Association for Pathology Informatics

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August 24, 2022

Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

RE: API's response to CMS-2022-0119-0001

The Association for Pathology Informatics appreciates CMS's recognition that the COVID-19 public health emergency (PHE) requires flexibility and that CMS is committed to taking critical steps to ensure America's clinical laboratories can respond during a PHE to provide reliable testing while ensuring patient health and safety. As such, as part of CMS welcoming of public comments regarding how the CLIA personnel requirements have affected the health system's response to the COVID-19 PHE and any potential opportunities for improvement to such requirements, we have two specific requests, which are as follows:

1. We, the Association for Pathology Informatics (API), would request permanent authority for the CLIA rules to allow for the remote review of slides without needing a separate CLIA certificate. Performing remote review of slides during the PHE happened without incident.

2. We also ask that CLIAC be tasked with developing recommendations, including this one about the remote review of slides, for how CMS could improve its response to the pandemic and public health emergencies.

API is also fortunate to have support for this position from the American Society for Clinical Pathology (ASCP).

Sincerely,

Toby Cornish, MD, PhD, API President
Ji-Yeon Kim, MD, MPH, API President Elect
S. Joseph Sirintrapun, API Past President
On behalf of the API Governing Council