Association for Pathology Informatics

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Attention: CLIAC Secretariat
1600 Clifton Road NE
Mailstop V24-3
Atlanta, GA 30333

Dear CLIAC Members:

The Association for Pathology Informatics (API) appreciates this opportunity to provide comments to CLIAC concerning the regulation of remote digital review and reporting of pathology slides under CLIA. As the only national organization dedicated exclusively to pathology informatics, the API endeavors to play an active role in contemporary legal, ethical, social, and regulatory issues related to pathology informatics. It counts amongst its membership many world leaders in informatics and seeks to further its relationships with professional societies, industry, and regulatory partners with similar interests and goals.

In brief, the API requests that CLIAC recommend extending the current enforcement discretion beyond the end of the COVID-19 public health emergency (PHE) so that a primary clinical laboratory site does not need to obtain separate CLIA certificates or submit multiple CMS 116 forms for all of its affiliated remote sites where pathology slides are reviewed. The API recommends that enforcement discretion should continue until CLIA regulations can be amended to provide a permanent exemption for remote review of pathology slides via digital pathology (i.e. telepathology).

Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations mandate that all laboratory testing is performed on the premises of a CLIA-certified laboratory. Such testing includes the review and reporting of glass pathology slides. To comply with CLIA regulations, pathologists who wish to review and sign out cases with glass slides remotely (e.g. in their home) need a separate CLIA certificate for each additional permanent site. Alternatively, a temporary site exception indicated on Form 116 might be used for non-permanent off-site testing. Until recently, reviewing cases at remote sites was rare given the physical nature of glass slides, but the recent emergence of digital pathology has renewed interest in remote pathology slide review and case reporting (i.e. "signout").

In November 2019, the mindset of on-site physicality being a necessity of practice started to shift. CLIAC recognized that access to a LIS in a secure environment is the same, whether via a workstation inside a CLIA-certified facility or via a remotely-connected workstation. CLIAC recommended that the CLIA program "consider that, when laboratory professionals provide patient care through selection, interpretation, and reporting of patient results by accessing data remotely in a secure environment, they get deemed as performing those services at the primary site housing the CLIA Certificate." [1]

The COVID-19 PHE brought new urgency to the issue of remote review and reporting of pathology slides. In March 2020, the CMS Center for Clinical Standards and Quality issued guidance for CLIA program State Survey Agency Directors to "exercise enforcement discretion to ensure pathologists may review pathology slides remotely" at temporary testing sites, including a pathologist's home [2]. This action, intended to “promote innovative uses of technology to increase capacity in order to avoid exposure risks to health care providers, patients, and the community,” was essential to the vulnerable aging majority of the pathology workforce [2, 3]. In April 2020, the Food and Drug Administration (FDA) issued its own enforcement discretion policy related to digital pathology devices [4]. Notably, while the loosening of CMS and FDA enforcement lowered barriers to deploying the remote review of slides, essential laboratory practices, such as digital pathology system validation, remained in place.

By October 2020, at least 6% of pathologists had used digital pathology devices for remote diagnosis, and more pathologists have since followed [5]. The enforcement discretion provided by the CMS and FDA produced a significant body of real-world evidence regarding the safe, secure, and effective review and reporting of digital pathology slides from sites remote to the primary clinical laboratory site. Concurrently there was an accumulation of operational knowledge regarding how modular approaches for digital pathology solutions can be effectively validated and used. Furthermore, to date, we are not aware of any negative consequences from the decision to enact enforcement discretion.

Regulation and legislation often lag behind advances in technology. CLIA was enacted in 1988 when the term “telepathology” was just two years old, whole slide imaging would not exist for another decade, and the FDA clearance of a digital pathology system was still 29 years in the future. While CLIA could not have anticipated the emergence of these digital technologies, the laboratory accreditation process it created provides a pathway to safely and responsibly incorporate digital technologies into laboratory practice. CMS and their respective accreditation organizations (e.g., College of American Pathologists (CAP), The Joint Commission, and NY State) have consistently allowed clinical laboratories to innovate and develop new testing methodologies, provided they follow proper method validation and prove a test’s safety and effectiveness.

In the near term, we are requesting an extension of the current enforcement discretion. Ultimately, we suggest that CMS reconsider how it defines a laboratory site by acknowledging digital innovations and removing the outdated requirement that a pathologist’s interpretation must occur within the boundaries of a physical address. We strongly believe that a clinical laboratory system, which now comprises both physical and digital worlds, should be accredited in its entirety (i.e., both on-site and remote locations together) by CMS to ensure consistent quality and safety across all areas of the laboratory. To this end, remote review of pathology slides can be treated like other aspects of the pathology lab, with requirements for validation, standard operating procedures, training, competency assessments, and documentation.

The API is aligned with CLIA's purpose to establish quality standards for laboratory tests performed on human specimens to diagnose, prevent, and treat disease. The API is grateful to work with CLIAC in our shared pursuit of the highest possible healthcare standards. Likewise, the API aligns with the FDA's priorities in risk management and efforts to establish a more agile and adaptive regulatory framework that can keep pace with accelerating medical innovation. Ultimately, the alignment of professional organizations such as API with regulatory stakeholders like CMS and FDA will foster innovation in the laboratory while ensuring safe and effective patient care. Thank you for considering these comments.

Sincerely,

Toby C. Cornish, MD, PhD
President, Association for Pathology Informatics
On Behalf of the API Governing Council

References:

1. AAMC 2020 Physician Specialty Report Data Highlights, *available at* https://www.aamc.org/data-reports/workforce/interactive-data/2020-physician-specialty-report-data-highlights
2. CLIAC Summary Report (Nov. 6-7, 2019) at 16, *available at* https://www.cdc.gov/cliac/docs/summary/cliac0919_summary.pdf.
3. Clinical Laboratory Improvement Amendments (CLIA) Laboratory Guidance During COVID-19 Public Health Emergency (March 26, 2020), *available at* https://www.cms.gov/files/document/qso-20-21-clia.pdf-0.
4. Enforcement Policy for Remote Digital Pathology Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (April 24, 2020), *available at* https://www.fda.gov/media/137307/download.
5. CAP COVID-19 Pathologist Impact Survey: Summary of Findings. October 2020