

Thinking Beyond HIPAA: Access to Records Containing Confidential Medical Information

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Four years ago at another Fall MARAC conference, I was part of a similar panel on privacy & access as the speaker on medical records. Then my main focus was on the HIPAA Privacy Rule and its effect on archives, and what I wanted to impress on the audience was that very few of them were likely to be bound by HIPAA. I'm happy to say that four years and a presidential administration later, that still holds true: few of you actually have to worry about the intricacies of HIPAA.

Which doesn't mean you shouldn't be aware of them. HIPAA and its Privacy Rule are both a cause and a symptom of a greater vigilance about disclosing personal medical information generally in society. HIPAA's Privacy Rule provisions should at least *inform* any policies regulating access to

records containing confidential medical information, even if those policies don't have to *conform* to them.

What I'd like to do in this talk is to discuss how archives that aren't subject to the rigors of the Privacy Rule, but which still hold sensitive medical records, should regulate access to those records.

But to do that I still have to speak about the HIPAA Privacy Rule. I promise not to be so long that I induce collective catatonia, while not simplifying so much that I leave you completely baffled.

Please be sure to refer to the handouts.

HIPAA, the US Health Insurance Portability and Accountability Act of 1996, is – to simplify a bit – a law designed to make it easier for Americans to obtain and retain health insurance. As part of the Act, it created for the first time federal guidelines for the protection of “personally identifiable health information.” For a variety of reasons not pertinent here, it took quite a while for the Dept.

of Health & Human Services to devise such guidelines, called the Privacy Rule, which only went into effect in April 2003.

So, some definitions. First, whose privacy is being protected? The Privacy Rule regulates access to “Protected Health Information,” or PHI, which is defined as “individually identifiable health information, held or maintained by a covered entity or its business associates...that is transmitted or maintained in any form or medium.” It’s important to emphasize – especially in a roomful of archivists – that PHI is *information*, not a specific type of *record*. So if the information is about health, can be linked to an individual, and is held or transmitted by a covered entity or its business associate, disclosure of that information – say to a researcher – is regulated by the Privacy Rule. It’s not just the traditional patient record.

Now, I've just used two terms that most of you have probably never heard before: "covered entities" and "business associates." What are they? Covered entities are "health plans, health care clearinghouses and any health care provider [which can mean an individual, as well as an institution] who transmits health information in electronic form in connection with a transaction for which HHS has adopted a standard." Any organization that is not included in this definition of "coveredness" is not subject to HIPAA. A Dept. of Health & Human Services publication is very clear about this:

"The Privacy Rule applies only to covered entities. Many organizations that use, collect, access, and disclose individually identifiable health information will not be covered entities, and thus, will not have to comply with the Privacy Rule."

Examples of covered entities would be hospitals, doctors' or dentists' offices, any laboratory engaged in human subject research, birth control clinics, or midwives. I should note that the Rule specifically exempts college and university student health clinic records from its regulations because they are covered by FERPA.

But as they say on late night TV commercials, "But wait, there's more!" Covered entities may further be comprised of both "covered" and "non-covered" parts in which case it is known as a "hybrid entity." Columbia University, for instance, is a hybrid entity -- with those parts of it that are involved in the faculty practice plan or engaged in human subject research considered "covered" while the rest of the University is "non-covered." Some institutions have designated the archives at their health sciences campuses to be "covered" – for instance at Columbia and the Johns Hopkins

University Medical Institutions – while others, like Harvard and the University of Alabama-Birmingham – have not.

Here we have the paradox of HIPAA: although a goal of the Privacy Rule was to impose uniformity on access to records with Protected Health Information, its result among libraries and archives has been exactly the opposite: different repositories are treating identical materials differently. It is the status of the institution holding the records that matters, not the records themselves.

While most archives will not be covered entities, could your repository be what HIPAA refers to as a “business associate?” These are defined as “a person or entity who, on behalf of a covered entity, performs or assists in performance of a function or activity involving the use or disclosure of individually identifiable health information.” Examples of these functions or activities are “legal, actuarial, ... management, administrative or financial services to or for a covered entity where

performing these services involves disclosure of individually identifiable health information...”

Under this definition, some archives, while not covered entities, might be seen as business associates. After all, we “disclose” protected health information to our patrons when they do research in records containing PHI. In fact, I think that status is a more accurate definition of what archives at health sciences institutions actually are. Unfortunately, determining business associate status for an archives can be difficult to discern. Obviously – or at least it would seem obvious – no such entity as a business associate could exist before the HIPAA Privacy Rule came into effect in 2003. Common sense tells us that an archives holding the records of a hospital that went out of business 30 years ago or the papers of a physician who died in the 1890s cannot retroactively sign a business associate agreement with them.

But what if your repository is an otherwise “non-covered” institution that has the pre-2003 records

of a hospital still in existence? Or the papers of physician who retired in 1990 but is still alive? The Privacy Rule is silent on this. Certainly, I would recommend that repositories currently acquiring records from covered entities have a business associate agreement in place to regulate access to these records. But even this is problematic. Access to records containing protected health information of *living* individuals – something contemporary records of covered entities are almost inevitably going to have – is supposed to be regulated by Institutional Review Boards, something your average historical society, for instance, is unlikely to have.

This opacity about what constitutes a business associate aside, I suspect very few of the people in this room work for archives that are regulated by the HIPAA Privacy Rule. Yet, of course, many of you may have collections that contain personal medical information. The fact that your repository

isn't regulated by HIPAA may lead to a silent sigh of relief but it doesn't mean HIPAA should be entirely ignored.

After all, I think we can all agree that protecting our personal health information is a *good* thing.

The HIPAA Privacy Rule is not radical. It builds on the idea of doctor-patient confidentiality that goes all the way back to Hippocrates; an idea that was then extended – if implicitly – to the patient record when it became an important medical tool starting in the late 19th century.

Nor did archives with significant holdings of biomedical records allow unfettered access to them before 2003. Long before HIPAA was a gleam in a bureaucrat's eye, archivists in charge of such collections had been sensitive to the issues of balancing the individual's right to privacy with the need to make these records accessible for scholarly research.

Archives that are not covered by HIPAA but possess records containing personal medical information are in an enviable position. They can make use of the parts of the Privacy Rule that work while ignoring those that make little sense in the archival setting.

There's never been a one size-fits-all solution to regulating access to medical information in archives. But there are some common sense, easily implemented rules. These rules relate to two aspects the archivist has to consider: the types of records involved and types of research being done in those records.

To talk about records -- First, does the record actually contain *personally-identifiable* medical information, that is, does it contain explicit information about the medical condition of an identifiable person? Not all medical records do. In our holdings, the account book of Dr. Alfred Trull, a physician in early 20th century Haverhill, Massachusetts, meticulously lists his practice

income; names and addresses of his patients are always given but there's no diagnosis: Trull only includes one word descriptions of his services – “confinement” “vaccination” “operation” “medicine.” By no stretch of the imagination can this volume be seen as containing sensitive medical information.

Additionally, contemporary records of biomedical research will often not include names; the information will have been de-identified as part of the research protocol. Again, this is not a record that can be considered confidential.

Second, how old is the record? Perhaps the most frustrating feature of the HIPAA Privacy Rule from the archivist's point of view is that it has no expiration date: it treats records created last week exactly the same as records created two centuries ago. As historian Susan Lawrence has noted, one of the most “perplexing aspects of the HIPAA Privacy Rule is its absolute present-

mindedness.” Fortunately, those of you not covered by the Privacy Rule don’t need to perpetuate this foolishness. It is perfectly legitimate to consider age in regulating access to personal medical information. Older records *are* less sensitive than newer ones. The records of individuals we can safely assume are dead are less sensitive than those where the subjects may be alive. Where exactly you draw the line will be influenced by other factors as well, but the age of a record is certainly *one* factor that may be considered.

Third, what type of medical information is documented in the record? Historically, access to archival records documenting mental illness and sexually-transmitted diseases has been set at a higher level than those of other illnesses – even for records of the deceased. This may be seen as perpetuating an unjust stigma but nevertheless it is a reality the archivist needs to be aware of.

After all, learning that great-grandfather had an appendectomy in 1907 is not the same as learning he was treated for the clap in 1907.

How well-known is the case? George Washington's bad teeth; Lincoln's melancholia; FDR's polio – these aren't exactly shocking revelations. In cases where the medical information in question is widely known and the patient is deceased, restricting access to that information may not make much sense.

Lastly, is the record or records containing the medical information essential to the collection? We discard all sorts of records when we process collections. No one saves telephone or gas bills; it may not be necessary to save a sole medical record in a collection whose main value is in another field.

To turn to research: what type of research is the patron proposing? Here there are really only two considerations: is the researcher only interested in medical information in the aggregate or is she interested in some specific *person's* medical information?

Examples of the first type of research might be might be medical treatment of slaves in the antebellum South; the geographic distribution of polio victims in New York City's great epidemic of 1916; or lead poisoning among workers in the paint trade in the 1920s. Research of this type doesn't need to be attached to names; if the researcher would like to use specific cases as examples, a pseudonym can easily be substituted and the key given to the archives in case future researchers want to verify the work. We have used this solution with success several times at Columbia.

A form signed by the researcher promising not to use names or personally identifiable information can usually regulate this type of access quite satisfactorily. This kind of form is also good insurance for research with collections where there's a possibility of confidential medical information being present but where the size of the collection precludes the archivist from knowing where that confidential information might be located.

Research into the confidential medical records of *specific* persons for the purpose of illuminating that person's life has been, is now, and will be among the most difficult access decision an archivist can make. There is no hard and fast rule that will tell you how to proceed in every case. Factors that I've mentioned earlier – age of the record, type of medical information involved, notoriety of the case – need to be taken into consideration. Obviously, records of persons living or presumed living should never be opened for this type of research without their prior permission. Certainly,

having identified potential access problems during the accession process will help you later. Deeds of gifts that regulate access to personal medical information are crucial. Consultation with your institution's lawyers may be necessary – though be aware that most lawyers working in academic settings may not be well-versed in health care law.

Beyond this, archivists must use their professional judgment. But as I think all of the panelists here today would agree, archivists are up to the task of resolving these delicate ethical issues.

Thank you.

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