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Modifications on HIPAA Privacy Rules

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Published Date: 04/25/2002

April 25, 2002

The Honorable Tommy G. Thompson
Secretary, Department of Health and Human Services
Office of Civil Rights
Attention: Privacy 2
Hubert H. Humphrey Building, Room 425A
200 Independence Avenue, S.W.
Washington, D.C. 20201

SUBJECT: Proposed Modification: Standards for Privacy of Individually Identifiable Health Information (45 CFR Parts 160 and 164) – Privacy Rules

Dear Secretary Thompson:

The Council on Governmental Relations (COGR) is an association of over 145 research-intensive universities in the United States. COGR works with federal agencies and research sponsors to develop a common understanding of the impact that policies, regulations and practices may have on the research conducted by the membership. We welcome the effort undertaken by the Department of Health and Human Services (DHHS) to modify the above referenced Privacy Rule particularly in those areas that affect the research enterprise. The proposed modifications provide considerable streamlining and clarification of the provisions. We also appreciate the opportunity to provide further comment to DHHS.

Exemption for Research

We continue to believe that research activities that are subject to review and approval by Institutional Review Boards (IRBs) under the Common Rule should be exempt from the Privacy Rules. Under the Federal Policy for the Protection of Human Subjects (45 CFR 46, Subpart A, 21 CFR Part 50, etc.), referred to as the Common Rule, one of the core requirements for approving research using human participants is the IRB determination that “there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data” [§45 CFR 46.111(a)(7)]. This section and other complimentary sections of the Common Rule already ensure the privacy protections, including the content and conditions of the documentation, as required by HIPAA.

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In defining the relationship between the Common Rule and the Privacy Rule, HHS emphasizes the Privacy Rule's focus on the content and conditions of the documentation of privacy protections, rather than the substantive consideration of the research itself. If the concern is the nature of the documentation, we believe that HHS can exempt research and, through the leadership of Office of Civil Rights and Office of Human Research Protections, issue guidance for the research community on how the IRB can best meet these concerns based on the requirement at §46.111(a)(7). The Common Rule serves as the framework for human participant research conducted by the federal agencies and while the Privacy Rule's research provisions fall under this umbrella, they are limited to HHS-regulated activities. HHS can extend the benefit of these privacy protections to all research participants by issuing guidance that affirms and strengthens the Common Rule.

This guidance could describe how the IRB review should include the privacy protections and documentation as outlined in the proposed modifications. Specially, the guidance can describe, in detail:

1. Combining the authorization for the use and disclosure of protected health information (PHI) for research with the consent to participate in the research documents [§46.109(b) and §46.116(a)(5)].
2. Using the criteria for waiver of authorization outlined in the proposed §164.512(b)(2) (ii) including an assessment of the minimum level of access necessary to conduct the research and documenting the use of these criteria for review in IRB meeting minutes [§46.111(a)(7) and §46.115(2)].
3. Requiring a description of a plan for maintaining the confidentiality of the records either in the consent to participate in research documentation or in a research proposal to use existing data or records and reviewed under the expedited process [§46.116(a)(5) and §46.110(b)].

HHS essentially affirms that research can be exempted from the Privacy Rule without diminishing the goal of protecting individually identifiable health information. In its discussion of the modifications to the waiver criteria, HHS suggests that research reviewed by an IRB under the Common Rule enhanced with additional guidance as we propose can meet the requirements of the Privacy Rule, particularly in its determination of minimum necessary.

The Privacy Rule permits a covered entity to reasonably rely on a researcher's documentation of an approval of [the] waiver criteria, and a description of the data needed for the research as approved by an IRB or Privacy Board, to satisfy [the covered entity's] obligation with respect to limiting the disclosure to the minimum necessary (67 FR 14795).

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The Common Rule educates the consumer and protects the privacy of their health information better than the Privacy Rule. For example, under the Common Rule, the IRB is required to ensure that the informed consent to participate is in language that is understandable and minimizes coercion of the participants [§46.116]. This focus on the understandability of the content of the documentation ensures that human participants are better informed of their privacy rights. As we suggested in a letter to the Secretary's Advisory Committee on Regulatory Reform, the research provisions of the Privacy Rule attempt to correct an undocumented problem of unauthorized releases of health information by researchers. We strongly recommend that research subject to the Common Rule be exempted from the Privacy Rule.

Proposed Modification: Standards for Privacy of Individually Identifiable Health Information

If research is not to be exempted from the Privacy Rule, further clarification and revisions of the Privacy Rule and its proposed modifications are necessary to ensure the continued, reasonable access to protected health information for research.

Modifications to Authorizations and Waivers of Authorizations Requirements

We support the proposed modifications that permit combining authorizations for use and disclosure of protected health information (PHI) with the consent to participate in research studies [§164.508(b)(3)(i)]. The proposed revisions to the review criteria for a waiver of patient authorization will allow the Institutional Review Board (IRB) or Privacy Board to focus on the more critical assessments including the risks to privacy and the investigator's plans to protect PHI as weighed against the benefits of the research itself [§164.512(i)(2)(ii)].

In addition, we request elimination of the proposed §164.508(c)(2)(iii) that requires the authorization to include a statement on the "potential" for information to be re-disclosed and, therefore, no longer protected. An IRB-approved research study already defines how an investigator can use PHI. Researchers must safeguard data and prevent unlimited, public disclosure of any information [§46.111(a)(7)]. Given these conditions, the potential for re-disclosure would be mere speculation of a worst-case scenario and an unnecessary addition.

We support eliminating any requirement for an expiration date in an authorization in the case of research [§164.508(c)(v)(A)]. Researchers need to be able to maintain the data for a reasonable period of time following the end of the study to make data available to other reputable scientists for limited purposes like peer review prior to publication and validation or replication of the results. It will be difficult to predict when the data will be needed for validation and using "end of study" could cause misunderstanding on the part of the individual and limit valuable long-term data analysis.

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We understand that the Privacy Rule does not prohibit limited, carefully monitored re-disclosures by the researchers for the purposes of validation [§164.512(i)(2)(ii)(A)(3)]. We ask HHS for clarification on the ability of researchers to re-disclosure for the purposes of validation and ask that the clarification be incorporated into the rule.

The ability to continue to use data for research purposes and to make the data available for validation has already come under unreasonable restriction by covered entities acting in anticipation of the implementation of the Privacy Rules. Our universities have received contracts with terms that prohibit these normal scientific uses for fear of violating the Privacy provisions. Some of these contracts require data to be returned or destroyed upon demand; others require the return or destruction of the data at the end of the study regardless of whether the research results have been or will be submitted to a journal for publication; and still other contracts prohibit any sharing of the data with a third party effectively preventing peer review or, in the case of the federal government's new information quality guidelines, the reproducibility of information defined as influential.

With regard to the documentation by the IRB of a waiver approval, we recommend that documentation of the privacy waiver approval [§164.512 (i)(2)], when approved by an IRB be combined with the same written notification of approval of the research study issued by the IRB as required by 45 CFR 46.109 (d). This proposed change is consistent with the "compound authorizations" proposed by HHS.

Public Health Research Disclosures

COGR requests that covered entities be permitted to disclose PHI to academic investigators and institutions and non-profit organizations for the creation of registries and repositories without authorization or waiver. This use would parallel the proposed modifications at §164.512(b)(1)(iii) to disclose PHI without authorization to sponsor-initiated registries, provided that these registries are created for the purpose of activities related to the quality, safety, or effectiveness of FDA-regulated products. Extending this level of access to academic and non-profit organizations will ensure that academic researchers can continue to conduct vital epidemiological and health sciences research. The use of the information maintained in the registries or repositories will be subject to review by an IRB when a study is proposed or will be de-identified before use by an investigator. Granting this request will eliminate an apparent double standard under which FDA-regulated research may receive PHI without authorization or waiver to construct registries for legitimate research purposes, but the academic and other non-profit communities may not receive the same consideration.

De-Identification

HHS asked for comments on how the standards for de-identification might be modified to accommodate research uses. HHS offers a “limited data set” model that requires a data use agreement signed by the investigator affirming that the information is for research purposes; that the investigator will not attempt to re-identify the individuals; and that the investigator will not disclose the information except as required by law. We support incorporating this type of strategy into the Privacy Rule.

In order to implement this model effectively, we suggest that DHHS establish only a minimum required level of de-identification: name, street address, telephone and fax numbers, email or electronic addresses and locations (URLs and IP addresses), social security numbers, vehicle identifiers including serial numbers, and photographic images of full face or full profile. The covered entity should be given flexibility in creating the limited data sets beyond this minimum level. Decisions on disclosing the entire date of birth, neighborhood, zip code or other identifier information should be made by the covered entity on a case-by-case assessment of a variety of issues including the vulnerability to re-identification of the information and the research activity proposed, the minimum information necessary to conduct the research, etc. Similarly, we believe the content of the data use agreement should be negotiated between the investigator and the covered entity on a case-by-case basis. For example, an investigator may need to provide limited access to the information for the purposes of scientific validation or as required by state or local laws.

We are concerned about the increased burden on IRBs of reviewing requests for PHI that do not fit the de-identification criteria that are too narrowly defined. Under the Common Rule, some research using existing data is exempt from IRB review “if the information is recorded by the investigator in such a manner that subjects can not be identified” [§46.101(b)(4)]. The manner of de-identification under the Common Rule is not defined. The Privacy Rule sets a standard for de-identification for PHI that is more stringent than the Common Rule. Because of the limits of the proposed de-identification, the need for a privacy review will bring some research formerly exempt from the Common Rule before the IRB with little evidence of benefit for the individual. These additional costs and regulatory burdens on covered entities and IRBs should be included in the assessment of costs of the proposed modifications. These costs and burdens would be avoided if research uses and disclosures of PHI were exempt from the Privacy Rules.

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Disclosure Accounting Requirements

The proposed modifications eliminate the accounting of disclosures based on the individual's authorization and we support this change. We urge HHS to consider further modification of the accounting requirements for research disclosures based on a waiver of authorization or de-identification of PHI.

Some covered entities, particularly academic medical schools and hospitals with a strong research mission, participate in a wide variety of clinical trials in the course of the year. In the case of the release of the limited, de-identified data sets, a significant number of records could be released to investigators. Smaller, community based hospitals that do not include research, as a primary mission will be challenged to adapt record systems to accommodate research disclosures according to the current Privacy Rule standards. The record-keeping burden of accounting for each research study with detailed information may discourage or limit the covered entities' participation in some research studies. Therefore, we urge you to consider alternatives to detailed, study-by-study records of disclosures. An alternative might include a general disclosure or list of all research studies, with the name and contact information for the principal investigator that the covered entity participated in during the previous six years. This type of approach would streamline the management of the accounting information and ensure the continuation of vital public health research.

Conclusion

The principal concern for the research community has always been and remains the protection of human research participants, including maintaining the confidentiality of individually identifiable health information. The current human research protection regulations provide sufficient mechanisms to ensure the privacy of research participants. We believe HHS should weigh whether it is more effective to incorporate the requirements of the HIPAA Privacy Rules via guidance into the Common Rule or by a separate, stand-alone and largely duplicative new rule. We believe that in order to maintain a productive research environment, research reviewed under the Common Rule should be exempt for the Privacy Rules. We urge the Department to reconsider its decision.

We thank you for the opportunity to comment on the proposed modification.

Sincerely

Katharina Phillips
President

Submitted Electronically to <http://erm.hhs.gov:9567/nprm/comments.cfm>
Comment Number 403275
Paper Copy by US Mail

