



March 7, 2025

VIA ELECTRONIC SUBMISSION

Anthony Archeval, Acting Director
Office for Civil Rights
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201

Re: Physician Clinical Registry Coalition's Comments on the Proposed Rule to Update the HIPAA Security Rule (RIN Number: 0945-AA22; Docket No. HHS-OCR-0945-AA22)

Dear Acting Director Archeval:

The undersigned members of the Physician Clinical Registry Coalition ("Coalition") appreciate the opportunity to provide comments to the Office for Civil Rights ("OCR") on its proposed rule modifying the Health Insurance Portability and Accountability Act ("HIPAA") Security Rule ("Proposed Rule"). The Coalition is a group of medical society-sponsored clinical data registries ("Registries") that collect and analyze clinical outcomes data to identify best practices and drive improvements in patient care and clinical outcomes, enhance general knowledge through research projects, and support public health. Members of the Coalition believe that safeguarding the privacy and security of electronic protected health information ("ePHI") is critical. Coalition members and their database vendors have successfully adopted robust cybersecurity programs under the current HIPAA framework.

The Coalition shares OCR's view that cybersecurity has become, and must continue to be, a central focus of HIPAA's cybersecurity framework to combat mounting cyberattacks and to account for evolving cyber risks. **However, we urge OCR to reconsider the Proposed Rule based on serious concerns regarding the financial and administrative burdens that would be associated with these proposals.** As OCR recognizes, the estimated financial costs associated with implementing the Proposed Rule's cybersecurity modifications would be significant for both covered entities and business associates. **In addition, we are concerned that the Proposed Rule would implement a more inflexible approach that fails to balance entity-level risks, costs, and other operational considerations and would be highly burdensome.**

For instance, the Coalition has concerns regarding the financial and operational burdens that would arise from the Proposed Rule's impact on business associate arrangements. Many Registries serve as business associates of the covered entity sites from which they receive PHI and perform services on behalf of those entities for quality improvement purposes; such Registries may also engage the

services of third-party database and technology vendors to provide their registry platform infrastructure under a sub-business associate arrangement. OCR's estimate of the time and costs required to update business associate agreements to comply with the Proposed Rule—\$309,258,768 annually—is premised upon one hour of attorney time per regulated entity to update a single business associate agreement. This vastly underestimates the burdens that would fall on entities like Registries which operate under multiple agreements, as they would be required to re-negotiate the substance of each agreement to account for both new compliance requirements and the individualized, entity-level changes that would be sought by participating covered entities based on their own interpretation and implementation of any new requirements. All of these changes would then need to be standardized, negotiated, and incorporated across the Registry's own subcontractor agreements. The time and costs required would be orders of magnitude higher than the Proposed Rule's one-hour estimate, demonstrating that OCR did not fully consider the full impact of either the Proposed Rule's business associate agreement-specific provisions or the higher-level impact that new cybersecurity requirements would have on established intra-entity relationships and operations.

Therefore, the Coalition respectfully requests that OCR halt efforts to finalize this Proposed Rule. We urge OCR to work with the Coalition and other stakeholders to come up with more practical solutions to address cybersecurity threats and the evolving electronic data security landscape.

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The Coalition appreciates your consideration of our comments. If you have any questions, please contact Leela Baggett or Jason Qu at Powers Pyles Sutter & Verville, PC (Leela.Baggett@PowersLaw.com or Jason.Qu@PowersLaw.com).

Respectfully submitted,

American Academy of Ophthalmology
American Academy of Otolaryngology- Head & Neck Surgery
American Academy of Physical Medicine and Rehabilitation
American Association of Neurological Surgeons
American College of Radiology
American College of Rheumatology
American Psychiatric Association
American Society of Plastic Surgeons
American Urological Association
Center for Professionalism and Value in Health Care (ABFM PRIME)
Congress of Neurological Surgeons
Society of Interventional Radiology
Society of NeuroInterventional Surgery
The Society of Thoracic Surgeons