding should be included to help laboratories implement the technology needed for compliance, as cost is the largest barrier to laboratories updating their information technology systems.

Once again thank you the time to discuss the CAP's concerns and recommendations and we welcome the opportunity for further dialogue. Please contact Andrew Northup at anorthu@cap.org or 202.297.3726.

Closing,

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