COLLEGE of AMERICAN PATHOLOGISTS

Statement to the Clinical Laboratory Improvements Advisory Committee on the CLIA Regulations Assessment Workgroup

The College of American Pathologists (CAP) appreciates the opportunity to provide written comments to the Clinical Laboratory Improvement Advisory Committee (CLIAC) on the **Clinical Laboratory Improvements Amendments of 1988 (CLIA) Regulations Assessment Workgroup Report.** 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.

From our experience as an accreditor, the CAP Laboratory Accreditation Program serves clinical laboratories providing leading-edge science and technology, while ensuring clinicians and patients receive accurate laboratory testing. The CAP finds that CLIA continues to provide an adequate baseline to ensure the accuracy and reliability of clinical laboratory results. At the same time, we recognize that specific updates to CLIA are needed to address changes in practice and technology to adapt to evolving practice models. Hence, the CAP offers the following comments to the CLIAC for consideration in any recommended changes to CLIA:

- Considerations for Remote Work
- Revamping the proficiency testing (PT) requirements to address the total testing process.

Remote Work Considerations

Many pathology and laboratory medicine departments in the United States have the infrastructure to support remote sign-out. This includes, but is not limited to, the use of validated digital pathology systems, remote access to electropherograms, dot plots, FISH images and charts. In March 2020, the CAP strongly advocated for the CMS to exercise regulatory flexibility to allow remote sign-out because its benefits during COVID-19 pandemic far outweighed the risks. The action was necessary to ensure appropriate pathology and laboratory medicine services were provided to patients and to decrease the risks to health care workers during the pandemic. The public health emergency (PHE) policy allows for pathologist to review slides, digital images, and electronic data from a temporary testing site, provided that remote site or home base is not used as the designated primary site and work performed in the temporary sites falls within the parameters of the primary's site's certificate[1].

The CAP supports the continuation of the remote sign-out waiver for the duration of the PHE; however, we recommend the CLIAC examine potential unintended consequences that could cause patient safety and testing quality issues. The primary site certification was required by CLIA to ensure quality testing and safety of patients by providing greater oversight for gynecologic cytology

[1] (§493.35(b)(1). 43(b)(1), 55(b)(1)) A temporary testing site is where, at various intervals of time, an entity that is not at a fixed or permanent location performs laboratory testing. Such a temporary testing site may be the pathologist's home.

laboratories. In recent years, we have similar quality concerns with regards to pod laboratories. Removal of the primary site CLIA certification allows for slides to be read at various locations other than the physician's practice, potentially increasing the volume of slides read and decreasing oversight. While the CAP recognizes the benefits in continuing to allow remote work, **we strongly recommend closely monitoring the following: remote sign-out usage to determine the settings, personnel qualifications, and documentation of compliance with primary site policies and procedures to ensure CLIA maintains quality practices for all testing settings and to prevent potential fraud and abuse by "Pap mills" and "pod laboratories". The CMS, prior to any rulemaking, should collect and report the on the above to CLIAC. This information should be collected for at least one survey cycle after the PHE declaration ends. Therefore, the CAP supports continued enforcement discretion following the expiration of the PHE while the practice and regulatory implications of the remote sign-out policy are further evaluated.**

In addition, the CMS should remove the pathologist's home address for the CLIA certification. Testing sites prior to the PHE declaration were required to obtain a CLIA certificate that including their home addresses. Since the beginning of the pandemic, health care providers have been attacked with higher frequency. This PHE has demonstrated that health facilities, medical transport units, patients and health care workers and their families can become targets everywhere. This alarming trend reinforces the need for improved measures to protect health care from acts of violence. During the COVID-19 pandemic, protecting the health and lives of frontline health care providers is critical to enabling a rapid and effective response. **As such, the CAP recommends that the CMS remove the home address for read only sites from the CLIA certificate and create an alternative mechanism for identifying these testing sites.**

PT Requirements for the Total Testing Process

Distributive testing occurs when clinical laboratory testing is performed on a specimen, or an aliquot thereof, and requires sharing it between two or more laboratories to obtain the necessary data in order to complete an interpretation or calculation necessary and provide a final test result. When such testing occurs at multiple locations with different CLIA certificates, it is considered distributive.[2] An important quality metric in determining clinical laboratory testing accuracy and reliability is proficiency testing. The CAP provides laboratories with a wide range of PT products and has the responsibility to evaluate the accuracy of test performance and interpretation in more than 23,000 laboratories worldwide. The program allows laboratories to regularly evaluate their performance and ensure and improve the accuracy of the patient results. Through these programs, the CAP provides individual laboratories with samples for testing.

Laboratories should perform PT by observing the same process that they do for patient samples, including moving samples among multiple sites to complete all aspects of testing. Doing so should not constitute intent to commit proficiency testing referral. The CAP launched in 2015 PT for NGS where laboratories can test up to 200 variants in a method-based challenge using either gene panels, exome, and/or whole genome sequencing. The initial NGS PT program, designed to assess the ability of laboratories to detect germline variants, was followed by NGS PT for the detection of somatic variants and other NGS clinical testing applications. The programs can test "wet" and "dry" bench components of NGS testing. Under the current regulatory paradigm, clinical laboratories are unable to test the entire system if portion of the test is performed in a "distributive testing model" such as bioinformatics and

[2] (https://www.lawinsider.com/dictionary/distributive-testing)

cloud-based software computing. This makes it difficult to assess the complete process (pre-analytic, analytic, and post-analytic) and is an insufficient quality indicator.

Conclusion

The CAP supports CLIAC efforts to examine the CLIA regulations to determine modifications to ensure that the regulations accommodate advancements in clinical laboratory practice; however, any modifications should assure patient access to quality testing by affording the least burdensome approach to oversight. CLIA is a very important tool that can ensure the integrity of clinical laboratory testing. As clinical laboratory testing continues to evolve, the CMS and interested stakeholders such as the CAP will need to work closely to ensure appropriate regulations and policies.

The CAP welcomes the opportunity to discuss our concerns and recommendations for implementation at your earliest. Please contact Helena Duncan at hduncan@cap.org or 202.354.7131.

Closing,

The College of American Pathologists