

HARVARD MEDICAL SCHOOL
DEPARTMENT OF HEALTH CARE POLICY

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To: Employers Concerned about HIPAA Privacy Regulations
From: Paul Cleary, Ron Kessler
Re: HIPAA Guidelines and Participation in the Harvard Health Care and Work Productivity Initiative.
Date: August 20, 2002

Executive Summary

Some employers have had questions about the legality of providing lists of their employee addresses and health plan memberships to Harvard Medical School for inclusion in our Health Care and Work Productivity survey.

Our reading of the final changes printed in the August 14 Federal register indicates that employers are free to provide identifying information of their employees for the purposes of conducting our survey.

We have not conducted a formal legal review, but the guidelines appear to be clear: HIPAA is explicitly limited to health plans, health care clearing houses and health care providers who conduct certain electronic transactions. It does not apply to employers.

Thus, legal concerns about the HIPAA guidelines should not be an issue in decisions to participate in the Harvard initiative. Additionally, our survey qualifies under all the established rules designed to protect employee privacy.

Details follow.

Background

The DHHS final changes to the privacy regulations issued under HIPAA were published in the Federal Register on August 14, 2002. We did not conduct a formal legal review of the entire Privacy Rule and the published changes, but we have thoroughly examined the relevant sections governing our situation.

In our interpretation of the Privacy Rule with regard to participation in HPQ surveys we distinguish two exchanges of information.

I. We ask employers to provide the names, addresses, telephone numbers, and health plans of their employees.

II. We ask employees to participate in a survey about their health.

The privacy issues differ between the two exchanges.

I. Employers providing information to researchers.

Our reading of the HIPAA regulations leads us to conclude that employers are free to give us identifying information of employees for purposes of carrying out the HPQ survey. We base this interpretation on the fact that HIPAA is explicitly limited to health plans, health care clearinghouses, and health providers who conduct certain electronic transactions. HIPAA does not apply to employers in their dealings with other organizations that do not involve the exchange of information involving employee health or health care. This is clearly stated throughout the December 2000 preamble to the Privacy Rule, in which DHHS repeatedly stated that the Privacy Rule does not apply to employers or the employment functions of covered entities (e.g. health plans).

There is a specific comment about disclosure of information involving name, address, choice of plan, amount of premiums-contributions for coverage, and employment status on page 53192 of the August 16, 2000 Federal Register (Vol. 67, No. 157). The comment states that this type of information is specifically protected when held by a fully insured group health plan. While such a plan cannot disclose this information to the Harvard researchers in carrying out an HPQ survey, there is no indication that the comment applies to employers. Employers are not covered entities under HIPAA. Once again, it appears that such information can be provided to Harvard researchers by employers.

There is the potential for confusion in the special case where a health plan wants to carry out surveys of their employees, as opposed to their clients. DHHS addressed this case in the final HIPAA modifications by adopting language that explicitly excluded employment records maintained by a covered entity (we do not believe non-health care employers are covered entities) from the definition of "protected health information."

Although we do not believe HIPAA restricts the release of such information, please rest assured that all possible steps will be taken to protect the privacy of the employee lists. Because we are asking for this information as part of a university sponsored research project, the release of lists and our provisions for the protection of that data will be thoroughly reviewed by the Harvard Medical School IRB. As part of the application process, we will provide detailed written descriptions of the procedures we will establish for protecting the confidentiality of such information.

II. Employees providing information to researchers.

Our survey will ask employees to provide us with health information. The final Rule issued on August 14 also clarified the requirements for a researcher to obtain IRB approval of research and to obtain a waiver of written authorization. These details may be of interest to employers who are concerned about other employee anonymity and privacy issues.

Specifically, the final rule adopted the three criteria that an IRB or Privacy Board must use in approving requests for a waiver of authorization for research. Under this final rule, to qualify for a waiver of written authorization:

(i) the use or disclosure of protected health information must involve no more than minimal risk to the privacy of the individual;

(ii) the research could not practicably be conducted without the waiver or alteration; and

(iii) the research could not practicably be conducted without access to the protected health information.

The HPQ survey qualifies under all three of these considerations. (i) Risk is minimal due to the fact that individual identifiers (e.g., name, address, telephone number) are not being linked to the survey reports at any stage of data collection or file preparation, making it impossible to identify the responses of any individual participant. (ii) It would be impossible to conduct the research without obtaining individually identifying data. (iii) No protected health information is being provided by employers.

In performing the 'minimal privacy risk' analysis, IRBs or Privacy Boards must consider whether there is:

(i) an adequate plan to protect the identifiers from improper use or disclosure;

(ii) an adequate plan to destroy the identifiers at the earliest opportunity, unless retention of identifiers is required by law or is justified by research or health issues; and

(iii) adequate written assurance that the PHI will not be used or disclosed to a third party except as required by law or permitted by an authorization.

The HPQ survey qualifies under all three of these considerations. (i) As noted above, identifiers will never be linked to survey data. (ii) Identifiers will be destroyed as soon as the survey data are collected. (iii) Both the Harvard researchers and the survey firm carrying out the HPQ surveys have submitted written statements guaranteeing that the identifying data provided by employers will not be used other than for purposes of selecting the HPQ sample.

We hope this answers all the relevant questions about the HIPAA guidelines and puts to rest any legal concerns about participating in our survey. If there are any questions please contact Elaine Veracruz at veracruz@hcp.med.harvard.edu.