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HIPAA and Its Impact on Health Research

Background

Public health research activities are being seriously compromised by the requirements of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and its associated regulations. The intent of HIPAA was to protect the privacy and health information of US citizens, but it also results in limited access to healthcare data among research professionals. The HIPAA Privacy Rule mandates that protected health information (PHI) be de-identified in 18 different ways in order to utilize it without permission from the individual (“HIPAA Privacy Rule”, n.d.). HIPAA also dictates that healthcare providers can only disclose individual health information for research if every patient provides explicit authorization to use a personal medical record (Ness, 2009). The 21st Century Cures Act of 2016 re-classified research purposes as “public health activities” (Bonamici, 2016) to allow researchers to have unauthorized access to PHI so long as they are legally appointed to do so (Office for Civil Rights, 2009). However, this strategy was not implemented due to delays from the executive branch as well as the Department of Health and Human Services. This leads to extended periods of time spent revising, delaying, or abandoning of research projects, as well as an increase in costs for researchers.

Methods

This research project was completed as a policy options paper to address challenges that researchers are encountering with accessing data for critical public health research activities as a result of HIPAA. Bardach’s eight step process was used as a policy problem-solving model to guide the process. The steps of Defining the Problem and Assembling the Evidence serve as the

lifeblood of this paper. Confronting Trade-offs allowed for analysis of the pros and cons of alternative policy options, and Projecting the Outcomes provided perspective for which option would work best to confront the issue of HIPAA and health research. Legislation, including HIPAA and the 21st Century Cures Act, were analyzed, as were the policy actions of the Department of Health and Human Service and the Government Accountability Office. This information was the basis to identify feasible options that could be pursued to improve research practices.

Results

Three options were considered to improve research practices in conjunction with HIPAA's privacy laws. The first option was the formation of a social welfare organization to coordinate lobbying activities across all research institutions. Research interests would be represented on a more cohesive level, rather than lobby with smaller groups advocating for individual institutions (Vernick, 1999). This strategy also potentially facilitates current or future legislation advocating for health research objectives in relation to privacy rights (Bonamici, 2016). The second option entailed the Secretary of Health and Human Services issuing regulations for research groups acting as public health authorities as called for by the 21st Century Cures Act. Under this policy, a covered entity such as a hospital may share PHI so long as it is deemed necessary to a facility's research purpose. This option also negates the need to spend time and labor de-identifying information, because public health authorities would have the ability to access PHI without these restrictions. The third option created a national database in which providers could enter de-identified information as it is received so that a consistently updated center is established for data that is already prepared for use. All of these options carry their own risks and obstacles. Each

constitutes a time-intensive method, interaction with government agencies, laws, and regulations, and coordination across research institutions.

Conclusion

Research practices under HIPAA are tedious, inefficient, and riddled with gridlock. Given the vital role medical research occupies in the health of the nation, it is essential to reevaluate how HIPAA affects and inhibits the state of research in the healthcare sector. In particular, incentivizing the Secretary of Health and Human Services to classify research as a public health activity greatly expedites the research process. This strategy is superior because, unlike other methods, the tedious legislative obstacles are already surpassed. It simply requires fulfillment of what was already federally approved under the 21st Century Cures Act. Using this tactic, the facilitation of medical research will greatly improve the status and potential of healthcare in the US.

Works Cited

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