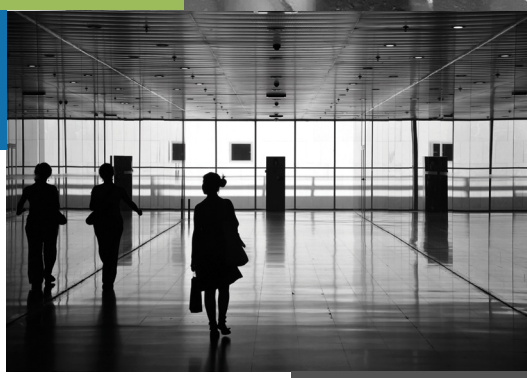
PRIVACY ANALYTICS

WHITE PAPER

# Will the 21st Century Cures Act Help or Hinder Secondary Use of Health Data?

The 21st Century Cures Act is proposed legislation that aims to accelerate the discovery, development and delivery of life-saving therapies for patients. The focus of this bill is not patient privacy, but it has privacy implications. Five provisions would impact existing HIPAA legislation covering the use and disclosure of protected health information (PHI). It is unclear whether these provisions will foster new research or, in fact, be a detriment to patient privacy.



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# Executive Summary

The 21st Century Cures Act easily passed the House of Representatives earlier this year with strong bipartisan support. The act aims to accelerate the discovery, development and delivery of life-saving and life-improving therapies for patients. It would do so by providing mechanisms for the Food and Drug Administration (FDA) to speed its approvals process for new drugs and medical devices and by making it easier to share protected health information (PHI) for research and other secondary uses.

While the focus of this bill is not on patient privacy, it has privacy implications. Five provisions in the proposed legislation would impact existing HIPAA legislation which covers the use and disclosure of PHI. The implication of these provisions is that there is research that could be done, but that is not happening because the HIPAA Privacy Rule makes it too difficult to legally share data with researchers and outside organizations.

It appears, however, that there is a general misunderstanding on the part of covered entities and business associates as to what is currently allowed under HIPAA. Clarifying the role of de-identification in permitting secondary uses of PHI could obviate the reasons behind these privacy provisions. The risk is that these new provisions – by broadening the definition of health research and public health activities and removing restrictions on the sale of PHI – would allow greater access to sensitive personal information and compromise patient anonymity.

The legislation now awaits a vote by the Senate. It is hoped that those with responsibilities for sharing and disclosing PHI will help ignite debate on this group of provisions so that this bill is not simply passed without deeper examination. It is unclear whether these provisions will foster research into innovative cures or, in fact, be a detriment to patient privacy.

## An Introduction to the 21st Century Cures Act

In July, the U.S House of Representatives passed the 21st Century Cures Act by a majority rarely seen in Washington of late – a vote of 344 to 77. Despite strong bipartisan support, there has been little reported on this bill. Although complex and substantial, the 21st Century Cures Act did not receive much debate in the House and moved swiftly through to the Senate.

What is the 21st Century Cures Act? Its stated aims are to accelerate the discovery, development and delivery of life-saving and life-improving therapies for patients. The specific provisions laid out to achieve these goals are wide-ranging and include much that is good - from extended funding for the National Institutes of Health (NIH) to the establishment of a new Cures Innovation Fund to making de-identified data from NIH-funded clinical trials more available to researchers[1].

The bill reflects the current emphasis on medical research and healthcare innovation in the U.S. and the frustration with the pace of advancement. The 21st Century Cures Act addresses two areas where there are perceived barriers to new medical discoveries and treatments.

The first is the speed with which the FDA's existing approvals process brings drugs and medical devices to market. Provisions in the 21st Century Cures Act allow for data outside of traditional clinical trials to be used by the FDA in order to speed up drug approvals. This has not been without controversy; critics feel it would reduce the rigor of the approvals process and bring the safety and efficacy of drugs into question[2].

The second barrier is the ease with which health information is made available for research and analysis. Provisions within the 21st Century Cures Act would impact HIPAA, the legislation which regulates the use and disclosure of PHI. There is a perception that it is currently too difficult to get information for research purposes and that more research could be done but is not happening because of limitations by HIPAA.

The changes proposed by the 21st Century Cures Act would make it easier for providers, payers and pharmaceutical companies to share and sell their data. This would seem to facilitate more PHI being put into the hands of pharmaceutical and medical device companies, and permit unlimited payments for the data. Entangled in this are consequences for patient privacy. Unfortunately, scant attention has been paid to these privacy provisions.

Anyone with responsibilities for the sharing and use of PHI or the protection of patient privacy should concern themselves with the issues raised here. This paper examines the provisions in the 21st Century Cures Act that impact privacy and data security and discusses the implications if they become law.

## What Could Change with 21st Century Cures

The 21st Century Cures Act is an extensive piece of legislation. While its main focus is not on patient privacy, it has privacy implications. Many of the areas covered in the bill – and that have received much of the attention to date – deal with significant spending for the NIH and FDA. However, the bill also addresses healthcare research and the ease with which data can be disclosed and shared for this purpose. Consequently, there is a small group of provisions that would impact privacy by forcing changes to the HIPAA Privacy Rule.

In general, the 21st Century Cures Act has received broad support from the healthcare and scientific community. Proponents say that, among other benefits like providing incentives to other

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benefits like providing incentives to develop drugs to treat rare diseases, this legislation would be effective in removing barriers to research collaboration.

The implication is that HIPAA is inhibiting medical research and innovation by making it too hard to get information. However, upon closer examination of what is permitted under the current Privacy Rule it is not evident that these changes are needed or that the perceived barriers to disclosing PHI are, in fact, real. Covered entities and researchers may often misconstrue what is and what is not allowed under HIPAA. This misunderstanding may be the impetus for creating provisions that would not only broaden the definitions of healthcare research and public health activities, but that would also remove restrictions on the sale of PHI.

The sharing and disclosure of health data are permitted under HIPAA provided that the PHI is de-identified so that a patient's information is anonymous. The HIPAA Privacy Rule clearly lays out two standards for de-identification – the Safe Harbor method and the Expert Determination method[3]. Once data is de-identified, then researchers and organizations are legally allowed to have access to it. The use of a risk-based methodology to de-identify PHI minimizes the chance of an individual being re-identified while also allowing for the disclosure of high-quality, granular data. It is why the Health Information Trust Alliance (HITRUST), the Institute of Medicine and the Council of Canadian Academies have all recommended risk-based de-identification as the standard for data sharing. Rather than supporting these globally-accepted standards, the 21st Century Cures Act moves in the opposite direction by broadening access to sensitive personal information.

It is unclear that these significant changes are necessary and what they will mean for existing privacy laws. No one has said how these provisions in the 21st Century Cures Act will alter the existing HIPAA Rule if they are passed as currently written. Unfortunately, these provisions could lead to further misunderstanding by redefining what is considered medical research, removing limitations on the sale of health data and propagating the risk of re-identification.

## Who is Affected by the Requirement for De-Identification?

Of the several hundred pages that comprise the 21st Century Cures Act, only a few deal with privacy issues. This section details the five provisions in the bill that would impact on privacy and discusses the possible consequences of this legislation if it is passed by the Senate.

### 1. Section 1142: Accessing, Sharing and Using Health Data for Research Purposes

The first provision in the 21st Century Cures Act that touches on privacy acknowledges that the changes laid out in Part 4 of the Act (Accessing, Sharing and Using Health Data for Research Purposes) will amend the HITECH Act of 2009. The HITECH Act was the last piece of legislation that made changes to HIPAA.

This effectively recognizes that it is the Department of Health and Human Services (HHS) Office of Civil Rights that is responsible for making any changes that arise from the passage of this bill. The Office of Civil Rights is responsible for enforcing HIPAA.

One such change could be to the sale of PHI. The HITECH Act effectively banned the sale of PHI by requiring organizations covered by HIPAA, i.e. covered entities and business associates, to get authorization from every individual in a dataset if the data is going to be sold as PHI. A

### 5 Things to Know About the HITECH Act

1. It was passed by Congress as part of the American Recovery and Reinvestment Act of 2009.
2. It implemented changes to HIPAA in January 2013 via the Final Omnibus Rule.
3. It introduced the requirement for entities covered by HIPAA to report data breaches affecting 500 or more people to HHS.
4. It effectively banned the sale of PHI by requiring organizations covered by HIPAA to get authorization from each person in a dataset if the data is to be sold as PHI.
5. At the time it was passed, it was considered "the most important piece of health care legislation to be passed in the last 20 to 30 years."

provision in 21st Century Cures Act could nullify this ban, resulting in changes to the HIPAA Privacy Rule. However, it is the purview of the regulators – the HHS Office of Civil Rights – to implement and enforce the change.

As it is written, this provision indicates that HHS will be instructed on ways to go into the HIPAA Privacy Rule to make these changes. It is important that the healthcare community recognizes that, once HHS goes into the Rules to make these changes, there is potential for them to make changes in a broader range of areas.

## 2. Section 13442: Defining Health Data Research As Part of Healthcare Operations

This is the first substantive provision in the act addressing privacy. Currently under HIPAA, covered entities can use and disclose PHI for treatment purposes, payment purposes and healthcare operations without needing permission from the patient to disclose this information.

The category of healthcare operations covers administrative activities where an organization uses its own data to conduct internal analyses. This includes using information for quality assessment and improvement, outcomes evaluation and the development of clinical guidelines. The stipulation is that this may be done provided that the obtaining of generalizable knowledge is not the primary purpose of any studies.

This provision, in effect, redefines healthcare operations to include research where the primary goal is to publish findings. It would revise the HIPAA Privacy Rule to allow the use and disclosure of PHI by a covered entity for research purposes, including studies where the purpose it to obtain generalizable knowledge, by counting this type of activity to be a part of healthcare operations.

This appears to have the goal of turning a lot of research into healthcare operations. It would permit a hospital to broadly share their data with other covered entities and business associates (e.g. contractors, service providers, etc.) for research by pulling it under the heading of healthcare operations, where patient permission is not required.

This raises questions with respect to the current rules. Research is currently its own category under HIPAA with processes to facilitate the sharing of data with researchers. Rules are in place to allow an

**What is a Covered Entity? What is a Business Associate?**

Under HIPAA, covered entities are defined as health plans, healthcare clearinghouses and healthcare providers that electronically transmit any health information. By law, the HIPAA Privacy Rule applies only to covered entities.

HIPAA defines a business associate as a person or entity that performs certain functions or activities that involve the use or disclosure of protected health information on behalf of, or provides services to, a covered entity.

independent review board to examine a research proposal and elect to waive the need for patient authorization. However, this provision eliminates the need for any such boards; we no longer have to obtain the patient's permission since this research now sits under the exempt category of healthcare operations.

It is unclear why the changes resulting from this provision are needed or what they will accomplish. While this provision opens up the disclosure of data to other covered entities, researchers – even if they work in hospitals – are not usually considered to be covered entities. A researcher may be affiliated with a hospital, but his or her work is generally outside of the hospital's main activities, putting them outside of the definition of a covered entity. It is not apparent, therefore, that this provision will help to get more data into the hands of researchers.

### 3. Section 13443: Treating Disclosures of Protected Health Information for Research Similarly to Disclosures of Such Information for Public Health Purposes

The HITECH Act made it illegal to buy or sell protected health information unless explicit authorization is received from each person within the dataset. Currently, there are limited situations that allow an organization to have their costs reimbursed when providing data for research purposes. This is meant to permit reimbursement only, not profit generation.

This provision removes the limits on profit and states that the HHS Secretary shall revise or clarify the HIPAA Privacy Rule so that disclosures of PHI for research purposes are not subject to the limitation on remuneration. For covered entities, this would mean that they are able to make a profit on sharing information for research purposes.

There's a second provision in this section that says the HHS Secretary shall revise or clarify the Rule so that research activities relating to the quality, safety or effectiveness of a product or activity regulated by the FDA are considered as public health. This allows information to be shared in the same way that it can be shared for public health activities. By saying that research activities are going to be treated like public health, this provision allows disclosure to an entity that is regulated by the FDA, in other words, pharmaceutical companies and medical device companies.

This is a controversial section of the 21st Century Cures Act. It would

seem to permit disclosure of PHI to pharmaceutical companies and medical device companies for any research purposes and, furthermore, without any limits on payments for that data. Should the 21st Century Cures Act pass with this provision intact it would appear to open up the potential for data monetization in healthcare.

### 4. Section 13444: Permitting Remote Access to Protected Health Information By Researchers

This next provision addressing privacy issues is straightforward although there are aspects which seem redundant and unnecessary.

Within HIPAA, there is a provision that allows easier access to data if you are trying to prepare a research study. It allows researchers to access and view health records provided that person does not remove anything from the room and does not make copies. The very language of the existing Rule makes it clear that it was written in reference to hard-copy paper records and prior to the growth in electronic medical records (EMRs) and electronic health records (EHRs).

This new provision corrects for the changes that have happened in healthcare over the past two decades, modernizing the current Rule. Its passage would permit remote access to health information so a researcher did not have to physically go to a location in order to access data. Such remote access would be allowed provided that 1) appropriate security and privacy safeguards are maintained by the covered entity and researcher, and 2) that PHI is not copied or otherwise retained.

While there is little controversy here, the specific mention of security and privacy safeguards required by the covered entity is odd as the rules today already necessitate appropriate security and privacy safeguards to be in place.

### 5. Section 13445: Allowing One-Time Authorization of Use and Disclosure of Protected Health Information for Research Purposes

Under the rules today, patients must provide consent for their PHI to be disclosed for research purposes. Additionally, this permission must be granted with respect to a specific use of the data.

Currently, the HIPAA Privacy Rule does not authorize patients to permit the use and disclosure of data for future unspecified research. Concerns over this limitation have been a topic of discussion by academics and researchers. It has been pointed out that individuals can, and have, authorized such uses under the Common Rule for Protection of Human Subjects which regulates research privacy in general and pre-dates HIPAA[4].

This provision would now unambiguously allow patients to authorize the use of their information for future research studies provided it is disclosed that the intent of the authorization is for future research and that the patient has the ability to revoke their permission at a later time.

This provision is not particularly controversial and can be seen as an important step forward in facilitating innovative medical research.

## Conclusion

The 21st Century Cures Act is a broad and ambitious piece of legislation that has, so far, brought together both sides of the aisle in Congress to try to advance medical innovations and treatments in the U.S. Unfortunately, the positive elements of the bill have overshadowed

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the concerns that this proposed legislation raises with respect to patient privacy. It would be negligent not to give these issues proper consideration and debate.

It is unclear what the barriers are to healthcare research that some claim is created by the HIPAA Privacy Rule. There is a perception among the pharmaceutical, biotechnology and medical device industries that the current rules are preventing innovative medical research from happening, but how HIPAA is doing this has not been made clear. The HIPAA Privacy Rule lays out two accepted standards for de-identifying PHI so that it can be legally shared for secondary purposes. The use of a risk-based approach, like HIPAA's Expert Determination, not only minimizes the risk of re-identification for patients, it provides for the sharing of granular data. Furthermore, this approach is consistent with the globally accepted guidelines for data sharing from HITRUST, the Institute of Medicine, PhUSE and the Council of Canadian Academies.

It is difficult to say whether the provisions in the 21st Century Cures Act will help forward medical discoveries and treatments since it is not evident that there are real problems that need to be solved. More attention, discussion and debate are needed on the privacy issues raised in this bill. While it remains to be seen whether all of the provisions end up being passed into law, it is contingent on Privacy Officers and others working with healthcare data for secondary uses to speak out about the potential downsides to these changes.

Learn more about the proposed changes to the HIPAA Privacy Rule by watching the webinar, 21st Century Cures Act Implications for Privacy and Research.

### Sources

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[3] For an overview of the Safe Harbor and Expert Determination standards, see Privacy Analytics' white paper, *De-Identification 201: Fundamentals of Data De-Identification*. http://www.privacy-analytics.com/de-id-university/white-papers/de-identification-201/.

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