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REPORT

Clinical Research After the August 2002 Privacy Rule Amendments

BY MARK BARNES AND CLINTON HERMES

On Aug. 14, 2002, the federal Department of Health and Human Services (''HHS'') made changes to the privacy regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 (''HIPAA''), with many of those changes directly affecting the conduct of clinical research. As HIPAA required, HHS previously had published privacy regulations entitled, ''Standards for Privacy of Individually Identifiable Health Information'' (the ''Initial Rule'') on Dec. 28, 2000. The Initial Rule essentially federalized what had been a varied patchwork of state laws regulating the privacy of medical information. The Initial Rule, which regulates most hospitals and physicians' offices and thus the human subjects research that is conducted there, required a specific type of consent before protected health information (''PHI'') could be used or disclosed for treatment, payment, or health care operations purposes; it required a specific type of authorization (different from the consent) before PHI could be used for most other purposes, including research; and it contained many additional requirements specific to human subjects research. An article previously published in BNA's *Health Law Reporter*, ''The Effect of HIPAA on Human Subjects Research,''[1] discussed the impact of the Initial Rule on the research community and highlighted many problems associated with conducting research under the Initial Rule.

In response to a flood of comments received on research and other issues, HHS published a Notice of Proposed Rulemaking (the ''NPRM'') in the *Federal Register* on March 27, 2002, announcing proposed modifications to the Initial Rule. The NPRM addressed many of the concerns raised with respect to the Initial Rule, but some significant problems remained unresolved. An article published in BNA's *Medical Research Law & Policy Report*, ''The Effect of the Proposed HIPAA Amendments on Human Subjects Research,''[2] discussed these concerns.

HHS solicited public comment on the NPRM for a period of 30 days from its March 27, 2002, publication date. In response to those comments, on Aug. 14, 2002, HHS officially amended the Initial Rule (the ''Final Rule''). The purpose of this article is to assess the impact of the Final Rule on the research community and to identify resolved, remaining, and new questions and concerns relating to HIPAA's effect on clinical research.

Subject Withdrawal of HIPAA Authorization after Conclusion of a Research Project.

Absent waiver by an Institutional Review Board (''IRB'') or a ''Privacy Board'' sitting as an IRB, researchers generally must obtain a HIPAA authorization to use or disclose PHI for research purposes. Subjects have the right, with certain exceptions, to revoke these authorizations at any time and thereby prevent further use and disclosure of their health information.[3] Doing so during a study effectively would end a subject's participation in the study.

While the Common Rule and Food and Drug Administration (''FDA'') regulations likewise permit subjects to revoke their consent to participate in a study and

[1] 10 BNA HEALTH L. REP. 1026 (6/28/01).

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[2] 1 BNA MED. RES. L. & POL'Y REP. 81 (4/17/02).

[3] *See* 45 C.F.R. § 164.508(b)(5).

thereby withdraw from the study,[4] subjects typically have incentives—for example, payment for participation, research-related treatment, altruistic desire to assist medical science, etc.—to remain in a study for its duration. Moreover, under the Common Rule and FDA regulations, revocation of consent to participate in a study after the clinical portion of a study has concluded would have no practical effect, as in such cases, researchers would typically continue to use the patient's data for study analysis. The Initial Rule, however, allowed subjects to revoke their HIPAA authorizations at any time, including *after* the clinical portion of a study had been completed and the subjects no longer had any incentive (aside from an altruistic desire to further human knowledge) to permit the continued use and disclosure of their PHI; such a revocation would render the research information collected from such a patient unusable, thus negatively affecting the scientific validity of the remaining data.

While the Initial Rule permitted covered entities to continue to use or disclose data under a revoked authorization to the extent that the covered entity had ''taken action in reliance thereon,''[5] this reliance exception was interpreted extremely narrowly in the commentary to the Initial Rule.[6] In response to researchers' concerns, the commentary to the NPRM expanded that interpretation, explaining that this 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.''[7]

Without changing the actual text of the regulations, HHS now has further expanded its interpretation of the reliance exception in the commentary to the Final Rule. According to the Aug. 14, 2002, commentary, this exception ''would permit the continued use and disclosure of protected health information to account for a subject's withdrawal from the research study, as necessary to incorporate the information as part of a marketing application submitted to the FDA, to conduct investigations of scientific misconduct, or to report adverse events.''[8] While the commentary gives these uses and disclosures as examples of preserving the ''integrity of the study,'' these examples arguably exceed the more narrow scientific integrity purposes suggested in the NPRM. Furthermore, one commenter requested clarification that the reliance exception did not permit covered entities to ''continue analyzing data once an individual has revoked his or her authorization,'' but HHS flatly disagreed.[9] The commentary notes, however, that the reliance exception would not allow a covered entity ''to continue disclosing additional protected health information to a researcher or to use for its own research purposes information not already gathered at the time an individual withdraws his or her authorization.''[10]

In short, it seems that most uses and disclosures of PHI already gathered when an authorization was revoked are now permissible for research purposes, in the view of HHS. Furthermore, while the scope of this exception should have been explicitly reflected in the text of the regulations, the ambiguity of the ''in reliance'' language (which, standing alone, is almost devoid of content in the absence of HHS interpretation), coupled with the commentary's examples, should provide some comfort for researchers and drug and device company research sponsors.

Compilation of Data Preceding Approved Research.

Many institutions that conduct research and treat significant numbers of patients with diseases of research interest maintain systems by which clinical data or tissue samples are archived to create data platforms for use in future research studies. These activities likely do not constitute the ''reviews preparatory to research'' allowed by the Initial Rule, and are not conducted for the purposes of treatment, payment, or health care operations; therefore, they would not be permitted under the Initial Rule without patient authorization. Although the guidance issued by HHS in July 2001 proposed the use of a Privacy Board or an IRB to waive the HIPAA authorization requirements and approve these data compilations,[11] the Initial Rule itself allowed such waivers only for actual investigations meeting the Initial Rule's definition of ''research.''[12] As we have argued, however, these pre-research data compilations may not constitute actual research and thus may not be eligible for an IRB or Privacy Board waiver of the authorization requirement.

In the commentary to the Final Rule, HHS responds to this concern (which was voiced in public comments received) by stating that the Office for Human Research Protections (''OHRP'') ''has interpreted the definition of 'research' to include the development of a repository or database for future research purposes.''[13] HHS interprets the HIPAA definition of research ''to be consistent with what is considered research under the Common Rule'' and concludes that, as a result, ''the development of research repositories and databases for future research are [sic] considered research'' for HIPAA purposes.[14]

In support of its position that these activities are considered by OHRP to be ''research,'' HHS cites the OHRP guidance documents available at http://ohrp.osophs.dhhs.gov/humansubjects/guidance/reposit.htm.[15] These guidance documents do not, however, seem directly responsive to the concern raised in the public comments. While the comments to HHS focused on a ''pre-research practice'' undertaken in the

[4] *See* 45 C.F.R. § 46.116(a)(8); 21 C.F.R. § 50.25(a)(8).
[5] 45 C.F.R. § 164.508(b)(5)(i).
[6] *See* 65 Fed. Reg. 82462, 82659 (Dec. 28, 2000) (''We intend for covered entities to refrain from further using or disclosing protected health information to the maximum extent possible once an authorization is revoked . . . . If the covered entity has not yet used or disclosed the protected health information, it must refrain from doing so, pursuant to the revocation.'')
[7] 67 Fed. Reg. 14776, 14794 (Mar. 27, 2002).
[8] 67 Fed. Reg. 53182, 53225 (Aug. 14, 2002).
[9] *Id.* at 53226.
[10] *Id.* at 53225.
[11] Department of Health and Human Services, *Standards for Privacy of Individually Identifiable Health Information* (July 6, 2001), *available at* http://www.hhs.gov/ocr/hipaa/finalmaster.html.
[12] 45 C.F.R. § 164.512(i)(1).
[13] 67 Fed. Reg. at 53231.
[14] *Id.*
[15] *Id.*

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absence of ''an actual research protocol,''[16] the guidance documents cited by HHS refer either to prospective tissue collection activities conducted under a protocol or to the submission of specimens to a central registry, or begin with the assumption that the activities in question ''include nonexempt human subjects research.''[17] Thus, while it is true that OHRP has interpreted the creation of a central database under a protocol or for the purpose of conducting or facilitating a *particular study* to be ''research'' under the Common Rule, it is unclear whether the internal aggregation of patient data in a particular format to make future research more efficient, but without any particular research use in mind, necessarily would be considered ''research'' under the Common Rule. Institutional policies will differ on this matter, and the analysis depends in part on whether the institution normally stores clinical data in an electronic format that can be queried and sorted at will (in which case the initial storage likely will not constitute research but may be described as operations) or whether the clinical data will be recorded for data platform purposes in a manner different and separate from how medical records typically are recorded, processed, and stored.

It is true, of course, that the HIPAA definition of research is the same as the Common Rule definition of research. Thus, for a particular data compilation, the HIPAA result nearly always will be the same as the Common Rule result,[18] depending on the primary purpose of the compilation and whether the compilation involves any prospective data collection: either the activity will not constitute research; or it will constitute research for which informed consent and HIPAA authorization can be waived; or subjects will be required to give their informed consent and to execute a HIPAA authorization before their PHI can be used for these purposes. Moreover, actual access to PHI in the database or tissue bank for research purposes will be ''research'' under both the Common Rule and HIPAA, and thus will require IRB (and/or Privacy Board) oversight under both regulatory regimes. Because the Common Rule and HIPAA results will be the same and because HHS has adopted a broad interpretation of what constitutes research for HIPAA purposes, however, the Final Rule may have a secondary effect on research by expanding the reach of IRB review under the Common Rule to include more of these pre-research data compilation activities. If an activity does not constitute ''research'' even under this broader view, it likely will be permissible under HIPAA as routine data storage or ''health care operations.''

One should note also that even if a HIPAA authorization is secured from the subjects in order to create a database, that authorization would not be sufficient to permit future research using that database because, according to HHS, the subjects would ''lack necessary information to make an informed decision'' regarding the unspecified future research at the time of giving the authorization.[19] Presumably, therefore, future uses would require either specific new HIPAA authorizations or IRB/Privacy Board waivers.

Duration of a HIPAA Research Authorization.

Under the Initial Rule, a HIPAA authorization was required to include a specific date or event upon which it would expire and after which additional uses and disclosures of PHI would not be allowed. The difficulty of selecting such a date or event in the context of research was described in our earlier articles. In the NPRM, HHS proposed to permit the statement ''end of the research study'' or ''similar language'' to meet this requirement for research authorizations,[20] but still failed to address researchers' and research sponsors' need to access the information for regulatory filings or for scientific integrity purposes well after conclusion of the study and publication of the results. The Final Rule alleviates this problem by permitting HIPAA research authorizations to state that they have no expiration date, thus continuing in effect until and unless revoked by the research subject.[21]

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

The Initial Rule required a researcher to obtain a special HIPAA authorization for research involving treatment, but it did not explicitly require a research authorization when the research involved no treatment.[22] This left many of the most sensitive types of research—for example, DNA studies on blood samples—arguably unprotected by HIPAA's research authorization rules. Moreover, the distinction between research involving ''treatment'' and research not involving treatment often is difficult to make and has been rejected by the weight of legal authority.

The Final Rule establishes a single authorization for all research, whether or not the research includes treatment, and thus nearly eliminates HIPAA's distinction between the two types of research.[23] Indeed, HHS commented that retaining the distinction ''would require overly subjective decisions without providing commensurate privacy protections.''[24] Note, however, that the distinction remains in an exception to an individual's right of access to his or her PHI; such access may be suspended only ''in the course of research that includes treatment,'' so long as the subject has agreed and certain other steps have been taken.[25] Thus, while the Fi-

[16] *Id.*

[17] Office for Human Research Protections, *at* http://ohrp.osophs.dhhs.gov/humansubjects/guidance/reposit.htm.

[18] The result conceivably could differ if the research were ''exempt'' research under the Common Rule but still ''research'' for HIPAA purposes. For example, the research could constitute ''research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens [where] the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects,'' and thus be exempt from the Common Rule under 45 C.F.R. § 46.101(b)(4). Nevertheless, the data still could be ''identified'' for HIPAA purposes and therefore still be subject to IRB or Privacy Board waiver review. In such cases, institutions should treat these compilations as ''research,'' thereby requiring consideration and approval under the Common Rule and preventing such inconsistencies.

[19] 67 Fed. Reg. at 53226.

[20] 67 Fed. Reg. at 14813.

[21] *See* 67 Fed. Reg. at 53269 (to be codified at 45 C.F.R. § 164.508(c)(1)(v)).

[22] *See* 45 C.F.R. § 164.508(f).

[23] *See* 67 Fed. Reg. at 53268-70 (to be codified at 45 C.F.R. § 164.508).

[24] 67 Fed. Reg. at 53225.

[25] 45 C.F.R. § 164.524(a)(2)(iii).

nal Rule secures the scientific validity of placebo-controlled clinical trials, this distinction remains problematic for mental health and psychology researchers, whose research often does not include treatment but whose experimental design may include withholding PHI from research subjects for study purposes.[26]

Use and Disclosure of PHI for Consideration and Enrollment of Subjects Into Research.

Under the Initial Rule, covered entities could neither use PHI nor disclose PHI to investigators or to other third parties for the purpose of proposing a patient or client for a research project, or discussing a patient's or client's suitability for a particular research project with any third party. The Initial Rule arguably would not have even allowed a physician to discuss clinical trial enrollment with his or her *own patient*, since doing so could constitute an unauthorized use of the patient's PHI. Because such conversations are not for treatment,[27] payment, or health care operations, a patient's HIPAA authorization would have been required.

The commentary to the Final Rule directly addresses subject recruitment. HHS correctly points out that ''research recruitment is neither a marketing nor a health care operations activity.''[28] The commentary then goes on to explain that a covered entity may disclose PHI to the individual who is the subject of that PHI, thereby permitting covered providers to discuss with their own patients ''the option of enrolling in a clinical trial without patient authorization, and without an IRB or Privacy Board waiver of patient authorization.''[29] However, HHS explains, covered providers may not disclose PHI to a *third party* ''for purposes of recruitment in a research study'' without an authorization or a waiver of authorization.[30]

While the commentary does not directly address whether treating physicians may disclose their patients' PHI to other workforce members within a single covered entity (for example, to other employees of the same hospital, which would be a ''use'' and not a ''disclosure'' under HIPAA) for purposes of recommending patients for clinical trials, such a use is not directly supported by the regulations and would be inconsistent with prevailing pre-HIPAA privacy practices for research recruitment. Moreover, while HIPAA permits researchers to access PHI for ''reviews preparatory to research,''[31] recruitment activities cannot be considered ''preparatory'' for HIPAA purposes because subject recruitment does not begin until a protocol already is in place and the endeavor is well beyond the ''preparatory'' stage. Finally, in the commentary to the Final Rule, HHS rejected the notion of a blanket authorization for recruitment purposes because, as with authorizations for future unspecified research, the authorization ''would not provide individuals with sufficient information to make an informed choice about whether to sign the authorization.''[32]

De-Identification of Data and the Limited Data Set.

HIPAA does not regulate ''de-identified'' data, but the Initial Rule's standards for de-identification were difficult to meet. Under the Final Rule as well, data are de-identified only if a statistical expert determines that there is a ''very small risk'' that the information could be used by others to identify the subject of the information, or if the data are stripped of all of a list of 18 enumerated identifiers.[33] These identifiers include ZIP codes and geographic subdivisions that epidemiologists and other researchers depend upon and that currently do not trigger Common Rule review.

In the commentary to the NPRM, HHS requested comments on an alternative approach that would permit uses and disclosures of certain data for research purposes, so long as the data were not ''facially identifiable.''[34] HHS has responded to comments from the research community by amending the Final Rule to allow the use and disclosure for research purposes of a ''limited data set'' if the covered entity enters into a ''data use agreement'' with the recipient.[35] A limited data set need only exclude certain ''direct identifiers,'' including names, addresses (other than city, state, and ZIP code), telephone numbers, and electronic mail addresses.[36] In general, the data use agreement must limit the recipient's uses and disclosures to research, public health, or health care operations purposes, and must require the recipient to: use appropriate safeguards to prevent use or disclosure of the information other than as permitted by the data use agreement; report to the covered entity any unauthorized uses or disclosures of the information of which it becomes aware; not ''identify the information'' or contact the individuals; and ensure that the recipient's agents agree to the same restrictions.[37] The prohibition on ''identifying the information,'' while not explained in the commentary, likely means simply that the covered entity may not reassociate any of the ''direct identifiers'' with any of the information in the limited data set.

The Minimum Necessary Standard.

Generally, when using or disclosing PHI or when requesting PHI from another party, a covered entity must attempt to limit its use, disclosure, or request to the minimum necessary amount of PHI to accomplish the intended purpose of the use, disclosure, or request. Under the Initial Rule, this ''minimum necessary standard'' did not apply to uses or disclosures ''pursuant to an au-

[26] For example, a study may proceed on the hypothesis that a particular gene sequence makes a person more likely to become an alcoholic, and study events include a blood draw (for the genetic test) and yearly follow-up questionnaires on drinking habits. Researchers may not wish to disclose to subjects whether they possess the particular gene sequence because such information could confound the researchers' observations; if a subject learns that she has the gene sequence, for instance, she may be more likely to abstain from drinking or otherwise alter her behavior.

[27] As argued in ''The Effect of the Proposed HIPAA Amendments on Human Subjects Research,'' 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 should not be considered ''treatment.''

[28] 67 Fed. Reg. at 53230.

[29] 67 Fed. Reg. at 53230-31.

[30] 67 Fed. Reg. at 53231.

[31] 45 C.F.R. § 164.512(i)(1)(ii).

[32] 67 Fed. Reg. at 53231.

[33] 45 C.F.R. § 164.514(b).

[34] 67 Fed. Reg. at 14799.

[35] 67 Fed. Reg. at 53270-71 (to be codified at 45 C.F.R. § 164.514(e)).

[36] *Id.*

[37] *Id.*

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thorization . . . , except for authorizations requested by the covered entity . . . .''[38] Thus, if a covered entity were to initiate the signing of the research authorization (which virtually always would be the case in the research context), the Initial Rule applied the minimum necessary standard to that request and all subsequent uses and disclosures under the authorization so gained.

This presented a problem for researchers, who are required to describe in their research authorizations which PHI the researchers are requesting to use and disclose. It often is difficult to know which medical information will be useful for research purposes and which will not, but that is precisely what the minimum necessary standard required researchers to know. Thus, under the Initial Rule, researchers could find themselves in an impossible dilemma: either request the subject's entire research and medical record and risk running afoul of the minimum necessary standard, or attempt a narrower description and risk having an authorization that fails to include all PHI needed for the study.

The Final Rule alleviates this problem by making the minimum necessary standard inapplicable to ''uses or disclosures made pursuant to an authorization under § 164.508.''[39] By eliminating the distinction between authorizations requested by the covered entity and authorizations requested by the individual or another party, the Final Rule allows researchers to request an authorization to use and disclose the subject's entire research and medical record without hesitation. Although disclosures made pursuant to an IRB or Privacy Board waiver of the authorization requirements are still subject to the minimum necessary standard, the covered entity is entitled to rely on an IRB's or Privacy Board's determination that a disclosure meets the minimum necessary standard.[40] Note, however, that the continued application of the minimum necessary standard in these circumstances places an additional analytical burden on IRBs and Privacy Boards in their considering and approving waivers.

Accounting for Disclosures.

The Initial Rule gave individuals the right to receive an accounting of disclosures of PHI made by a covered entity in the six years prior to the date on which the accounting was requested.[41] This right did not apply to disclosures made to carry out treatment, payment, or health care operations, and was not required for disclosures made before the covered entity's compliance date.[42] Because research is not considered to be treatment, payment, or health care operations, however, the Initial Rule required covered entities to account for every disclosure of PHI made for research purposes by providing the date of disclosure, the name and address of the recipient, a description of the PHI disclosed, and certain other information.

The research community complained that this accounting requirement would be very difficult to satisfy in the context of research disclosures. In response, the NPRM proposed to waive the requirement for disclosures made pursuant to a HIPAA authorization.[43] The NPRM still would have required covered entities to account for disclosures of PHI for reviews preparatory to research or pursuant to an IRB or Privacy Board waiver of the authorization requirement—for example, disclosures for retrospective chart reviews or database studies—and thereby would have imposed tremendous costs on covered entities permitting access to PHI for these purposes.

In the commentary to the Final Rule, HHS recognized that the Initial Rule's accounting requirements presented an ''administrative obstacle for research'' and ''could have the undesired effect of causing covered entities to halt disclosures of protected health information for research.''[44] Thus, the Final Rule not only waives the accounting requirement for disclosures made pursuant to an authorization, as the NPRM had proposed, but it also permits covered entities to satisfy their accounting obligations for research purposes in a simplified fashion where the disclosures were made *without* a HIPAA authorization.[45] Specifically, if the disclosure involves at least 50 individuals' records, then in lieu of the detailed accounting required by the Initial Rule, covered entities may provide individuals with a list of all protocols for which the individual's PHI may have been disclosed without a HIPAA authorization.[46] The accounting also must include the purpose of the study, the criteria used for selecting particular records, the type of PHI disclosed, and the time frame of the disclosures in response to the request (including the date of the last such disclosure during the accounting period).[47] Finally, if requested by the individual, the covered entity must provide assistance in contacting any sponsor or researcher to whom it is ''reasonably likely'' that the individual's PHI was disclosed.[48]

Note that disclosures of PHI in limited data sets need not be included in any accounting of disclosures.[49] HHS concluded that the burden of such an accounting ''is not warranted, given that the data may not be used in any way to gain knowledge about a specific individual or to take action in relation to that individual.''[50]

Proposed Amendments Adopted by Final Rule.

The Final Rule adopted without change several of the proposals made in the NPRM, including:

- *The Standards for Privacy Board Consideration of Waiver or Alteration of HIPAA Authorization Requirements*. Many researchers and IRBs had found alarming the ambiguity associated with the eight criteria that an IRB or Privacy Board was required by the Initial Rule to consider when assessing applications for waiver or alteration of the research authorization requirements. The Final Rule eliminates two of these criteria and relegates three others to mere indicia of minimal privacy risk, as

[38] 45 C.F.R. § 164.502(b)(2)(ii).
[39] 67 Fed. Reg. at 53267 (to be codified at 45 C.F.R. § 164.502(b)(2)(iii)).
[40] *See* 45 C.F.R. § 164.514(d)(3)(iii)(D).
[41] *See* 45 C.F.R. § 164.528.
[42] *See* 45 C.F.R. § 164.528(a)(1).
[43] 67 Fed. Reg. at 14801.
[44] 67 Fed. Reg. at 53245.
[45] *See* 67 Fed. Reg. at 53272 (to be codified at 45 C.F.R. § 164.528).
[46] *See* 67 Fed. Reg. at 53272 (to be codified at 45 C.F.R. § 164.528(b)(4)).
[47] *See id.*
[48] *Id.*
[49] *See* 67 Fed. Reg. at 53272 (to be codified at 45 C.F.R. § 164.528(a)(1)(viii)).
[50] 67 Fed. Reg. at 53237.

the NPRM had proposed.[51] Note that HHS also has promised to issue guidance documents on interpreting the waiver criteria.[52]

- *Two HIPAA Authorizations for Research*. We have described in our earlier article the Initial Rule's requirement of two authorizations to conduct most clinical trials, which, in connection with other provisions in the Initial Rule regarding authorizations, added unneeded layers of complexity to the subject enrollment process from both the subject's and the researcher's points of view. The Final Rule largely solves this problem by eliminating the consent requirement and by combining the different types of authorizations into a single, simpler form.[53] Of particular interest to researchers, the research authorization need no longer specify whether the use or disclosure would result in ''direct or indirect remuneration to the covered entity from a third party''; HHS believed that the ''complexity of such arrangements'' in the research context made such a specification difficult.[54]

- *Transition Provisions*. The Initial Rule adopted differential treatment in the transition provisions between research including treatment and research not including treatment; the former, if begun before the regulations' April 14, 2003, compliance date (the ''Compliance Date''), effectively was grandfathered into compliance by the Initial Rule, and the latter was not. The Final Rule adopts the NPRM's solution of grandfathering in *all* research—whether or not it includes treatment and whether or not it is conducted under an IRB-approved waiver of informed consent—begun before the Compliance Date.[55] Under the Final Rule, therefore, a waiver of informed consent gained before April 14, 2003, will operate to waive informed consent and HIPAA authorization requirements. Similarly, informed consents gained prior to the Compliance Date generally will be effective for HIPAA authorization purposes after the Compliance Date. Nevertheless, studies approved before April 14, 2003, and enrolling subjects before that date will need to gain both an informed consent and a HIPAA authorization for all subjects enrolled on April 14, 2003, and thereafter.

[51] *See* 67 Fed. Reg. at 53270 (to be codified at 45 C.F.R. § 164.512(i)(2)(ii)).
[52] *See* 67 Fed. Reg. at 53230.
[53] *See* 67 Fed. Reg. at 53268-70 (to be codified at 45 C.F.R. § 164.508).
[54] 67 Fed. Reg. at 53220.
[55] *See* 67 Fed. Reg. at 53272 (to be codified at 45 C.F.R. § 164.532(c)).

Issues Unaddressed by Final Rule.

The Final Rule failed to address, and the commentary failed to mention, other problems or outstanding issues associated with the Initial Rule, including:

- *Certificates of Confidentiality*. The Initial Rule required a covered entity to permit the secretary of HHS to access PHI when necessary to ascertain compliance with HIPAA and did not provide an exception for research records protected by a Certificate of Confidentiality.[56] This conflict remains in the Final Rule.
- *Privacy Boards and Unaffiliated Researchers*. While the Initial Rule and the Final Rule both contemplate the establishment of Privacy Boards, they say nothing about how Privacy Board governance will map onto the existing IRB system. For example, Privacy Boards presumably will need policies and procedures (as will their related institution) with respect to who can access and appear before the institutions' affiliated Privacy Boards, but there is no guidance on what their content and form should be. In addition, independent and for-profit Privacy Boards, though not specifically contemplated by either the Initial Rule or the Final Rule, likely will be necessary to evaluate HIPAA waiver applications from researchers not affiliated with any institution and/or those researchers who now use for-profit IRBs to review their studies.

Conclusion.

It is the stated goal of HHS that ''[p]atient privacy . . . be balanced against other public goods, such as research.''[57] With that as a benchmark, the Final Rule is a notable improvement over the Initial Rule. Still, questions remain, and researchers and IRBs will have a great deal of work ahead of them to come into compliance by April 14, 2003. Even research sponsors and contract research organizations, which generally will not be covered directly by the Final Rule, nonetheless will be affected by the Final Rule; if the sites conducting research for them fail to obtain appropriate authorization forms, for example, sponsors may be denied access to the data they need. Thus, while covered entities must push forward in developing internal policies, procedures, and forms necessary for compliance, sponsors must work with the research community and should amend their clinical trial agreement and sponsored research agreement templates to ensure that clinical research is not thwarted by a failure to comply with HIPAA's true ''Final Privacy Rule.''

[56] *See* 45 C.F.R. § 160.310(c)(1).
[57] *See* 67 Fed. Reg. at 53226.

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