ACMG
American College of Medical Genetics and Genomics
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Comments to the Clinical Laboratory Improvement Advisory Committee
Regarding CLIA Regulation of Remote Laboratory Work
April 12-13, 2023

The American College of Medical Genetics and Genomics (ACMG) would like to highlight aspects of the CLIA regulations that require clarification as they relate to working remotely. Specifically, we ask this committee to continue to push forward its 2019 recommendation that "*when laboratory professionals are providing patient care through selection, interpretation, and reporting of patient results by accessing data remotely in a secure environment, they should be deemed as performing those services at the primary site that houses the CLIA certificate*".

We recognize that the CLIAC has already made this recommendation and two similarly worded recommendations to CMS on three separate occasions.[1,2,3] However, we are concerned that with the end of the Public Health Emergency (PHE) and the continued lack of clarification on this matter, we will return to a situation where the now well-established practice of use of secure portals to review digital laboratory data from locations that may be on-site or remote is in jeopardy. We are further concerned that the February 2022 CMS statement and subsequent fact sheet regarding the enforcement discretion allowed for pathologists will lead to a scenario where it is only the particular board-certification of the individual rather than the nature of the work that will determine the ability of the work to be performed in a remote setting without an additional CLIA license, which is a nonsensical position.[4,5] This topic is reflected in the CLIAC's November 2022 recommendation which clarifies that "*the CLIA regulations should be revised to allow remote analysis for any CLIA specialty or subspecialty*".[3] While a permanent change to the CLIA regulations is needed, CMS in the meantime should clarify its related enforcement discretion to make clear that it applies to all specialties examining laboratory data at remote locations. Such clarification is needed prior to the end of the PHE to avoid disruption to the already strained laboratory testing workforce.

The advent of COVID-19 has challenged the American workforce to rethink the traditional employment paradigm by shifting into distance working. Across many disciplines, individuals have adapted the use of secure portals, such as VPNs, to ensure secure and accurate data review while maintaining the same level of quality, safety, timeliness, accessibility and productivity. Even as COVID-19 restrictions are relaxed, many institutions have and will continue to maintain a hybrid

[1] Clinical Laboratory Improvement Advisory Committee (CLIAC) Recommendations, November 6-7, 2019 (https://www.cdc.gov/cliac/docs/april-2023/cliac_recommendationstable_apr2023.pdf)
[2] Clinical Laboratory Improvement Advisory Committee (CLIAC) Recommendations, April 13-14, 2022 (https://www.cdc.gov/cliac/docs/april-2023/cliac_recommendationstable_apr2023.pdf)
[3] Clinical Laboratory Improvement Advisory Committee (CLIAC) Recommendations, November 9-10, 2022 (https://www.cdc.gov/cliac/docs/april-2023/cliac_recommendationstable_apr2023.pdf)
[4] Centers for Medicare and Medicaid Services Notice to State Survey Agency Directors, QSO-22-13-CLIA, February 28, 2022 (https://www.cms.gov/files/document/qso-22-13-clia.pdf)
[5] Laboratories: CMS Flexibilities to Fight COVID-19 (https://www.cms.gov/files/document/laboratories-cms-flexibilities-fight-covid-19.pdf)

working model in which work can be performed on-site or remotely, as long as a comparable level of quality, accuracy, and security is reached. This has become the "new normal" moving forward.

Currently, much of the data generated from genetic testing laboratories are stored and accessed digitally within medical laboratory information systems that are designed to be accessed from any securely networked computer. In contrast to telemedicine, where physical examinations may be less complete, secure remote work is as complete as that done on-site. This is true for quantitative results, gene sequencing tests, digital images of a Southern blot, PCR fragment length profiles, digitized images of metaphase spreads, fluorescence in-situ hybridization signals within a cell, computer-generated or digitized images of chromatograms, and many other data types. Recognition of this equivalency occurred even prior to the COVID-19 pandemic.[1] However, the CLIAC's past recommendations have not been specifically reflected in the current regulations or supporting guidance documents.

There are current regulations that have restricted some forms of digital pathology testing, such as cytology slides needing to be evaluated on the premise of the laboratory. This has on occasion also been presumed to apply to other examples of digital image review. Moreover, there have been instances in which remote work has been viewed as "distributive testing" and "referral testing", both of which imply that at least some part of testing is performed in another laboratory with a different CLIA license number. Confusion on the appropriate application of the existing regulatory wording has led to significant concern about the continuation of secure remote data review to meet the workforce requirements.

The ACMG appreciates the rapid response from CMS at the beginning of the COVID-19 pandemic allowing for the remote review of pathology slides with certain defined conditions to ensure quality and security.[6] We support the permanent continuation of this practice beyond the pandemic, given the demonstration of its successful application over the past two years, and we request clarification through the enforcement discretion and eventually within the regulatory language on the applicability of remote work to genetic testing, whereby laboratory data and images are reviewed in a secure but alternative environment. We also request that language clarify that this work may be performed by additional laboratory professionals beyond just the pathologist regardless of whether they are on-site or at a remote location. Further, we contend that remote analysis and case sign-out of genetic and genomic data produced in a CLIA-certified laboratory and accessed through secure data portals, such as VPN, does not qualify as "distributive testing" or "referral testing", but should instead be considered as a virtual extension of the primary CLIA-certified site, which is a rational update consistent with modern technology and now proven practice equivalency.

For additional discussion or questions about these concerns and recommendations, please contact Dr. Michelle McClure, ACMG Director of Public Policy, at mmcclure@acmg.net.

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[6] Centers for Medicare and Medicaid Services Notice to State Survey Agency Directors, QSO-20-21-CLIA, March 26, 2020 (https://www.cms.gov/files/document/qso-20-21-clia.pdf-0)