Association for Pathology Informatics

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March 7, 2025

Robert F. Kennedy, Jr.
Department of Health and Human Services
Office of the Secretary
200 Independence Avenue, SW
Washington, DC 20201

SUBJECT: **45 CFR Parts 160 and 164**
RIN 0945-AA22
Concerns Regarding the Proposed 2025 HIPAA Changes and Their Impact on Clinical Laboratories, Patient Care, and Life-Saving Research

Dear Secretary Kennedy:

I am writing on behalf of the Association for Pathology Informatics Governing Council to formally express our deep concerns regarding the proposed changes to HIPAA scheduled for implementation in 2025. While we recognize that these modifications aim to bolster patient privacy and strengthen cybersecurity, the practical implications for clinical laboratories, pathology practices, and critical research initiatives are significant. These changes risk affecting diagnostic turnaround, straining IT infrastructures, overwhelming administrative resources, and hindering essential data sharing—all of which may compromise the quality of healthcare delivery.

Based on input from academic centers, small community laboratories, commercial facilities, and large reference laboratories, we have consolidated our key concerns as follows:

1. **Delayed Diagnostic Turnaround and Patient Care Disruption:**
   The accelerated patient record access timeline—from 30 days to 15 days—combined with increased documentation requirements risks delaying the reporting of critical diagnostic results by diverting human resources towards meeting these demands. Such delays can directly impact timely patient care, particularly when test data is fragmented across multiple legacy systems.
2. **Operational and IT Infrastructure Challenges:**
   The new mandates require laboratories to integrate comprehensive cybersecurity measures, including maintaining detailed technology asset inventories, conducting frequent risk analyses, and ensuring encryption for legacy systems. These requirements impose significant operational challenges that threaten the reliability and efficiency of diagnostic operations, all while increasing the operating costs.
3. **Excessive Administrative and Audit Burden:**
   The expanded compliance protocols and the imposition of more frequent, rigorous audits (including detailed risk assessments, vulnerability scans, and penetration tests) place an enormous administrative load on laboratory staff. This burden diverts critical resources from patient care and essential diagnostic activities.
4. **Financial and Resource Constraints:**
   The substantial costs associated with upgrading IT infrastructure, training personnel, and meeting new documentation and cybersecurity standards are particularly concerning for resource-limited and smaller laboratories that may be operating in underserved areas or

aiming to provide novel specialized testing. These financial strains could lead to cutbacks in high-quality diagnostic services and impact overall patient outcomes.

5. **Impediments to Data Sharing and Collaborative Research:**
   Stricter data sharing restrictions and enhanced security protocols may inadvertently hinder the seamless exchange of clinical data. This limitation poses a risk to collaborative research efforts, potentially delaying scientific discoveries and the development of innovative, life-saving treatments.

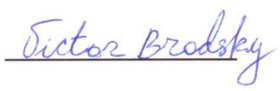
In light of these challenges, we respectfully urge the Department of Health and Human Services to consider the following recommendations:

- **Engage in Targeted Dialogue:**
  Initiate discussions with representatives from all sectors of the pathology and clinical laboratory community to develop realistic timelines and technical standards that reflect the operational nuances of our diverse institutions.
- **Implement Phased Transitions:**
  Provide transitional support—including financial assistance and technical guidance—to enable a gradual implementation of the new documentation, audit, and cybersecurity requirements. A phased approach is especially critical for smaller and rural laboratories facing resource constraints.
- **Reassess Audit Protocols:**
  Adopt a risk-based approach to audits that balances the need for enhanced security with the operational demands of clinical laboratories. This adjustment will help ensure that appropriately tuned audit frequency and scope do not unduly disrupt essential diagnostic services.
- **Safeguard Research Collaboration:**
  Ensure that HIPAA revisions preserve secure pathways for data sharing critical to collaborative research. Maintaining these channels and providing clear guidance to enable appropriate sharing of genomic and other important data is essential for advancing innovative treatments and ensuring that scientific breakthroughs continue to enhance patient care.

Our community remains committed to upholding the highest standards of patient privacy and data security. However, it is imperative that these protections do not inadvertently undermine the efficiency and effectiveness of our diagnostic and research operations. We stand ready to collaborate with HHS to refine these proposals in a manner that safeguards both patient privacy and the integrity of our healthcare system.

Thank you for your attention to these pressing matters. I look forward to the opportunity to discuss our concerns further and contribute to a constructive path forward.

Sincerely,



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cc: API Council and API Members