



COLLEGE of AMERICAN PATHOLOGISTS

March 13, 2020

Admiral Brett Giroir, M.D.
Assistant Secretary for Health and head of the Public Health Service
US Department of Health and Human Services (HHS)
200 Independence Ave., SW
Washington, DC 20201

Dear Admiral Giroir,

Given President Donald Trump's emergency declaration today providing the Department of Health and Human Services Secretary broader authority to waive provisions of law and regulation to give doctors and hospitals "maximum flexibility to respond to the virus", the College of American Pathologists requests the Secretary to direct the Centers for Medicare and Medicaid Services (CMS) to allow greater flexibility administering the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Specifically, we are requesting a temporary waiver of the CLIA requirements in regard to working remotely and to allow local laboratories to determine what is best for their particular situation.

Pathologists and other licensed healthcare professionals can utilize remote review and sign out for pathology interpretation/diagnosis and other data reviews utilizing virtual private network (VPN) data access. This would allow laboratories to employ appropriate protocols to reduce the risk of infection among their own teams and to avoid hindering their ability to test and treat patients. If laboratory personnel were to be significantly impaired, it could become difficult for the country to continue to respond to this crisis. Providing this waiver will serve to minimize the disruption to the workforce that is occurring while maintaining the best possible patient care.

Furthermore, the CMS has notified the CAP to continue survey/inspection activities as usual during this crisis time. The CAP is again requesting that we be permitted to temporarily postpone routine inspections of CAP accredited laboratories, allowing laboratory personnel to fully verify/validate new coronavirus testing assays, and escalate laboratory operation redesign to accommodate the emerging technologies and testing. Continuing inspections puts the workforce in jeopardy by increasing the risk of inter-laboratory disease transmission, threatens the ability of laboratories to insure the best possible patient care, and could interfere with timely reporting of test results. Assuredly, the CAP would continue to conduct critical inspections and complaint investigations during this brief hiatus of routine assessments.

Sincerely,

Patrick Godbey, MD, FCAP
President, College of American Pathologists

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Richard M. Scanlan, MD, FCAP
Chair, Council on Accreditation
College of American Pathologists

Cc: Alex Azar, Secretary, Health and Human Services
Seema Verma, Administrator, Centers for Medicare and Medicaid Services