



# COLLEGE of AMERICAN PATHOLOGISTS

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September 3, 2024

The Honorable Gavin Newsom  
Governor of California  
1021 O Street, Suite 9000  
Sacramento, CA 95814

**RE: Support for Assembly Bill 2107 (Clinical Laboratory Technology: Remote Review)**

Dear Governor Newsom,

On behalf of the California Society of Pathologists, the College of American Pathologists urges your signature of Assembly Bill 2107 authorizing pathologists to remotely review digital materials under the appropriate Clinical Laboratory Improvements Amendments (CLIA) certificate pursuant to the Department of Public Health's (CDPH) affirmation of compliance with the federal CLIA requirements.<sup>1</sup>

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.

Amid the COVID-19 pandemic and the myriad challenges it posed, the Center for Medicaid & Medicare Services (CMS) utilized enforcement discretion to ensure pathologists could review slides and sign out remotely so long as the primary site or laboratory had a CLIA certificate. After the end of the public health emergency, CMS retained this flexibility recognizing the value of pathologists' remote review of digital data, results, and images. The CAP strongly advocates for the continuation of this waiver to preserve quality, ensure continuity of care for patients, and provide necessary flexibility as needed for clinical laboratories and pathologists.

California is the only state that does not yet recognize CMS's continued enforcement discretion for pathology's remote review of digital materials. CMS retains the right as does any federal agency to utilize enforcement discretion to permit reasonable flexibility in the interpretation of its CLIA regulations to respond appropriately to present and future conditions while still complying with statutory requirements. CMS's enforcement discretion does not violate the federal requirements of CLIA. The CAP urges California to recognize and wholly trust CMS's judgment, as the sole agency that regulates all clinical laboratory testing pursuant to CLIA, to permit remote review.

Bringing California into alignment with federal guidance would allow California pathologists the flexibility to sign-out remotely as they can in nearly all states, even in New York, a CLIA-exempt state. As workforce constraints continue to be a challenge, this flexibility is key to ensuring timely review of tests and the quickest diagnosis possible for California patients. In the 49 other states, patients have benefitted by receiving timely care and continued to benefit from robust quality measures that are in no way circumvented by CMS's enforcement discretion.



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Pathology and laboratory services are the cornerstone of health care decisions, accounting for over 75% of patient diagnoses based on laboratory testing. Pathologists and clinical laboratories continue to provide vital health care services during unprecedented times and beyond. Such flexibility as encompassed under AB 2107 serves to benefit not only pathologists but California patients across the state.

We therefore urge your signature of Assembly Bill 2107 which safeguards continuity of patient care, decreases unnecessary patient delays for timely diagnosis, and equips the pathology workforce to continue to serve California patients in a safe and efficient manner.

Thank you for your consideration and courtesies.

Sincerely,

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

<sup>1</sup> QSO-23-15-CLIA (cms.gov)