JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 4, No. 2, February 2008 "Can You Handle the Truth?"

HIPAA Complaints in Clinical Research

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Healthcare providers and related organizations obtain vast quantities of very personal medical information from their patients. If this information falls into the wrong hands, patients may suffer damages to their employment, insurance, relationships and dignity. Do you want to receive postcards in the mail asking about an embarrassing disease?

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) protects the privacy of patient information, among other things. The privacy provisions became effective on April 14, 2001. Compliance was required beginning on April 14, 2003, with a one-year delay for small health plans.[1]

The Office for Civil Rights (OCR) in the Department of Health & Human Services (DHHS) is responsible for responding to HIPAA complaints related to privacy. OCR provides instructions for filing HIPAA complaints at http://www.hhs.gov/ocr/hipaahowto.pdf. A complaint form is available at http://www.hhs.gov/ocr/howtofileprivacy.pdf. OCR's web pages related to privacy have received over 5.5 million visits.[1]

Between April 14, 2003 and December 31, 2007, OCR received 32,487 HIPAA complaints. Of these complaints, 17,544 were not eligible for enforcement under HIPAA. Of the remaining 14,943, OCR has completed investigations of 8,199. It found violations in 5,509 complaints and no violations in 2,690. It identified 419 "knowing" privacy violations and referred them to the Department of Justice (DOJ) for criminal investigation. (It also referred 215 complaints related to HIPAA's security rules to the Centers for Medicare and Medicaid Services (CMS) for enforcement.) The balance of 6,744 complaints are in process.[1]

Based on these numbers, it is clear that OCR is actively publicizing and facilitating the HIPAA complaint process.

Clinical Research Complaints

HIPAA applies to clinical research. (Volunteers unafraid of criminal prosecution are invited to help clarify in court some ambiguities in HIPAA's definitions of "covered entity" and "medical care.")

On July 16, 2005, the author filed a Freedom of Information Act (FOIA) request with DHHS, requesting copies of all HIPAA complaints relating to clinical research. DHHS provided the requested copies on January 16, 2008. Given the number of HIPAA complaints received by OCR, the delay is understandable.

DHHS found a grand total of 17 HIPAA complaints relating to clinical research, all of which have been resolved by OCR. Because of heavy redaction, very little information can be gleaned from the documents, even about the nature of the complaints. However, stamped receipt dates can be discerned for the period February 11, 2002 through April 30, 2007. It is possible that OCR was unable to classify other HIPAA complaints as relating to clinical research, but it is probably safe to assume that OCR has received very few such complaints.

Counting just industry-sponsored clinical trials, at least two million study subjects sign HIPAA authorization forms each year. Since HIPAA enforcement began in 2003, at least ten million people have signed the forms. The OCR complaint rate is thus about 1 per 600,000 subjects. The rate is probably ten times lower (1 per 60,000) if we include people who

participated in studies not sponsored by industry or who were contacted but did not enroll in a study.

Explanations for the low complaint rate might include:

1. The complaint rate in clinical research is comparable to the rate for regular medical care, which is also low.
2. Study subjects complain to the IRB rather than OCR.
3. The HIPAA authorization process immunizes sites from complaints.
4. Research sites successfully protect subject information.
5. Most subjects do not care much about HIPAA.
6. Close subject relationships with study personnel minimize complaints to the IRB or OCR.

1. The complaint rate in clinical research is comparable to the rate for regular medical care, which is also low. If 30 million people per year (10% of the U.S. population) are exposed to HIPAA each year at some point in their regular medical care, the OCR complaint rate is roughly 1 per 5,000. Complaints related to clinical research are thus 100 to 1,000 times less frequent than complaints related to regular medical care. This explanation is probably incorrect.

2. Study subjects complain to the IRB rather than OCR. It is possible that OCR receives so few clinical research-related complaints because subjects complain first to the IRB (institutional review board). Informed consent forms suggest contacting the IRB when issues arise. However, an informal survey of six large academic and independent IRBs revealed fewer than ten such complaints. Most of the complaints were from people who believed that their privacy had been violated when they were unexpectedly contacted about participating in a study. These people had not yet seen the HIPAA authorization for the study. In most or all cases, investigations revealed no HIPAA violations. This explanation is probably incorrect.

3. The HIPAA authorization process immunizes sites from complaints. Subjects in industry-sponsored studies probably receive HIPAA authorization forms almost 100% of the time. However, comprehension of the complex content in the forms is probably very low. Most subjects focus on the informed consent material, which is challenging enough. In all likelihood, most subjects understand that research sites take steps to protect their private health information, but pay little attention to the details. Just knowing that they have privacy rights probably contributes to the low frequency of complaints. However, it is not clear that subjects want to read about their rights in detail. A simple sentence or two may suffice, with the option of reading about the details in a separate document. (Have you ever read the fine print on your bank statements?) In contrast, most regular patients signed their healthcare HIPAA authorization forms years ago without paying much attention. This explanation probably contributes to the low frequency of complaints from study subjects, but not from the larger number of potential subjects who have not seen the study HIPAA form.

4. Research sites successfully protect subject information. It is possible that research site personnel protect private information better than regular healthcare personnel. If there is an improper release, several steps must occur before the subject files a complaint with the IRB or OCR. First, the subject must discover the information release. Second, the subject must object to it. Third, the subject must be dissatisfied with (or uninterested in) the response from the investigator or study coordinator. This explanation may contribute to the low frequency of complaints.

5. Most subjects do not care much about HIPAA. If patients care about HIPAA, study subjects probably care as well. As discussed above, most study subjects probably want to know they have privacy rights, but are not very interested in the details; they can read the

details when it matters to them. Unlike in regular healthcare, they have been informed relatively recently of their HIPAA rights. This explanation probably does not contribute to the low frequency of complaints.

6. Close subject relationships with study personnel minimize complaints to the IRB or OCR. Close subject/coordinator relationships are critical to the success of clinical trials. (Investigator/subject relationships are often cursory.) Physician/patient and nurse/patient relationships can be limited by the time constraints in healthcare. Close subject/coordinator relationships may minimize HIPAA issues and resolve those that occur before they reach the IRB or OCR. This explanation probably contributes to the low frequency of complaints.

Conclusion

There is a 100- to 1,000-fold lower frequency of HIPAA complaints related to clinical research vs. regular healthcare. Likely explanations include (a) good compliance, (b) reminding potential subjects of their privacy rights during informed consent, and (c) developing close subject/coordinator relationships.

Given the information overload in most informed consent forms, it is not at all clear that adding two pages about HIPAA benefits potential subjects. Making the details available as an option may serve just as well, and reduce the information overload.

Further research on the huge difference in complaint frequency may yield useful information for both clinical research and regular healthcare. For example, it would be helpful to know if study subjects would prefer most of the HIPAA information to be optional. If so, significant time and cost savings are available. If it costs a research site only five minutes per signature, we are investing at least 10 million minutes per year, to say nothing of the subjects' time. If the site's time costs $60/hour (including overhead), we are spending at least $10 million dollars per year obtaining HIPAA authorizations.

Reference

1. Privacy Rule Enforcement Highlights, last accessed 1/26/08 at http://www.hhs.gov/ocr/privacy/enforcement/12312007.html

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