ACRO
ASSOCIATION OF CLINICAL RESEARCH ORGANIZATIONS

SUBMITTED ELECTRONICALLY

February 7, 2019
U.S. Department of Health and Human Services
Office for Civil Rights
Hubert H. Humphrey Building
Room 509F
200 Independence Avenue SW
Washington, DC 20201

RE: Request for Information, RIN 0945-AA00

Dear Secretary Azar and Director Severino:

Introduction

The Association of Clinical Research Organizations (ACRO) represents the world's leading clinical research and technology organizations. Our member companies provide a wide range of specialized services across the entire spectrum of development for new drugs, biologics and medical devices, from pre-clinical, proof of concept and first-in-man studies through post-approval and pharmacovigilance research. In 2018, ACRO companies managed or otherwise supported a majority of all FDA-regulated clinical investigations worldwide. With more than 130,000 employees engaged in research activities in 114 countries, the member companies of ACRO advance clinical outsourcing to improve the quality, efficiency and safety of biomedical research.

In general, ACRO member companies are not Covered Entities (CEs) subject to the HIPAA Privacy and Security Rules, though they may at times contract to be Business Associates (BAs). In most clinical research projects, however, ACRO research and technology companies work with investigators and IRBs, many of which are subject to the HIPAA rules. Further, beyond our work in clinical investigations, the member companies of ACRO regularly use de-identified data and limited data sets (as defined by HIPAA) in the course of late-phase work, including safety surveillance and epidemiology studies, patient registry and health outcomes analyses, comparative effectiveness research (CER), and other information-based research. In addition to providing development solutions, ACRO member companies may also deploy data analytics tools to support biopharmaceutical commercialization, pricing and market access decisions, and may consult to biopharmaceutical companies, payers and providers in regard to value-based contracts.

We thank the Department of Health and Human Services (HHS or the Department) and the Office for Civil Rights (OCR) for issuing the above-referenced Request for Information.

As a key stakeholder in the health research/health care enterprise, ACRO is keenly interested in provisions of the HIPAA Rules "that may impede the transformation to value-based health care or that limit or discourage coordinated care... without meaningfully contributing to the protection or security of individuals' protected health information."

ACRO
ASSOCIATION OF CLINICAL RESEARCH ORGANIZATIONS

In responding to this RFI, ACRO will focus on topic *e. Additional ways to remove regulatory obstacles and reduce regulatory burdens to facilitate care coordination and promote value-based health care transformation* and suggest one answer to question 54 b) "What modifications to the HIPAA Rules would facilitate care coordination and/or case management, and/or promote the transformation to value-based health care?"

ACRO strongly commends to OCR a proposal passed by the House of Representatives

In July 2015, the U.S. House of Representatives passed, by a vote of 344-77, HR 6, the 21st Century Cures Act. At Sec. 1124 the bill included several provisions relating to "accessing, sharing, and using health data for research purposes." Among the changes to HIPAA overwhelmingly approved by the House was a proposal to include the use of health data for research purposes in the definition of *health care operations.*

The Privacy Rule, at part 164.501 of title 45 CFR, permits, but does not require, Covered Entities to use and disclose protected health information (PHI) for purposes of treatment, payment and health care operations (TPO). However, the definition of TPO specifically excludes studies whose "primary purpose" includes the "obtaining of generalizable knowledge." As a result, CEs can, and do, use PHI without individual authorization to improve care and services – but only "within the walls" of the institution or organization, creating data silos and preventing the generation and sharing of knowledge to improve clinical care and the transition to value-based care.

By contrast, HR 6 proposed the following:

"SEC. 13442. DEFINING HEALTH DATA RESEARCH AS PART OF HEALTH CARE OPERATIONS.
"(a) IN GENERAL.—Subject to subsection (b), the Secretary shall revise or clarify the Rule to allow the use and disclosure of protected health information by a covered entity for research purposes, including studies whose purpose is to obtain generalizable knowledge, to be treated as the use and disclosure of such information for health care operations described in subparagraph (1) of the definition of health care operations in section 164.501 of part 164.
"(b) MODIFICATIONS TO RULES FOR DISCLOSURES FOR HEALTH CARE OPERATIONS.— In applying section 164.506 of part 164 to the disclosure of protected health information described in subsection (a)—
"(1) the Secretary shall revise or clarify the Rule so that the disclosure may be made by the covered entity to only—
"(A) another covered entity for health care operations (as defined in section 164.501 of part 164);
"(B) a business associate that has entered into a contract under section 164.504(e) of part 164 with a disclosing covered entity to perform health care operations; or
"(C) a business associate that has entered into a contract under section 164.504(e) of part 164 for the purpose of data aggregation (as defined in section 164.501 of part 164); and
"(2) the Secretary shall further revise or clarify the Rule so that the limitation specified by section 164.506(c)(4) of part 164 does not apply to disclosures that are described by subsection (a).
"(c) RULE OF CONSTRUCTION.—This section shall not be construed as prohibiting or restricting a use or disclosure of protected health information for research purposes that is otherwise permitted under part 164.

This revision to the definition of TPO would have allowed Covered Entities to use PHI for research purposes, without individual Authorization or IRB waiver, with certain clear limitations. Most importantly, only a Covered Entity, or a Business Associate under a contract (BAA) with a Covered

Entity, would be permitted to use PHI for *research purposes*; neither a Covered Entity nor a Business Associate could disclose that PHI to an unaffiliated researcher or other third party under the newly defined *health care operations*. Simply, this meant that the data would stay within the confines and protections of the HIPAA Rules and could not be given to marketers, pharmaceutical companies or any other entity not covered by the HIPAA Rules.

Moreover, as with other health care operations, this opportunity for HIPAA Covered Entities to use health data for *research purposes* would have been permitted, not required. And if a Covered Entity did choose to use health data for research under the definition of *health care operations* it would be required to do so subject to the "minimum necessary" requirement and would have to disclose the practice in its HIPAA Notice of Privacy Practices. Further, under the House-passed language, a Covered Entity would not be precluded from seeking individual consent for such use of health data if it chose to. And although an IRB would not have been required to provide a waiver of Authorization, IRB review of the design of the data research project and its methodology for protecting confidentiality could still be utilized.

Finally, this change to the definition of TPO would have affected HIPAA requirements for research involving health data (PHI) only; it would not have changed other existing requirements, such as the obligation to obtain informed consent for interventional research, like a a clinical trial studying a new treatment.

Discussion

Today, Covered Entities use 'their' data (PHI) to improve care coordination and quality and assessment of value only "within the walls" of the organization. As OCR is aware, the definitional prohibition against the "obtaining of generalizable knowledge" is taken to mean, quite literally, that hospital A on one side of the street cannot disclose to hospital B on the other side of the street findings from an outcomes evaluation, such as a comparison of treatment alternatives for a local or regional parasitic infection.

ACRO believes that including the use of PHI for research under the definition of *health care operations* would facilitate the sharing of data across CEs and comparative effectiveness research to underpin the parameters of value-based care, without reducing the confidentiality of PHI or diminishing individuals' privacy. Simply, there would be no greater exposure to privacy risks than created by existing uses and disclosures for TPO, but an enormous increase in the value of data would be gained, enabling fuller, more coordinated care plans and a robust research basis for the transformation to a value-centered care system. For instance, Covered Entities would have significantly improved abilities to identify individuals for inclusion in clinical trials and to offer a clinical trial as a care option when that would be appropriate. Further, the ability to contract with another entity – as a Business Associate, under a clearly delineated BAA – to perform such patient-findings functions would offer an alternative pathway to *reviews preparatory to research* under which researchers not covered by a BAA can access PHI, but cannot "remove" such PHI from the CE, a prohibition that has led to a common interpretation that researchers cannot identify specific individuals back to the Covered Entity for recruitment into a research project.

Today, notwithstanding the enormous promise of "big data," huge quantities of health data are effectively locked up in each of thousands of health care facilities and organizations. Including data research in the definition of *health care operations* would be one step toward facilitating the use of health data, under the carefully controlled conditions of the HIPAA framework, and fostering a *learning health system* in which care quality and coordination are improved and a value-based system evolves.

ACRO
ASSOCIATION OF CLINICAL RESEARCH ORGANIZATIONS

Conclusion

ACRO thanks HHS and OCR for taking up an overdue evaluation of provisions of the HIPAA Rules that may impede coordinated and value-based care without meaningfully contributing to the protection of privacy and the security of health data. Although the HIPAA provisions of HR 6 were not included in the final version of the 21st Century Cures Act signed into law in December of 2016, we urge OCR and the Department to give strong consideration to including the use of health data for research purposes in the definition of *health care operations* at section 164.501 of part 164 with the modifications to the rules for disclosures for health care operations at section 164.506 that were contained in HR 6 (as quoted above.)

ACRO looks forward to further dialogue with the Department about our recommendation to facilitate the use of PHI for essential research purposes.

Respectfully submitted,

Douglas Peddicord
Executive Director