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REPORT

The Effect of the Proposed HIPAA Amendments on Human Subjects Research

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In response to a congressional mandate in the Health Insurance Portability and Accountability Act of 1996 (''HIPAA''), the Department of Health and Human Services (''HHS'') published a rule entitled ''Standards for Privacy of Individually Identifiable Health Information'' (the ''Final Rule'') in December 2000. The Final Rule imposes far-reaching and complex requirements on most people and institutions that treat patients, and as a result, those requirements extend to human subjects research. Broadly, the Final Rule requires a specific type of HIPAA written consent (different from an ''informed consent'' form and allowing data uses for treatment, payment and health care operations) in any research involving medical treatment of human subjects; it requires a HIPAA ''authorization'' for all research uses and disclosures of protected health information (''PHI''); and it imposes additional requirements on institutional review boards (''IRBs'') beyond what the Common Rule and Food and Drug Administration (''FDA'') regulations demand.

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One impact of these HIPAA consent and authorization requirements will be that before initiating a study, an investigator must assess the extent to which research information will be used by the researchers, as well as used by or disclosed to others outside the research team, so that subjects may authorize all of these uses and disclosures during the research consent process.

Since the publication of the Final Rule, the research community has been increasingly perplexed about the application to human subjects research of certain of the rule's aspects. [1]

In response to many comments received on research as well as other issues, HHS opened a comment period for the Final Rule at the end of February 2001.[2] After a year of evaluating solicited and unsolicited comments, HHS published a Notice of Proposed Rulemaking (''NPRM'') in the *Federal Register* on March 27, 2002 (67 Fed. Reg. 14775), announcing HHS' proposed modifications to the Final Rule. The NPRM successfully resolves many of the concerns that have been raised regarding the impact of HIPAA on human subjects research. Nevertheless, the NPRM fails to address some other problems, as described below. The purpose of this article is to identify the major areas in which the NPRM has addressed research issues; in these respects to contrast the NPRM with the provisions of the Final Rule; and to suggest some alternative amendments that could be considered by HHS in its present deliberations.

[1] Many of these aspects were highlighted in an article previously published in BNA's *Health Law Reporter*, ''The Effect of HIPAA on Human Subjects Research,'' 10 BNA *Health Law Reporter* 1026 (6/28/01, 2001).

[2] *See* 66 Fed. Reg. 12738 (Feb. 28, 2001).

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Compilation of Data Preceding Approved Research

The national research community has been alarmed that in the absence of an approved research protocol, the Final Rule does not seem to permit covered entities to compile potentially useful research data. Many institutions that conduct research maintain systems by which patient data are compiled and sorted by diagnosis, diagnosis related groups (''DRGs''), procedure codes, or other data categories. Further, many institutions archive human tissues, in order to have the tissue banks available so that future research studies might be possible; patient-specific data are attached to those tissue specimens. Generally, this practice makes research more efficient and less costly by aggregating information (or human tissue) in easy-to-use formats, thus forming ''data platforms'' from which future specific research studies may be launched. Nothing in the Final Rule, however, specifically permits these data compilation activities unless a HIPAA authorization has been gained from the patients whose data are used.

Although the Final Rule allows uses and disclosures of PHI for ''reviews preparatory to research,''[3] neither the Final Rule nor the accompanying commentary appears to contemplate the use or disclosure of PHI for such pre-research data compilation. Moreover, such database ''use'' of PHI is not permitted by a subject's HIPAA consent because it is not a use for ''treatment, payment, or health care operations.'' Although the guidance issued by HHS in July 2001 includes a question and answer section that arguably seeks to address these issues,[4] the guidance's proposed solution—the use of a ''Privacy Board,'' or the use of an IRB sitting as a Privacy Board, to waive the HIPAA authorization requirements and thus effectively approve these pre-research compilations of data—is not supported by the Final Rule itself. The Final Rule arguably allows such Privacy Board or IRB waivers only for ''research,'' i.e., only for an actual investigation designed to develop or contribute to generalizable knowledge, not for pre-research compilations of data so that the data might be used in the future for research.

The ambiguity here is that these pre-research data or tissue compilations may not be treated as ''research'' by various institutions, and hence may not have been considered and approved by an IRB. Thus, the data or tissue compilation projects themselves would arguably not meet the Common Rule's definition of ''research.'' Yet the HIPAA drafters deliberately adopted the Common Rule's definition of ''research.'' Thus, we are left, under the guidance, with the odd result that such a data compilation practice would be ''research'' for the purpose of waiving HIPAA authorization requirements, but not under the Common Rule—at least in some institutions—for IRB approval and oversight purposes. It may be that this simply points out the need for institutions to treat these data and tissue compilation projects as formal ''research,'' requiring consideration and approval under the Common Rule, and thus preventing or eliminating any such inconsistencies.

In the commentary accompanying the NPRM, HHS has indicated that one acceptable method for the creation and maintenance of these databases would be for institutions simply to gain individual authorizations from patients, presumably at the time of admission. For these purposes, HHS suggests that an acceptable termination date for the authorizations might be ''none,'' thus allowing the creation, maintenance and use of these data aggregations in perpetuity.[5] The practical difficulty here is that this system would require seeking and obtaining such an authorization from all patients, and would not allow the continued use after the compliance date (April 14, 2003) of patient data that had not been so authorized by the patients themselves.

Alternately, HHS could have proposed in the NPRM expressly to amend the Final Rule to allow for Privacy Board or IRB approval of data and tissue aggregation without patient authorizations, outside of the ''research'' context, thus recognizing the pre-research nature of these data aggregations. HHS also could have broadened the research authorization exception relating to reviews ''preparatory to research'' to include these pre-research data compilation activities. Yet, the NPRM failed to do either, thus, as set forth above, creating an incentive for institutions: (1) to view more strictly the pre-research practice of data and tissue banking in order to assure consistency between HIPAA and other research regulations, and/or (2) to develop policies and procedures by which all patients are asked routinely to authorize data bank compilations and uses with no termination date.

Subject Withdrawal of HIPAA Authorization After Conclusion of Research Project

The Final Rule generally requires that research subjects sign a HIPAA authorization to allow the investigators, the IRB, research administrators, and others to use and disclose PHI for research purposes. At the same time, the Final Rule provides that a person who has signed a HIPAA authorization has the right, with few exceptions, to withdraw that authorization at any time. Likewise, under the Common Rule and under applicable standards for the ethical conduct of research, a subject is allowed to withdraw his or her consent to participate in the research at any time and may not be compelled to continue participation in a research study.[6]

The Final Rule, however, presents a problem for human subjects research that the Common Rule and other regulations do not. Revocation of an informed consent under the Common Rule would have no practical effect once the subject's participation is no longer needed. But if a subject revokes a HIPAA authorization even after the research data have been collected (for example, after all clinical interactions with a subject have been completed during a clinical trial), the Final Rule forbids any additional use or disclosure of that subject's PHI. Thus, a subject's withdrawal of authorization could, in some circumstances, seriously affect the scientific validity of the research project in a way that a withdrawal of informed consent to participate in the study would not. This is extremely problematic for human subjects research.

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[3] 45 C.F.R. § 164.512(*i*)(1)(ii).

[4] Department of Health and Human Services, *Standards for Privacy of Individually Identifiable Health Information* (July 6, 2001), *at* http://www.hhs.gov/ocr/hipaa/finalmaster.html.

[5] *See* 67 Fed. Reg. 14796 (March 27, 2002); 67 Fed. Reg. 14813 (March 27, 2002) (proposed modification at 45 C.F.R. § 164.508(c)(v)(B)).

[6] *See* 45 C.F.R. § 46.116(a)(8).

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In the commentary accompanying the NPRM, HHS expressly declined to restrict the individual's right to revoke his or her research authorization.[7] Instead, HHS chose to broaden its interpretation of a provision in the Final Rule permitting continued use and disclosure of PHI, even after an authorization is withdrawn, to the extent that the covered entity had taken action in reliance on the now-revoked authorization.[8] Therefore, while a revocation would still prohibit a covered entity from further using or disclosing PHI for research purposes, the commentary explains that the reliance exception ''is intended to allow for certain continued uses of the information as appropriate to preserve the integrity of the research study, e.g., as necessary to account for the individual's withdrawal from the study.''[9]

This solution may be inadequate depending on how strictly courts, prosecutors, and HHS apply the ''reliance'' exception in these situations. The problem remains that a subject's withdrawal of his or her HIPAA authorization might, depending on the number of subjects in a study and the statistical significance of the findings, substantially impair the scientific integrity of research results if that subject's data may no longer be used or disclosed. Continuing to use the subject's data ''to account for the subject's withdrawal from the study'' would not vindicate all these research integrity purposes. For example, if a subject has suffered a severe adverse event during a trial and revokes her HIPAA authorization as a result, the investigator would not be able to discuss the case with his or her colleagues. The researcher in this case has not ''relied'' on the data, but scientific accuracy is compromised—and the research endeavor thwarted—if such data cannot be used in professional discussions.

Further, the commentary's suggested use of the ''reliance'' exception in these cases puts a large burden of doubt and risk on researchers, who if they continue to use data, could nevertheless be the subject of complaints from persons who have revoked authorizations but whose data have been used. The researcher would then have the burden of establishing that the continued uses were allowed under the ''reliance'' exception. This will predictably have a chilling effect on researchers' decisions about whether to continue to use these data, with researchers erring on the side of legal safety under HIPAA rather than research integrity. Indeed, the legal risk to researchers and their institutions is heightened in these circumstances, since the subject who has become so distraught or angry that she has revoked her HIPAA authorization is the likeliest of all subjects to file a compliant regarding the continued use of her data by a researcher.

A preferred solution here would be simply to allow researchers to continue to use data of subjects who have revoked their HIPAA authorizations, when their data are scientifically meaningful within the context of the study. Obviously, researchers would continue to be bound by the terms and conditions of their research approvals and could not publicly disclose subjects' PHI. Indeed, since a subject's personal privacy would continue to be preserved, and his or her PHI shared only as needed among researchers, the IRB, the sponsor, and the FDA, allowing the subject to thwart data integrity in a study to which the subject willingly agreed in the first instance amounts, some might say, to a *reductio ad absurdum* of the autonomy principle.

Duration of HIPAA Research Authorization

Under the Final Rule, a HIPAA authorization must contain a specific date or event upon which the HIPAA authorization will expire and after which additional uses and disclosures of PHI will not be allowed. It is quite difficult, however, to specify a termination date or event in the context of human subjects research. For example, in clinical research conducted to support an FDA application, the investigators, sponsors, and the FDA itself may need to revisit, re-examine, re-use, and re-disclose PHI to consider adverse events, to analyze new use applications or new proposed clinical guidelines for the drug, device, or biological agent, or to investigate charges of research misconduct. Research data should be available for these purposes indefinitely, as they are often needed after a research project has concluded and its results reported. Similarly, in nonclinical research conducted by or in a covered entity, reuse and re-disclosure of PHI might well be necessary for academic or research integrity oversight purposes long after the research project has been completed.

The NPRM attempts to assuage concerns about the expiration of authorizations by providing that the statement ''end of the research study'' or ''similar language'' is sufficient to meet this requirement.[10] The commentary further elaborates that such a statement would also be sufficient to encompass additional time after the conclusion of the research to allow for the use of the PHI ''as necessary to meet record retention requirements to which the researcher is subject.''[11]

Interestingly, the NPRM's solution to this problem was already implicit in the Final Rule, which allowed an event to satisfy the expiration requirement; it is difficult to imagine what would be a permissible termination event if ''end of the research study'' were not. As explained above, PHI must be available for use and disclosure beyond the ''end of the research study.'' But by specifying an acceptable but remote termination event for research authorizations, the NPRM commentary may imply that any significantly more distant termination event would be unacceptable. By the same token, the NPRM's express permission to use PHI to meet record retention requirements may imply that other more remote termination events limiting post-study uses or disclosures are not appropriate.

HHS could remedy this situation either by (1) explicitly allowing researchers to define the expiration event as ''the termination of the research project, or the extinguishing of the need to review, analyze, and consider the data generated by a research project, whichever is later,'' or (2) providing for a process by which an IRB or Privacy Board could accept, even on an expedited review basis, applications for additional uses and disclosures of research data after that research has terminated. Otherwise, the HIPAA regulations might unnecessarily obstruct vital post-study uses and disclosures.

[7] *See* 67 Fed. Reg. 14794 (March 27, 2002).
[8] 45 C.F.R. § 164.508(b)(5)(i).
[9] 67 Fed. Reg. 14794 (March 27, 2002).
[10] 67 Fed. Reg. 14813 (March 27, 2002) (proposed modification at 45 C.F.R. § 164.508(c)(v)(A)).
[11] 67 Fed. Reg. 14796 (March 27, 2002).

Absence of Requirements for HIPAA Authorization in 'Research Not Involving Treatment'

The Final Rule made a distinction between research involving treatment and research not involving treatment, specifically requiring a researcher to obtain a HIPAA research authorization only when research involves treatment.[12] The odd result is that the Final Rule arguably does not apply the HIPAA research authorization requirement to some of the most sensitive research information. For example, research involving extraction of blood or tissue specimens from subjects for genetic research may not involve any treatment at all, but the privacy of PHI resulting from and preceding such research may be of vital concern to research subjects.

The NPRM fills this gap by proposing a single authorization to replace the multiple kinds of authorization found in the Final Rule, including the authorization for uses and disclosures of PHI ''created for research that includes treatment of the individual.''[13] Thus the authorization required by the HIPAA regulations would apply to all types of research, whether or not treatment is involved, equalizing the privacy protections given to the two types of research. In fact, in this regard and in the transition provisions discussed later, the NPRM would essentially abandon any distinction in the HIPAA regulations between research involving treatment and research not involving treatment. This is a welcome development, as it simplifies and rationalizes the HIPAA research requirements.

Use and Disclosure of PHI for Consideration and Enrollment of Subjects into Research

Under the Final Rule, physicians and other providers acting within covered entities may not use or disclose PHI to investigators for the purpose of proposing a patient or client for a clinical trial or for other types of research projects, or to discuss with an investigator a patient's or client's suitability for a particular research study. (In fact, a strict reading of the Final Rule would not even allow the treating physician to discuss clinical trials enrollment with a patient, since the conversation itself would be an unauthorized use or disclosure of the patient's PHI.) A HIPAA consent does not enable the treating physician to engage in such conversations because the conversations are not for treatment,[14] payment, or health care operations. Thus a HIPAA authorization would be necessary for each such use or disclosure—a huge and unnecessary burden on those acting in covered entities who wish to propose patients and clients for study enrollment, and a huge burden on patients who wish to enroll in clinical studies.

The NPRM does not fully solve this problem, but it does give researchers some relief. The commentary clarifies that the Final Rule's (and the NPRM's) provisions governing IRB or Privacy Board authorization waivers were meant to encompass a partial waiver of authorization to allow researchers to receive and use PHI to recruit potential study participants.[15] But while Privacy Board approval would enable these researchers to contact potential subjects in certain circumstances, it would not extend to most treating physicians seeking to enroll (or even suggest) their patients for clinical trials.[16]

An alternative that would alleviate those difficulties would be for the regulations expressly to permit uses and disclosures for clinical trial enrollment purposes. HHS could allow treating clinicians and others in a relationship with a patient or client to make research eligibility inquiries and to have subject suitability and eligibility discussions with investigators, provided that: (1) the information disclosed is the minimum necessary to accomplish the purpose of the use and disclosure (for example, not disclosing information, such as a name, that might identify the patient); (2) the investigator with whom the discussion is held and to whom the PHI is disclosed is himself or herself subject to the HIPAA regulations as acting for or within a covered entity; and (3) the provider has discussed with the patient his or her intentions to seek clinical trial participation for the patient, and the patient has agreed with this.

A related alternative perhaps more acceptable to privacy advocates would be to allow the physician or other provider to acquire from the patient a HIPAA authorization allowing the use of the patient's PHI for seeking

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[12] *See* 45 C.F.R. § 164.508(f).

[13] § 164.508(f).

[14] Even if the intent is to enroll a patient in the clinical trial of an experimental therapy for the patient's medical condition, use or disclosure for that purpose probably does not qualify as ''treatment'' under the HIPAA regulations. ''Treatment'' usually refers to already-approved therapies. For example, the IRB Guidebook distinguishes between ''treatment'' in a clinical trial and proven therapy: ''Research itself is not therapeutic; for ill patients, research interventions may or may not be beneficial. Indeed, the purpose of evaluative research is to determine whether the test intervention is in fact therapeutic.'' Department of Health and Human Services, *IRB Guidebook, Chapter 1: Institutional Administration, at* http://ohrp.osophs.dhhs.gov/irb/irb_chapter1.htm (last visited April 2, 2002). Thus the safest practice under the Final Rule would be to consider the purpose of such a use or disclosure to be ''research,'' not ''treatment,'' thereby preventing the use or disclosure without a HIPAA authorization.

[15] 67 Fed. Reg. 14794 (March 27, 2002).

[16] The NPRM would permit uses or disclosures of PHI ''[a]s incident to a use or disclosure otherwise permitted or required by'' the HIPAA regulations. 67 Fed. Reg. 14811 (March 27, 2002) (proposed modification at 45 C.F.R. § 164.502(a)(1)(iii)). At first glance, this language suggests the possibility that any use necessary to accomplish a permitted use or disclosure under the HIPAA regulations would be permissible. The commentary, however, all but negates that possibility. The commentary defines an incidental use or disclosure as ''a secondary use or disclosure that cannot reasonably be prevented, is limited in nature, and that occurs as a by-product of an otherwise permitted use or disclosure.'' 67 Fed. Reg. 14785 (March 27, 2002). While this definition does not itself definitively exclude uses necessary to enroll patients in research studies, the commentary's examples of ''incidental'' uses and disclosures indicate that this provision was not intended to cover enrollment conversations.

For example, the commentary explains that this modification was proposed to allow ''[physicians] to talk to patients in semi-private hospital rooms or nurses to communicate with others in public areas, and [to avoid] the costs covered entities might have incurred to reconfigure facilities as necessary to ensure absolute privacy for these common treatment-related communications.'' 67 Fed. Reg. 14805 (March 27, 2002). Other such incidental uses or disclosures include coordinating services at hospital nursing stations orally, calling out a patient's name in a waiting room, using sign-in sheets in waiting rooms, and maintaining non-isolated X-ray lightboards. Although this ''incident to'' modification seems designed to allow otherwise-impermissible uses or disclosures as a ''by-product'' of (and not to arrive at) permissible uses or disclosures, it opens at least a window for argument where previously there was none.

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enrollment of the patient into clinical trials, without requiring that the HIPAA authorization specify the persons to whom the PHI would be disclosed and the exact information to be disclosed. Under this alternative, the authorization requirements of specified duration and purpose would be retained, as would the requirement for the minimum necessary disclosure. In this alternative, HHS could require that the physician disclose to the patient any remuneration received by virtue of referral of the patient into a clinical trial or other research study. This approach would allow the patient to discuss clinical trial enrollment with his or her physician, and the patient could choose whether to execute such a written authorization.

Standards for Privacy Board Consideration of Waiver or Alteration of HIPAA Authorization Requirements

One of the aspects of the Final Rule that provoked great concern has been the ambiguity of the eight criteria that a Privacy Board, or IRB sitting as a Privacy Board, must consider when addressing applications for waiver or alteration of research authorization requirements. For example, under the Final Rule, an IRB or Privacy Board must find that the use or disclosure would involve ''minimal risk to individuals,'' that it ''would not'' adversely affect the privacy rights of individuals, and that the privacy risks would be ''reasonable'' in relation to the anticipated benefits of the study.[17] But if the IRB or Privacy Board must determine that the waiver will not affect the individual's privacy rights, it is hard to see how even a ''minimal risk'' would be acceptable, or how a reasonableness test could be applied. Moreover, while the commentary to the Final Rule indicates that an IRB or Privacy Board should consider only subjects' privacy interests, those interests are inextricably interwoven with subjects' overall safety and welfare (the focus of an IRB's assessment under the Common Rule); as a result, the relationship between HIPAA's privacy considerations and the Common Rule's overall welfare considerations has remained unclear.

The NPRM simplifies the criteria that the IRB or Privacy Board must consider, by reducing the number of criteria from eight to three. The proposed requirements remaining under the NPRM are that: (1) the use or disclosure must involve ''no more than a minimal risk to the privacy of the individuals,'' (2) the research ''could not practicably be conducted without the waiver or alteration,'' and (3) the research ''could not practicably be conducted without access to and use of'' the PHI.[18] The NPRM provides more specific prerequisites for the first requirement. In assessing whether the privacy risk to the individual is ''minimal,'' the IRB or Privacy Board would be required to consider the presence of: (1) an adequate plan to protect the identifiers from improper use and disclosure; (2) an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and (3) adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research permitted by the HIPAA regulations. These indicia of ''minimal risk'' are separate and distinct criteria under the Final Rule, but in the NPRM are relegated to the status of evidence of minimal risk to the subject in the waiver of the authorization requirement. HHS promises in the NPRM commentary to furnish ''interpretations, guidance, and technical assistance'' to help the research community further understand the interaction on this point between the HIPAA regulations and the Common Rule.[19]

The modifications to the waiver criteria proposed in the NPRM are a substantial improvement over the Final Rule's waiver criteria. The NPRM would eliminate some ambiguities found in the Final Rule and make the waiver criteria under HIPAA more similar to the Common Rule's criteria for waiver of informed consent.

Standards for De-Identification of Data

''De-identified'' data are not subject to the HIPAA privacy regulations. The Final Rule's standards for de-identification of data, however, are quite demanding: a covered entity may either (1) obtain from a statistical expert a documented determination that there is a ''very small risk'' that the information could be used by others to identify the subject of the information, or (2) remove all of a list of 18 enumerated identifiers.[20] Applying these strict de-identification standards to current research practices would result in more research being done on ''individually identifiable health information'' subject to federal regulations because these standards require more to achieve de-identification than the Common Rule does.[21] This poses a particular challenge for epidemiological research, for which identifiers such as complete ZIP codes and geographic subdivisions—both included in the Final Rule safe harbor's enumerated list—are crucial.

In the commentary to the NPRM, HHS candidly admits that ''the de-identification safe harbor was not designed to be used for research purposes.''[22] While the NPRM does not propose any modifications to the de-identification standards, HHS is requesting comments on an alternative approach that would permit uses and disclosures of certain data for research purposes, so long as the data are not ''facially identifiable.''[23] Such data, according to the NPRM commentary, might include admission, discharge, and service dates; date of death; age (including age 90 or over); and five-digit ZIP codes.[24]

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[17] 45 C.F.R. § 164.512(*i*)(2)(ii).

[18] 67 Fed. Reg. 14814 (March 27, 2002) (proposed modification at 45 C.F.R. § 164.512(*i*)(2)(ii)).

[19] 67 Fed. Reg. 14794 (March 27, 2002).

[20] 45 C.F.R. § 164.514(b).

[21] First, under the Common Rule, information is exempt if it is ''publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.'' 45 C.F.R. § 46.101(b)(4). One can easily imagine information by which subjects ''cannot be identified'' as a practical matter but that does not fully satisfy the Final Rule's de-identification standards. Second, information that is recorded by the researcher in a de-identified manner but is identifiable when received by the researcher would be exempt from the Common Rule but not from the Final Rule.

[22] 67 Fed. Reg. 14794 (March 27, 2002).

[23] 67 Fed. Reg. 14799 (March 27, 2002).

[24] *Id.*

Two HIPAA Authorizations for Research

Under the Final Rule, many covered entities must obtain two authorizations to conduct clinical trials: an authorization for the use and disclosure of PHI to be created during the clinical trial (as required by 45 C.F.R. § 164.508(f)), and another for the use and disclosure of PHI already in existence at the commencement of the trial (as required by 45 C.F.R. § 164.508(d)).[25] Thus, researchers conducting a clinical trial could be required by the Final Rule to present each subject with at least five documents: two HIPAA authorizations, a HIPAA consent, an informed consent to participate in the study, and a HIPAA Notice of Privacy Practices.

The Final Rule attempts to alleviate this burden by providing that: (1) an authorization for the use and disclosure of PHI to be created during a clinical trial can be combined with the HIPAA consent, the informed consent, and the Notice of Privacy Practices,[26] and (2) authorizations may be combined with one another.[27] Unfortunately, the Final Rule took with one hand what it gave with the other, rendering these seeming accommodations not entirely sufficient.

First, under the Final Rule's general prohibition on combining authorizations, the authorization that allows use and disclosure of PHI already in existence at the commencement of a clinical trial must be kept separate from a HIPAA consent and an informed consent under the Common Rule.[28]

Second, researchers will typically want to condition the provision of any research-related treatment on the signing of an authorization so that subjects who refuse to permit (or who revoke permission for) their PHI to be used for the study will not receive the research-related treatment. The Final Rule allows this conditioning of treatment with respect to an authorization for the use and disclosure of PHI to be created during the clinical trial, but not with respect to an authorization for already-existing PHI, and hence it does not allow conditioning treatment on a document in which both authorizations are combined.[29]

Further complicating the research authorization process under the Final Rule is the absence, as described above, of a research authorization requirement for research not involving treatment. Despite this gap, most IRBs, institutions, and researchers would likely seek research authorizations from all human subjects as a ''best practice.'' It would be awkward, however, to provide subjects enrolled in research not involving any treatment with an authorization (or an informed consent form) combined with a HIPAA consent, since a HIPAA consent is really not applicable to such subjects or needed by the researchers for such studies. Thus, as a practical matter, the path of least resistance under the Final Rule would be to keep all five documents mentioned above separate—an intensely burdensome and paper-heavy requirement for researchers.

The NPRM successfully resolves these issues. First, the NPRM collapses the various types of HIPAA authorizations into one authorization form.[30] Second, the NPRM allows covered entities to condition the provision of any research-related treatment on the signing (and continued effectiveness) of this single authorization.[31] Third, this unified authorization may be combined with ''any other type of written permission for the same research study,'' such as an informed consent for the research itself.[32] Finally, one of the most fundamental overall changes proposed by the NPRM simplifies the research process in particular: under the NPRM, a HIPAA consent is never required.[33] Thus, regardless of whether research involves treatment, an informed consent form combined with a HIPAA authorization, plus a HIPAA Notice of Privacy Practices, would suffice under the NPRM to comply with the HIPAA regulations.

Privacy Boards and Unaffiliated Researchers

Each IRB currently has, or should have, policies in place delineating who may apply to the IRB for review of a research protocol. Such policies customarily require that the investigator have at least some existing relationship with the institution before its IRB will accept an application to review a proposed study. Providers in independent or group practices who do not have access to an IRB by virtue of an institutional affiliation (e.g., as attending physicians at a covered entity) must usually seek review from an independent (often for-profit) IRB, or from some other IRB that will review protocols of unaffiliated investigators. While HIPAA's effect on these arrangements is unclear, two issues are emerging.

First, each institution will need to adopt new policies with respect to who may apply to its Privacy Board (or IRB) for a waiver or alteration of the HIPAA authorization requirement. Presumably, these institutional policies will be consistent with existing institutional policies relating to investigator access to IRB review.

Second, neither the Final Rule nor the NPRM appears to contemplate the creation of independent (even for-profit) Privacy Boards. Nevertheless, in cases where an investigator does not have access to an existing IRB or Privacy Board, independent Privacy Boards will be as necessary as independent IRBs are now. Researchers must therefore proceed on the assumption that independent Privacy Boards are permissible under the HIPAA regulations, although the regulations are silent on this point. An additional complication is that Business Associate Agreements may be required for disclosure of any PHI to such an independent Privacy Board or IRB, since there will rarely be any affiliation between the researcher and the Privacy Board or IRB, and since the Privacy Board or IRB will be performing a service for or on behalf of the provider, enabling the provider to fulfill its regulatory and HIPAA obligations.

Certificates of Confidentiality

Under the Public Health Service Act, the secretary of HHS may issue a ''Certificate of Confidentiality'' that al-

[25] *See* 65 Fed. Reg. 82521 (Dec. 28, 2000).
[26] *See* 45 C.F.R. § 164.508(f)(2).
[27] *See* 45 C.F.R. § 164.508(b)(3)(iii).
[28] *See generally,* 45 C.F.R. § 164.508(b)(3).
[29] *See* 45 C.F.R. § 164.508(b)(3)(iii); 45 C.F.R. § 164.508(b)(4); 65 Fed. Reg. 82520 (Dec. 28, 2000).
[30] *See* 67 Fed. Reg. 14813 (March 27, 2002) (proposed modification at 45 C.F.R. § 164.508).
[31] *See* 67 Fed. Reg. 14812 (March 27, 2002) (proposed modification at 45 C.F.R. § 164.508(b)(4)(i)).
[32] *See* 67 Fed. Reg. 14813 (March 27, 2002) (proposed modification at 45 C.F.R. § 164.508(b)(3)(i)).
[33] 67 Fed. Reg. 14811-12 (March 27, 2002) (proposed modifications at 45 C.F.R. §§ 164.502, 164.506).

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lows a researcher to protect the privacy of research subjects by withholding subjects' identifying information from persons not connected with the study.[34] Thus, researchers who receive a Certificate of Confidentiality may not be compelled by any authority—including the HHS secretary—to reveal subjects' PHI. Both the Final Rule and the NPRM, however, require a covered entity to permit the HHS secretary to access PHI when pertinent to ascertaining compliance with HIPAA.[35] The Final Rule's commentary passes over this inconsistency by stating that ''nothing in the final rule overrides Certificates of Confidentiality.''[36] In essence, by issuing a Certificate of Confidentiality, HHS permits a covered entity to refuse to do something that HHS has itself made mandatory, without guidance on how this conflict would be handled. This could present genuine dilemmas for researchers in making representations to subjects about the circumstances under which their PHI will be disclosed. HHS should clarify this, either to indicate that Certificates of Confidentiality may still be used to bar access to subjects' PHI even when the HHS secretary requests access for HIPAA enforcement, or to establish the secretary's access for HIPAA enforcement as a clear exception to a Certificate's protection.

Transition Provisions

Compliance with the HIPAA privacy regulations—in whatever final shape they take—is required beginning on April 14, 2003 (the ''compliance date''). For research that includes treatment, the Final Rule provides that if an informed consent form signed by a subject prior to the compliance date specifically permits uses and disclosures of PHI for the clinical trial, then that ''legal permission'' will remain effective after the compliance date, and researchers will be allowed to use and disclose the research PHI until the permission is revoked.[37] For research that does not include treatment, however, an informed consent obtained before the compliance date would only be valid under the Final Rule with respect to PHI obtained before the compliance date.[38] The Final Rule's transition provisions do not address research studies begun before the compliance date in which no informed consent or other legal permission was sought—e.g., for epidemiological or outcomes research involving only chart reviews—thus leaving open the possibility that such research would have to be halted on the compliance date, unless waiver of authorization is granted by a Privacy Board.

Under the NPRM, however, researchers would be permitted to use or disclose PHI created or received either before or after the compliance date as long as an informed consent was obtained before the compliance date.[39] The NPRM thus puts all research on the same footing, whether or not the research involves ''treatment.'' Moreover, the NPRM's transition provisions eliminate the distinction between research conducted with patients' informed consent and research conducted with an IRB-approved waiver of informed consent: the NPRM will allow continued use and disclosure of PHI also in cases in which the IRB has waived informed consent, as long as an IRB has done this in accordance with the Common Rule.[40]

Conclusion

HHS is soliciting public comment on the NPRM until April 26, 2002—30 days from the date (March 27, 2002) the NPRM was published in the *Federal Register*. HHS has informally stated its intention to have the comments reviewed, and the changes finalized, before September 2002. Not until then will institutions, IRBs, and researchers know how or whether the issues highlighted here will be resolved.

In the meantime, investigators and institutions that conduct research and IRBs should re-evaluate their privacy and informed consent practices and their HIPAA compliance plans in light of the NPRM. Investigators and institutions also should examine the impact of the HIPAA privacy regulations on their operations in order to submit meaningful comments to HHS during this comment period. Although HHS has attempted with NPRM and in its accompanying commentary to address various research-related concerns, there remain various ambiguities and compliance difficulties, as described above. Particularly troubling are areas in which the HIPAA privacy regulations appear to pose problems for research, but HHS has tried to assuage these concerns by assuring that the regulations will not be enforced literally. This is troubling because such assurances in no way bind future courts, prosecutors, or even HHS officials, and are a shaky foundation on which to rest a comprehensive HIPAA compliance program.

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[34] 42 U.S.C. 241(d).

[35] *See* 45 C.F.R. § 160.310(c)(1); 67 Fed. Reg. 14811 (March 27, 2002) (showing no change from the Final Rule).

[36] 65 Fed. Reg. 82656 (Dec. 28, 2000).

[37] 45 C.F.R. § 164.532(b)(3).

[38] *See id.*

[39] *See* 67 Fed. Reg. 14815 (March 27, 2002) (proposed modifications at 45 C.F.R. §§ 164.532).

[40] *See id.*