



FROM: Michael Rivers, President, Digital Pathology Association
DATE: March 24, 2020
RE: Authorizing Pathologists to Employ Remote Pathology Practices in Response to the COVID-19 Pandemic

Pathologists serve at the frontline of the diagnostic process and are critical to ensuring that patients receive the right treatment at the right time.

In order to ensure continuity of service to patients and to protect the health of the significant number of Pathologists who are in the higher risk demographics for COVID-19, the Digital Pathology Association requests that the Department of Health and Human Services exercise the authority granted under the President's March 13, 2020 national emergency declaration to waive regulatory requirements and *grant Pathologists and laboratories the flexibility to render primary diagnoses remotely*. We also ask for temporary waiver of CLIA regulations that restrict the location where Pathologists can render diagnoses.

Other medical organizations that have stated support for remote pathology include the 18,000-member College of American Pathologists and the 130,000-member American Society for Clinical Pathology.

The Trump Administration in recent days expanded telehealth services for Medicare beneficiaries and relaxed HIPAA requirements to allow doctors to provide services via their phones. Pathologists have the resources to fully analyze stained tissue slides or whole slide images from remote offices or homes using conventional microscopy or digital technology, just as they do in hospital laboratory settings. Requiring Pathologists to perform this work in the laboratory unnecessarily exposes them to high risk of COVID-19 infection, and denies patient care when Pathologists quarantine themselves due to possible exposure or actual infection. Permitting remote diagnosis, which would still be subject to rules for the practice of good medicine and laboratory validation, would reduce potential COVID-19 for Pathologists and patients, speed diagnoses, and ensure that Pathologists continue their vital work even when quarantined. Any technology concerns can be mitigated with appropriate remote IT support.

The non-profit Digital Pathology Association is comprised of Pathologists, scientists, technologists and industry representatives dedicated to advancing the field of digital pathology. For more than 10 years, the Association has worked through its membership to demonstrate the efficacy of digital pathology solutions. The Association's 1,600 members are committed to partnering with the DHHS to help make a positive impact in this difficult situation. We appreciate your consideration and look forward to a productive engagement on this issue.