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Proposed U.S. HITECH Act Data Privacy And Security Rules: How Would They Impact Pharmaceutical Companies?

By Nancy L. Perkins, of Arnold & Porter LLP, Washington.

In a move meriting attention by the pharmaceutical industry, the Department of Health and Human Services ("HHS") recently issued a notice of proposed rulemaking ("Proposal")[1] to implement certain of the health information privacy and security requirements of the Health Information Technology for Economic and Clinical Health ("HITECH") Act (*see report at WDPR, July 2010, page 22; analysis at page 4 of this issue*).[2] If adopted, the Proposal's modifications would amend portions of the data privacy and security regulations promulgated by HHS pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") — generally referred to as the HIPAA Privacy and Security Rules.[3]

Although pharmaceutical companies are rarely governed by those regulations because they do not meet the definition of a HIPAA "covered entity,"[4] the Proposal nevertheless has important implications for pharmaceutical company operations, particularly in the areas of marketing and research.

In the Proposal, HHS has described plans to implement new HITECH restrictions on marketing of health care products and services, and also suggested certain Privacy Rule changes, unrelated to the HITECH Act, that would help facilitate certain types of research. HHS has specifically requested comment from the public on these and other aspects of the Proposal, and privacy advocates and others will be weighing in with HHS on how it should handle these issues in its forthcoming final rule. Members of the pharmaceutical industry should also consider filing comments with HHS, to ensure that the agency understands relevant facts and can properly take the industry's interests into account in promulgating the final rule. All comments must be filed by September 13, 2010.

Background

The HIPAA Privacy Rule and Security Rule collectively serve to protect the privacy and security of individually identifiable health information — defined by HHS as "protected health information" ("PHI"). The Privacy Rule's overarching framework is a general prohibition on the use or disclosure of an individual's PHI without a written authorization from the individual that includes specific disclosures about the individual's privacy rights (a "HIPAA authorization"). There are several exceptions to the general authorization requirement, including for PHI uses and disclosures for purposes of treatment, payment, and "health care operations" (certain activities undertaken by health care providers and health plans as part of their daily health-related functions).

The use of PHI for marketing and for research purposes, however, almost always requires a HIPAA authorization. The parameters and objectives of "marketing" and "research," and various special concerns relating

to these activities, were key issues for HHS in formulating the Privacy Rule and have continued to raise questions since the Rule was adopted. The Proposal's suggested modifications in these areas have both positive and negative implications for pharmaceutical companies, as they would constrain certain marketing activities, while relaxing restrictions on particular types of research.

Marketing

Under the Privacy Rule, "marketing" means making a "communication about a product or service that encourages the recipient of the communication to purchase or use the product or service."[5] The Privacy Rule excepts from that definition, however, communications to the purpose of: 1) describing a health-related product or service that is provided by, or included in a plan of benefits of, the covered entity; 2) providing treatment to the recipient; or 3) case management or care coordination, or directing or recommending alternative treatments, therapies, health care providers, or settings of care.[6] Prior to the relevant effective date of the HITECH Act (January 18, 2010), these exceptions applied *even if the covered entity was paid by a third party to make the communication.*

The HITECH Act altered this legal framework, however, by prohibiting a covered entity from using PHI to make any of the three above-described types of communications without a HIPAA authorization if the covered entity is paid — directly or indirectly — to make the communication. The only statutory exception to this new prohibition is for a communication that "describes only a drug or biologic that is currently being prescribed for the recipient of the communication," *if* the payment for making the communication is "reasonable in amount." Essentially, this means that a covered entity can accept payment for marketing purposes only to provide refill reminders — and then only for payment up to a "reasonable amount." It is up to HHS to define what constitutes a "reasonable amount."

The Proposal includes provisions to implement these HITECH Act mandates by broadening the Privacy Rule's definition of "marketing," while creating a new, narrow exception from the definition for communications that are made:

> To provide refill reminders or otherwise communicate about a drug or biologic that is currently being prescribed for the individual, only if any financial remuneration received by the covered entity in exchange for making the communication is reasonably related to the covered entity's cost of making the communication.[7]

Thus, HHS is proposing to define "reasonable amount" in this context as an amount "reasonably related to the covered entity's cost of making the communication." HHS is seeking comments on this definition, noting that:

> [W]e considered proposing a requirement that a covered entity could only receive financial remuneration for making such a communication to the extent it did not exceed the *actual cost* to make the communication. However, we were concerned that such a requirement would impose the additional burden of calculating the costs of making each communication. Instead, we propose to allow costs that are *reasonably related* to the covered entity's cost of making the communication. We request comment on the types and amount of costs that should be allowed under this provision.[8]

In addition, HHS has specifically requested comment on the key question of whether a "drug or biologic that is currently being prescribed for the individual" must be a *particular* drug or may include generic alternatives. As stated in the Proposal, HHS wants input on "whether communications about drugs that are related to the drug currently being prescribed, such as communications regarding generic alternatives or new formulations of the drug, should fall within the exception."[9] This invitation suggests that HHS recognizes that it may be just as appropriate to provide reminders to patients of their prescription needs "generically" as to remind them of the particular drugs they have previously been prescribed to fulfill those needs.

Although the HITECH Act itself exempts only refill reminders from the new prohibition on using or disclosing PHI for remunerated treatment-related communications, the Proposal states that, in HHS's view, Congress did not intend to obstruct providers from making other meaningful treatment recommendations to their patients about specific products or services. Instead, HHS believes Congress sought to curtail only those remunerated treatment communications that are "motivated more by commercial gain or other commercial purpose . . . than for the purpose of [an] individual's health care . . . ."[10] In accordance with this understanding, HHS is not proposing to require health care providers to obtain HIPAA authorizations from their patients whenever remuneration is received from a third party in exchange for sending the patient treatment communications about health-related products or services. Instead, HHS is proposing to require health care providers to 1) include in their "notices of privacy practices" (which must be given to all patients pursuant to the Privacy Rule) a statement that the provider intends to send such subsidized treatment communications; 2) disclose, in each such subsidized communication, the fact that the communication is being made in exchange for financial remuneration; and 3) provide in each such communication a "clear and conspicuous" statement that the recipient has the opportunity to elect not to receive any further such communications.

The Proposal emphasizes that the latter "opt-out" opportunity must be designed to ensure that an individual who chooses to opt out will not thereby incur an undue burden or more than a nominal cost. For example, if a covered entity required individuals to send a letter to the covered entity in order to opt out, HHS would consider that to be unduly burdensome. Accordingly, HHS suggests that providers give patients a toll-free phone number or an e-mail address to use to opt out, or find other ways to make opting out simple, quick and inexpensive.

Regarding the effect of an individual's opt out, HHS is seeking comment on whether an individual's opt out should be deemed to prevent *all* future subsidized treatment communications from the provider or, instead,

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prevent future communications about only the *particular product or service* described in the current communication. This is an important question, and how it is resolved could significantly affect pharmaceutical marketing. HHS also is soliciting comment on whether there should and could be a way to enable patients to opt out before receiving *any* subsidized treatment communication — *i.e.,* some way to afford individuals an opportunity to opt out prior to the receipt of even one such communication.

Pharmaceutical companies that have an interest in subsidizing communications by health care providers to patients about particular products or services may want to air their views on these issues in comments to HHS. For example, pharmaceutical companies may want to address the benefits of provider communications to patients describing new drug formulations, the costs to providers of sending such communications, and the additional costs to providers of providing the proposed opt-out notice. An understanding by HHS of these benefits and costs may help ensure that the final rule will preserve health care providers' continued willingness to send sponsored communications that promote particular products or services to individual patients.

Research

The HITECH Act did not specifically address the Privacy Rule's provisions relating to research. However, HHS is taking the opportunity of rulemaking pursuant to the Act to propose certain research-related modifications to the Privacy Rule based on input it has received since the Rule was adopted. In particular, HHS is suggesting changes to the Privacy Rule's requirements for the content and format of authorizations for the use and disclosure of PHI for research purposes. As HHS has been informed, certain of these requirements have created unintended obstacles to research, particularly clinical trial research coupled with other activities such as tissue banking for future research.

Compound Authorizations

One aspect of the Privacy Rule that HHS proposes to change in this area is the Rule's limitation on the use of "compound" authorizations — *i.e.,* the combining of an authorization for the use and disclosure of PHI with some other legal permission. Currently, the Privacy Rule generally prohibits compound authorizations, but permits a HIPAA authorization for purposes of a clinical trial to be combined with the informed consent to participate in the trial, subject to certain limitations. In addition, although the Privacy Rule generally prohibits covered entities from conditioning treatment (as well as health benefits coverage) on the provision of a HIPAA authorization, it permits a covered entity to condition the provision of *clinical trial treatment* on obtaining such an authorization. As HHS has recognized, "[p]ermitting the use of protected health information is part of the decision to receive care through a clinical trial."[11]

However, the Privacy Rule does not permit a treatment-conditioned HIPAA authorization for clinical research purposes to be combined with any authorization for a separate purpose that, under the Rule, may not be so conditioned. As the Proposal explains, this limitation was intended to help ensure that individuals understand that they may decline the activity described in the unconditioned authorization yet still receive the clinical trial treatment by agreeing to the conditioned authorization.

In practice, however, this limitation has proven problematic. For example, many researchers seek to combine clinical trials with a corollary research activity, such as the creation or contribution of trial data (including identifiable specimens) to a central research database or repository. Under the current Privacy Rule, separate authorizations must be obtained for the use and disclosure of PHI for 1) the clinical trial (assuming the treatment provided in the trial is contingent on obtaining a HIPAA authorization) and 2) the collection of tissue or other specimens. Various groups, including researchers and professional organizations, have informed HHS that this may be hampering recruitment into clinical trials.[12] As these groups have explained, some clinical research trials call for thousands of participants, and documenting and storing multiple authorizations for each patient is a substantial burden and imposes considerable additional costs. In addition, multiple forms may be confusing for trial enrollees. For example, redundant information provided by two authorization forms (one for the clinical study and another for related research) could distract an individual from focusing on key statements describing how and why his or her PHI may be used.

To address these problems, HHS is proposing to allow a covered entity to combine "conditioned" and "unconditioned" authorizations for research, provided that the authorization *clearly differentiates* between the conditioned and unconditioned research components and *clearly allows the individual the option to opt in* to the unconditioned research activities. Thus, under the proposed rule modifications, a covered entity could combine a HIPAA authorization for clinical trial purposes, upon which treatment is conditioned, with an authorization for specimen collection, upon which treatment is not conditioned, so long as the "clarity" requirement is met.

HHS has suggested several ways in which covered entities could design such compound research authorizations to ensure they provide the requisite level of clarity. For example, a compound authorization could describe the unconditioned research activity on a separate page. Alternatively, the authorization could provide a separate check-box for the unconditioned research activity to signify whether an individual has opted in to the unconditioned research activity, while maintaining a single signature line for the entire authorization. Or, there could be a separate signature line for the unconditioned authorization, which would highlight for individuals that they are being solicited for additional, optional research that, whether authorized by them or not, will not affect their ability to receive research-related treatment. HHS is soliciting ideas for other ways to ensure that a compound clinical research authorization clearly differentiates the conditioned from the unconditioned research activities involved in a particular study.

Authorizing Future Research Use or Disclosure

HHS also is considering — but has not actually proposed — amendments to the Privacy Rule's requirement that a HIPAA authorization for purposes of research identify *specifically* the nature and scope of the research involved.[13] As noted, researchers often seek to combine clinical trials with corollary research activities, such as the creation of a research database or repository where individually identifiable specimens obtained from a research participant during the trial are transferred and maintained for future research. The scope and nature of future research, however, are not always known at the time such specimen collection occurs and, thus, the Privacy Rule's requirement that a research authorization be "study-specific" has proven problematic. As the Proposal notes, the requirement often encumbers secondary research because it means participants in a clinical trial often have to be re-contacted to sign multiple authorization forms at different points in time. Not only is this cumbersome — indeed, in some cases, impossible — but it also appears inconsistent with current practice under the "Common Rule," which allows a researcher to seek subjects' consent to future research so long as the future research uses are described in sufficient detail to allow an informed consent.[14]

To address these problems, HHS is considering whether to modify the Privacy Rule's "study-specific" authorization requirement. The Proposal suggests several ways in which this might be done:

1. The Privacy Rule could permit a HIPAA authorization for future research purposes to the extent such purposes are adequately described in the authorization, such that it would be reasonable for the individual to expect that his or her PHI could be used or disclosed for such future research;

2. The Privacy Rule could permit a HIPAA authorization for future research only to the extent the description of the future research included certain specified elements or statements; or

3. The Privacy Rule could permit option 1. as a general rule, but require certain disclosure statements on the authorization in cases where the future research may encompass certain types of sensitive research activities, such as research involving genetic analyses or mental health research, that might alter an individual's willingness to participate in the research.[15]

HHS is seeking comment on each of these options, including their impact on the conduct of research and patient understanding of authorizations. In addition, noting that none of these suggested changes would affect an individual's right to revoke the authorization at any time (which right is guaranteed under the Privacy Rule) and that all HIPAA authorizations must include a description of how the individual may exercise this right, HHS has invited comment on how a revocation would operate with respect to future downstream research studies.

Although HHS has not actually proposed specific changes to the Privacy Rule addressing the "study-specific" requirement, it plans to take any comments it receives on the issue into consideration and to coordinate with the HHS Office for Human Research Protections, as well as the Food and Drug Administration ("FDA"), to ensure that any Privacy Rule modifications in this area are appropriately harmonized with the policies under the HHS human subjects protections regulations[16] and FDA's human subjects protections regulations governing informed consent for research.[17]

Conclusion

As indicated, the Proposal contains significant provisions relevant to the pharmaceutical industry that could affect the design and success of future marketing initiatives and research studies for many years to come. Members of the industry that intend to engage in these activities should seriously consider voicing their opinions, and informing HHS of pertinent facts, in comments on the Proposal.

NOTES

[1] Modifications to the HIPAA Privacy, Security, and Enforcement Rules Under the Health Information Technology for Economic and Clinical Health Act; Proposed Rule, 75 Fed. Reg. 40,868 (July 14, 2010) (to be codified at 45 C.F.R. pts. 160 & 164).

[2] Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, enacted on February 17, 2009.

[3] Standards for Privacy of Individually Identifiable Health Information, 45 C.F.R. Part 160 and Part 164, Subparts A and E; Standards for Security of Electronic Protected Health Information, 45 C.F.R. Part 160 and Part 164, Subpart C.

[4] There are three types of HIPAA "covered entities": 1) health plans, 2) health care clearinghouses, and 3) health care providers who perform certain transactions involving health information in electronic form. Pharmaceutical companies very rarely are any of these types of entities (although the employee health plans sponsored by pharmaceutical companies are HIPAA covered entities).

[5] 45 C.F.R. § 164.501.

[6] *Id.*

[7] 75 Fed. Reg. at 40,918 (proposed amendment to 45 C.F.R. § 164.501).

[8] *Id.*

[9] *Id.* at 40,885.

[10] *Id.* at 40,884.

[11] *Id.* at 40,892.

[12] *See id.* at 40,892-93 (citing HHS's Advisory Committee for Human Research Protections in 2004 (Recommendation V, in a letter to the Secretary of HHS, available at http://www.hhs.gov/ohrp/sachrp/hipaalettertosecy090104.html; Institute of Medicine, "Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research" (2009) (Recommendation II.B.2).

[13] The Proposal explains that HHS has considered this requirement a proper interpretation of the Privacy Rule's mandate that a HIPAA authorization include a "description of each purpose of the requested use or disclosure" in order to enable individuals to make a fully informed decision whether to sign the authorization. *See* 75 Fed. Reg. at 40,893 (citing 67 Fed. Reg. 53,182, 53,226 (August 14, 2002).

[14] *See* 45 C.F.R. §§ 46.116-46.117.

[15] 75 Fed. Reg. at 40,894.

[16] 45 C.F.R. pt. 46.

[17] 21 C.F.R. pt. 50.

Nancy L. Perkins is Counsel in the Washington office of Arnold & Porter LLP. She may be contacted at nancy.perkins@aporter.com.

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