

Primer: HIPAA and PHRs

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In the US, many federal and state laws condition the treatment of personal health information. But HIPAA is the 440-pound gorilla in this zoo, and it's a natural to ask how HIPAA might apply to the health information in personal health records (PHRs).

The term PHR itself embraces a spectrum of possible technical platforms. At one end are simple, stand-alone "my health record on a USB stick" implementations created entirely by the data subject's efforts. At the other are comprehensive personal health data collections synchronized with institutional electronic medical records (EMRs), thus containing data from both the data subject and institutional sources. The particular technical implementation is among the factors conditioning the answer to "does HIPAA apply?"

WHAT IS COVERED BY HIPAA

The content of PHRs would certainly be within the reach of HIPAA. Under its provisions, any information that is, or reasonably could be, linked to an individual is [protected health information](#) -- in HIPAA-speak, simply "PHI."

HIPAA defines PHI very broadly as anything related to the "past, present or future physical or mental health condition" of a person. Only fully [de-identified](#) health information is excluded – where every explicit identifier of a person has been removed, as well as data that could potentially establish identity via statistical techniques.

Note that HIPAA's [Privacy Rule](#) applies to PHI in "any form or medium." (This is in contrast to HIPAA's [Security Rule](#), which applies only to PHI in electronic form.) That includes paper records as well as electronic ones, faxes, emails, exchanges in phone conversations, and even just talking face-to-face. If it's health data and it's identifiable, it's covered, and that would certainly include the stuff of PHRs.

WHO IS COVERED BY HIPAA?

The question here is not the "what" of PHRs, but the "who" – that is, what sorts of natural or legal "person" are within HIPAA's reach? HIPAA defines as [covered entities](#) the following major groups:

- health care providers (e.g., physicians);
- health care facilities (hospitals, clinics, physician offices);
- health plans (HMOs, insurers); and
- health information clearinghouses¹

That puts almost every US organization that provides or pays for health services, or exchanges health data of any kind, within the reach of HIPAA. HIPAA reaches even to the [business associates](#) that handle health data on a covered entity's behalf.

DO PHRs INVOLVE "CLEARINGHOUSES"?

Individuals, unless they happen to be health care practitioners, are not covered entities. A PHR conceived as a stand-alone "health data on a USB stick" repository would appear to be outside the realm of covered entities. However, almost no one with ambitions for PHRs wants to leave them at this level.²

Ensuring the integrity and availability of PHR data whenever and wherever a patient may need access to it requires both backup copies and a communications platform to reach those backups. Hence, the emergence of a myriad of players providing a “repository” service. The most recent major entrant is Microsoft’s [HealthVault](#), with the emergence of rival Google Health soon to follow.

Robust functionality for PHRs requires the ability to exchange their data with the parties that provide health services to the patient – e.g., physicians in clinics, hospitals, pharmacies. Hence sources like Health Vault feature the capacity to “catalog existing health records, receive test results, or monitor current physical readings.” If any of the sources or destinations of such information is a covered entity – and it is hard to see how they would not be – then the PHR service appears to be functioning as a health information clearinghouse.

Repository providers like HealthVault promise that “[y]ou decide who can see and use your information on a case-by-case basis” and that any recipients of such data must, as a condition of participation, agree “not to disclose your data without your express consent.” If HealthVault is a covered entity, that cannot be true. HIPAA allows – indeed, requires – many types of information disclosure without the data subject’s permission (see next section). HealthVault navigates around this problem in its Privacy Statement (emphasis supplied):

“Microsoft may access and/or disclose your personal information if we believe such action is necessary to: (a) comply with the law or legal process served on Microsoft; (b) protect and defend the rights or property of Microsoft (including the enforcement of our agreements); or (c) act in urgent circumstances to protect the personal safety and welfare of users of Microsoft services or members of the public.”

SHOULD PHRs BE COVERED BY HIPAA?

Whether PHRs are covered by HIPAA is a question ultimately for the courts – or for Congress, should it choose to add a paragraph or two to amend HIPAA. Whether it should be covered is a harder question.

There can be no doubt that HIPAA’s security provisions have had a beneficial effect on the health sector, forcing covered entities to attend to data protection in a more focused manner. The balance for privacy is a harder call.

HIPAA allows uses and disclosures without consent for a broad range of purposes, including transactions related to [treatment](#), [payment](#), and a broad range of other core [health care operations](#). Neither does HIPAA require specific permission for a broad range of activities required by law, including [public health](#) and [health system oversight](#) activities, reporting about victims of [abuse](#), [neglect or domestic violence](#), content for [judicial and administrative proceedings](#), and activities related to “specialized government functions” like [national security](#), [military and veterans activities](#), [corrections](#) and [law enforcement](#), or anything required to avert a serious, imminent threat to public safety. HIPAA does require a signed permission (called an “authorization”) for many – but decidedly not all – uses or disclosures for [research](#), [marketing](#) and [fundraising](#).³

In other words, when it comes to consent in HIPAA, the exceptions are the rule. Would a similar breadth of allowed uses and disclosures without consent have a chilling effect on PHRs? That would depend on whether the parameters of accessibility, by type of information and type of use, could be crafted in a way that satisfied both data subjects and the constituencies of potential data users. The experience with HIPAA to date demonstrates how difficult a task that is.

It is certainly not irrational to prefer to keep information out of institutional records if you can't control its use and it can be used to hurt you – a rationality that applies to PHRs if that content will reappear in institutional backups. However, providing a strong consent model for PHRs is not without costs. The information in such records has value, for all the reasons that institutional health records have value. Making PHRs attractive from a personal privacy perspective trades off that value, though in ways that are obviously extremely difficult to quantify.⁴

ACKNOWLEDGEMENTS

Michael Froomkin of the UM ELSI team contributed to this paper.

NOTES

¹ More expansively, definitions of covered entities at [45 CFR 160.103](#) and [45 CFR 164.501](#) include:

- *health plan* means any individual or group plan that provides, or pays the cost of, medical care -- including public and private health insurance issuers, HMOs or other managed care organizations, employee benefit plans, the Medicare and Medicaid programs, military/veterans plans, and any other "policy, plan or program" for which a principal purpose is to provide or pay for health care services;
- *health care provider* means a provider of medical or health services, and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business; and
- *health care clearinghouse* means a public or private entity, including a billing service, repricing company, community health information system, and "value-added" networks and switches, that either processes or facilitates the processing of health information.

The last of these is further qualified by whether "the business or agency processes or facilitates the processing of health information from nonstandard format or content into standard format" or vice-versa.

See also [Covered Entity Charts \(DHHS\)](#).

² Attempting to apply a HIPAA-like regime to privately created and privately held health data raises a number of difficult legal issues that both Congress and the courts are likely to try to avoid. As a practical matter, the disclosure and consent issues arise only when that data is disclosed to a health-care provider or to a third party such as HealthVault – but then they arise with a vengeance.

³ If a repository service like HealthVault is considered a clearinghouse, one response would be for the covered entity to secure a business associate contract before transferring information to it. Alternatively, covered entities could require the patient's specific authorization for single or on-going transfers to any PHR repository.

⁴ IF PHRs were given greater privacy protections than institutional records, they could come to be the preferred venue for persons' most sensitive health data – a sort of Gresham's law of health information. "Sensitivity" tends to correlate with both the social stigma and the financial risk associated with a disease or condition. Data on the latter is potentially of greatest value for improving the cost-effectiveness of health care delivery.