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The Effects of HIPAA's Privacy Rule on Medical Research

The HIPAA Privacy Rule has been instated for over a decade, but a high level of ambiguity and confusion still resonates within the medical and scientific research community. This has resulted in researchers and healthcare organizations experiencing misinterpretation and burdens attempting to remain compliant. HIPAA's Privacy Rule, implemented in 2003, required covered entities to protect PHI, protected health information, and maintain certain disclosure regulations. Covered entities include health plans, health care clearing houses, and health care providers (HIPAA Creating Barriers to Research and Discovery, p. 2). HIPAA was created to place safeguards on patient's protected health information by granting patients new rights for accessing medical records, restricting disclosure of PHI, and establishing new sanctions for improper use of PHI. Research was not a formal consideration of HIPAA; however, there have been many negative indirect effects on the research community. In most cases, researchers are not considered covered entities; however, if they are employed or workforce members of a covered entity they may have to comply with that entity's HIPAA privacy policies and procedures. Across the nation, researchers have found the HIPAA Privacy Rule has negatively impacted the scope, pace, and cost of research (The HIPAA Privacy Rule, p. 3).

Although HIPAA was not originally intended to have effects on research, it has created “a web of confusion, misinterpretation, and obstacles that now threaten the research enterprise” (HIPAA Creating Barriers to Research and Discovery, p. 2). The Association of Academic Health Centers utilized several focus groups to determine the underlying causes of HIPAA’s negative impact on the different aspects of research. The results revealed HIPAA had very confusing and vague writing which led to confusion amongst all facets of research from “participants to privacy boards and institutions and even states” (p. 2). This inherent lack of understanding has led to inconsistent interpretations and implementation of HIPAA between institutions and states which poses issues for multi-site and interstate research (p.2). In addition to confusing language within the rule, the Privacy Rule creates issues for the non-covered portion of a hybrid entity. Although there exists a great deal of leniency in terms of sharing PHI within a covered entity, it becomes much more problematic when attempting to share information with researchers or other health professionals not employed by the entity. “Thus, in addition to the hundreds of researchers at institutions that were not covered entities, a significant number of researchers at the hybrid entities would not be able to access critical information for research purposes” (The HIPAA Privacy Rule, p. 4).

The Privacy Rule also grants every patient the right to access records of each instance the institution disclosed his or her PHI with another institution within a six year period. HIPAA has also added an additional requirement, on top of informed consent, that all participants must sign an authorization document permitting the use of his or her PHI for the specific study (The HIPAA Privacy Rule, p. 5). However, Institutional Review Boards (IRBs), according to HIPAA, can grant waivers of authorization when a researcher can prove minimal risk to a participant’s privacy thereby allowing the researcher to use PHI without gaining authorization from individual

participants (The HIPAA Privacy Rule, p.6). Although each of these additional safeguards seem beneficial to the patients/participants and their security, they impose a “clunky” process on researchers and institutions which results in less benefits for the public in the long-run. Therefore, despite the advancements the Privacy Rule has created for patient privacy, changes must be made to ensure research of future treatments is protected.

HIPAA’s implementation has provided many benefits to patients and research participants. The Privacy Rule allows patients to determine and authorize the institutions or entities with whom their PHI can be disclosed. HIPAA has increased the safeguards for patient information and pushed forth the need for more patient knowledge about treatments and research they are participating in. In addition to informed consent, HIPAA requires patients to sign an authorization document. This document provides the patient with further control of the use and disclosure of his or her PHI by allowing them to determine specific studies in which their information can be used. Concurrently, the Privacy Rule allows research participants to revoke the authorization at any point during the study, preventing the entity from disclosing any non-disclosed or unused information (Clinical Research and the HIPAA Privacy Rule, p. 2-3). Furthermore, the Rule allows patients to request records of all instances within the past six years of when their PHI was used or disclosed (The HIPAA Privacy Rule, p.4). Overall, the HIPAA Privacy Rule has been beneficial in providing security and control for patients and research participants.

Despite the benefits patients receive through the HIPAA Privacy Rule, there are many more negative consequences that the entire research enterprise experiences. Research institutions face issues attempting to comply with different requirements of the Privacy Rule. Amongst the research community, “the greatest concern was expressed about the negative

impact on the costs of research” (The HIPAA Privacy Rule, p. 3). In order to stay compliant with the requirement “Accounting for Disclosures,” institutions have to “maintain large quantities of detailed information on every patient and research participant and have it readily and easily accessible to fulfill requests at any time” (The HIPAA Privacy Rule, p. 5). Maintaining this information, despite the lack of actual requests, has increased expenditure and staff and caused changes in organizational structure (p. 5). According to the Association of Academic Health Centers, the increased costs and changes will prove troublesome in times of “fiscal constraint when institutions must be sure that resources are allocated and used in the most effective fashion and applied to the conduct of essential research” (p.5). Institutional Review Boards, which are responsible for evaluating research protocol and assessing its effects on the health, safety, and privacy of research participants, are also negatively impacted by the Privacy Rule. Since its implementation, many institutions have placed additional responsibilities on their IRBs. A survey taken by the AAHC found approximately 76.6% of respondents had their IRBs assume additional roles to manage the different aspects of the Privacy Rule. Out of the 76.6%, 62.3% reported the impact of adding these additional responsibilities to IRB members as negative or strongly negative. Handling the waiver facet of the Privacy Rule has increased the workload for IRBs. The additional workload is caused by the need for additional allotted time in IRB meetings to discuss HIPAA issues thereby increasing the process (The HIPAA Privacy Rule, p.6).

In addition, the ambiguity of the HIPAA Privacy Rule has led to misinterpretation amongst all parts of the research community. This leads to not only increased costs, but also contributes to a significantly slower pace of research. One specific example is in terms of multi-site research. According to the AAHCA, because of the multiple restrictions the Privacy Rule

places on covered entities releasing PHI to other institutions, “community partners have been reluctant to participate in this research in the face of added administrative hurdles and complications... which arise from misinterpretation in the Rule” (The HIPAA Privacy Rule, p.8). Although there are no requirements stating the need for multiple approvals for multi-site research, “a lack of clarity in the Privacy Rule, along with its guidance and a fear of liability” has led to many institutions utilizing multiple approvals (HIPAA Creating Barriers to Research and Discovery, p.3). These multiple approvals significantly impede the research process. HIPAA’s Privacy Rule has created barriers to research because its vague wording causes confusion which has forced decision makers to place more focus and funds on decoding the complex law and less on the actual research (HIPAA Creating Barriers to Research and Discovery, p.2).

The HIPAA Privacy Rule was created in response to concern over abuse of the privacy of health information. The Privacy Rule defines a category of health information, PHI, for which it has placed strict disclosure and usage regulations. Some of the defined permitted disclosures and usages are to the individual who is the subject of the information, treatment, payment, and health care operations (HIPAA Privacy Summary). The Rule also defines specific administrative policies which covered entities must comply with. HIPAA also outlines penalties that entities can incur for noncompliance. For civil lawsuits, a covered entity may be fined \$100 per failure to comply with a requirement and up to \$25,000 per year for multiple violations of an identical requirement. For criminal penalties, “a person who knowingly obtains or discloses individually identifiable health information... faces a fine of \$50,000 and up to one-year imprisonment” (HIPAA Privacy Summary) The penalty then increases to “\$100,000 and up to five years imprisonment if the wrongful conduct involves false pretenses, and to \$250,000 and up to ten years imprisonment if the conduct involves the intent to sell, transfer, or use individually

identifiable health information for commercial advantage, personal gain, or malicious harm” (HIPAA Privacy Summary). Depending on the charge, civil or criminal, the Department of Health and Human Services or the Department of Justice, respectively, will enforce compliance.

Protecting the privacy of patient information is important for patient safety in both administering health care and when using the data for research. However, the HIPAA Privacy Rule has created consequences that have slowed the pace of research and scientific discovery. In addition, institutions have increased expenditures to hire more personnel to maintain compliance. The overall approval and conduction time has increased thus increasing the cost of research exponentially. The best way to solve the cost and pace issues is to exempt research from the requirements of the HIPAA Privacy Rule and revert back to the previous use of the Common Rule with some revisions, which has been adopted by seventeen federal agencies including the Department of Health and Human Services. The Common Rule also provided “requirements to ensure that institutions and researchers protect the safety and privacy of human research subjects, including the protection of patient information” (The HIPAA Privacy Rule, p. 2). It also requires all research on human subjects, funded or conducted by a federal agency to be approved by an IRB and that all subjects provide informed consent prior to participation. The Common Rule has been successful for over thirty years in protecting patient safety and privacy. The only revision necessary to the Common Rule would be to integrate stricter health information privacy standards and to revise the protections to adapt to new technologies and threats to patient safety and privacy. Much like the HIPAA Privacy Rule, under the Common Rule, all research organizations should create a “common set of procedures...to verify the credentials of and to authenticate persons requesting and accessing information through the network” (HIPAA Safeguards, p. 2). The Common Rule should also ensure that research organizations utilize a

centrally controlled “exchange network, network equipment, and exchange conduits” to make sure the process is “protected by a single set of safeguards and security mechanisms.” These revisions will make a more adaptable and strict Common Rule for medical research.

Even though the HIPAA Privacy Rule has been in place for over a decade, its ambiguity and resulting misinterpretations has created barriers to the advancement of scientific and medical research in the United States. The resulting slowed pace of research from vague wording of HIPAA has increased costs for research institutions. By utilizing a revised Common Rule, the many issues resulting from misinterpretation of HIPAA will be eliminated. Avoiding the diversion of funds to hiring new personnel will allow the research enterprise to flourish.

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