



March 17, 2020

Alex M. Azar II, MD
Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Emergency Authorization of Telepathology Services and Response to COVID-19 Pandemic

Dear Secretary Azar:

In light of President Trump's national emergency declaration over coronavirus, I am writing on behalf of the members of the American Society for Clinical Pathology (ASCP) to urge the Department to waive the Clinical Laboratory Improvement Amendments' (CLIA) of 1988 requirement that pathologists and laboratory professionals must review digital slides and images and interpret data *in* a CLIA certified laboratory. ASCP believes the conditions warrant this, at least on a temporary basis.

The ASCP is a 501(c)(3) nonprofit medical specialty society representing over 100,000 members. Our members are board certified pathologists (including medical examiners), other physicians, clinical scientists (PhDs), certified medical laboratory scientists/technologists and technicians, and educators. ASCP is one of the nation's largest medical specialty societies and is the world's largest organization representing the field of laboratory medicine and pathology. As the leading provider of continuing education for pathologists and medical laboratory personnel, ASCP enhances the quality of the profession through comprehensive educational programs, publications, and self-assessment materials.

Allowing pathologists and other laboratory professionals to provide distance diagnostic interpretations would further allow these critical front-line healthcare professionals to continue providing essential diagnostic services while simultaneously adhering to the Administration's recommended social distancing procedures. In addition, allowing pathologists this authority could facilitate their ability to handle secondary consultations from other pathologists and physicians using digital slides. This would enhance quality by ensuring complex patient cases are thoroughly reviewed. To ensure quality, this should be done with oversight from a CLIA-certified laboratory.

We note that telepathology services are already being provided. As part of [ASCP's Partners in Cancer Diagnosis Project](#), we developed a cloud-based cancer diagnostics platform to deliver a dynamic image-based environment for efficient and high-quality diagnostics. This enables collaboration between pathologists in the United States with healthcare facilities in Sub-Saharan Africa, providing secure access to the pathology and laboratory clinical multimedia, including digital whole slide images. Given technological advancements, digital imaging quality rivals that of a microscope.

Additionally, as our nation's clinical laboratories grapple with the challenges of rapidly expanding our testing capabilities to identify the virus responsible for COVID-19, we are experiencing unforeseen challenges. Concerns about potential shortages of certain equipment, supplies, reagents, tests kits, and

The Honorable Alex M. Azar II, MD

March 16, 2020

Page 2

even laboratory personnel now exist. There may be a need for additional waivers, from CLIA and from other laws pertaining to laboratory diagnostic devices. As we identify these needs, we will coordinate with the Department in pursuit of a nimble and effective response.

In closing, I strongly urge the Department to provide pathologists and other laboratory professionals authority to review slides at remote locations and to do so under the certificate of the primary CLIA certified laboratory. If I can be of service, please do not hesitate to contact me, or Matthew Schulze, ASCP's Director for Public Policy, at matthew.schulze@ascp.org or 202.403.9027.

Sincerely,

A handwritten signature in blue ink that reads "Gene P. Siegal". The signature is fluid and cursive, with the first name "Gene" and last name "Siegal" clearly legible.

Gene Siegal, MD, PhD, FASCP
President, ASCP

cc: Admiral Brett P. Giroir, MD, HHS
Seema Verma, CMS
Kimberly Brandt, CMS
Brady Brookes, CMS
Demetrios Kouzoukas, CMS
Jean Moody-Williams, CMS, CCSQ
Carol Blackford, CMS, CCSQ
Jeneen Iwugo, CMS, CCSQ
Shari Ling, M.D., CMS, CCSQ
David R. Wright, CMS, CCSQ, QSOG
Tennille Rogers, CMS, CCSQ, QSOG
Karen Dyer, CMS, CCSQ, QSOG, CLIQ