Association for Pathology Informatics

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March 24, 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 Remote Telepathology Services in Response to COVID-19 Pandemic

Dear Secretary Azar:

President Trump's emergency declaration provides the 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 Association for Pathology Informatics (API) requests the Secretary to direct the Center for Medicare and Medicaid Services (CMS) to allow greater flexibility administering the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Specifically, API is requesting a temporary relaxation of CLIA requirements regarding remote diagnosis of pathology cases digitally and allowing local laboratories to determine what is best for their situation.

It is easy to focus on the risks of performing remote rendering of pathologic diagnoses through digital systems. Laboratories across the U.S. and internationally, however, have properly validated digital systems for remote diagnoses. Selected laboratories across the U.S. are more than able to render diagnoses remotely utilizing only secure virtual private network (VPN) data access. Studies have already shown no decrease in the quality of diagnoses via digital pathology (1,2).

API understands the CMS perspective and the historical context behind the CLIA requirements with disincentivizing multi-site practices. Yet API feels the current state of CLIA regulation is impractical during this COVID-19 pandemic. Digital pathology allows remote distribution of patient caseloads. The current state of CLIA regulation would impede a pathology department with many pathologists, for example sixty, to safely and accurately diagnose from home. Sixty separate CLIA licenses would be required, with all the ramifications of obtaining and maintaining a CLIA license – clearly this is an impractical, time-consuming, and expensive proposition that cannot be accomplished.

Now consider the risks of NOT performing remote rendering of pathologic diagnoses, particularly given such trying circumstances with the COVID-19 pandemic. In a survey conducted seven years ago, the average age of the pathologist workforce was 55-63 (3). Seven years later, the bulk of the pathologist workforce is older and in the highest risk demographic for COVID-19. Regardless of the measures taken today, the number of COVID-19 cases will increase and peak over the next two months. The demand for the physical presence of pathologists under CLIA potentially jeopardizes half of this country's pathologist workforce.

Given there is already a projected shortage of pathologists (3), COVID-19 makes an already looming future public health dilemma potentially worse.

As you are aware, the pathologic diagnosis is the most critical component of patient care and the foundation of most clinical data. Treatment decisions cannot start, and clinical trials cannot precisely target populations without the proper pathologic diagnosis. In the near term, under the COVID-19 pandemic, one envisions multiple adverse scenarios. 1) Unnecessarily delayed diagnoses that arise from the shortage of physically present pathologists to render diagnosis under traditional CLIA rules. 2) Unrendered diagnoses from urgent biopsies because at-risk pathologists become unavailable from providing optimal care. 3) Incorrect diagnoses resulting in wrong treatment and adverse outcomes because many experienced pathologists are at-risk. These adverse scenarios are preventable by removing the CLIA requirements for those digitally enabled institutions that have validated remote diagnoses under digital pathology platforms.

API hopes to have convinced you that enforcing strict CLIA requirements, in the end, unintentionally defeats the desire for CMS to ensure the quality of delivery of patient care and additionally jeopardizes the pathologist workforce. API is quite amenable to working with CLIA to find a workable mitigating strategy. Such mitigating strategies might address revisions to a) CLIA location licensing and b) expedited WSI validation.

In summary, two of pathology's largest organizations, the College of American Pathologists (CAP) and the American Society for Clinical Pathology (ASCP), support the temporary relaxation of CLIA requirements regarding remote diagnosing of pathology cases digitally. API recognizes that the government does not want to be a barrier. If an institution has sufficiently validated digital pathology systems, API is asking you to facilitate the temporary relaxation of CLIA requirements regarding remote diagnosing of pathology cases digitally. This temporary relaxation grants selected digitally enabled institutions the flexibility needed to help patients in delivering the diagnostic quality and throughput patients deserve, to reduce the risk for the aging pathologist workforce, and to ensure the future sustainability of the pathologist workforce. Your help is much appreciated.

Sincerely,
API Council

References:

1. Hipp J et al. CAP Pathology Resource Guide: Digital Pathology. Version 6.0(1). College of American Pathologists 2016.
2. Hanna MG et al. Whole slide imaging equivalency and efficiency study: experience at a large academic center. Mod Pathol. 2019 Jul;32(7):916-928.
3. Robboy SJ et al. Development of a predictive model to examine factors influencing supply. Arch Pathol Lab Med. 2013 Dec;137(12):1723-32.