Revised HIPAA Privacy Rule:
Implications For Research and Marketing

By Nancy L. Perkins

As of March 26, 2013, a set of new requirements and restrictions govern the use and disclosure of "protected health information" (PHI) under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the 2009 Health Information Technology for Economic and Clinical Health ("HITECH") Act [1]. The new provisions, which were published as a final rule by the Department of Health and Human Services (HHS) on January 25, 2013 (the "Final Rule"),[2] impose multiple burdens on HIPAA "covered entities" (health plans, health care "clearinghouses," and health care providers who perform certain transactions involving health information in electronic form) and their "business associates."[3] But they also affect many entities that regularly deal with PHI, including pharmaceutical and medical device companies, irrespective of those entities' status as covered entities or business associates.[4]

Compliance with most of the new provisions is required by September 23, 2013, and covered entities and business associates will be adjusting their operations and activities accordingly. Pharmaceutical and medical device companies will benefit from an awareness of how the new provisions may affect their current and future programs and plans, particularly in two areas: research and marketing.

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Background

Under the privacy regulations implementing HIPAA (the "Privacy Rule"),[5] covered entities and business associates generally may not use or disclose an individual's PHI without the individual's written authorization. Such authorizations must conform to specific requirements and contain specific statements. In addition, an authorization for the use/disclosure of PHI generally may not be combined with

any other authorization, so that an individual's choice regarding the use/disclosure of his her PHI may be made independently or other choices.

With limited exceptions, uses and disclosures of PHI for either research or marketing require HIPAA authorizations. In the Final Rule, HHS altered the parameters of those exceptions in significant ways. Overall, those changes provides new flexibility for research, and should be welcome news to the pharmaceutical and medical device industry. On the marketing side, however, the Final Rule narrows the options for communicating with individuals, without first obtaining their written authorization, to inform them about particular healthcare products or services.

Research

The Final Rule impacts research in three principal contexts: (1) where PHI is purchased for purposes of research; (2) where two types of research will involve use of the same PHI; and (3) where PHI is desired for future research not yet specifically defined.

Purchasing PHI for Research

One of Congress' key concerns in enacting the HITECH Act was the extent to which health care providers and plans could be paid to disclose PHI. To address that concern, the HITECH Act generally prohibits covered entities from receiving remuneration in exchange for an individual's PHI unless the individual has provided a written authorization that expressly acknowledges the remuneration.[6] As interpreted by HHS, this prohibition applies not only to sales of PHI, but also to any remunerated license, lease, or provision of access to PHI.[7] It also applies where the remuneration is in the form of in-kind benefits, not just financial payments.[8] However, HHS does not consider payments in the form of research grants to be "remuneration" for purposes of the prohibition, because PHI disclosed under such grants "is a byproduct of the service being provided."[9] Thus, a research sponsor may pay a covered entity to conduct a research study without regard to the "remunerated disclosure" restriction, even if the covered entity provides the sponsor with research findings that include PHI, so long as the disclosure of PHI occurs during the course of the study.

If a research sponsor seeks to pay a covered entity to provide PHI for research purposes, but not to conduct the research, the "remunerated disclosure" restriction will apply, unless the amount of the payment is limited to a "reasonable cost-based fee to cover the cost to prepare and transmit the [PHI] for such purposes."[10] Such costs may include direct and indirect costs, such as "labor, materials, and supplies for generating, storing, retrieving, and transmitting" the PHI and ensuring the PHI is disclosed in a permissible manner; as well as "related capital and overhead costs."[11] However, any amount that would constitute a profit to the covered entity for disclosing the PHI may not be included. HHS intends to work with the research community to facilitate a common understanding of what constitutes an appropriate cost-based fee in this context.

Compound Authorizations

As noted, the Privacy Rule generally prohibits combining an authorization for the use or disclosure of PHI with another type of legal permission (i.e., using a "compound authorization").[12] There is an exception to this general rule with respect to informed consents to participate in research, where use of an individual's PHI is integral to the research.[13] However, HHS traditionally took the position that, if researchers want to use the PHI both for purposes of research involving treatment of the individual and for other, non-treatment research, two separate authorizations must be obtained for each research activity.

This separate authorization requirement stemmed from the principle that treatment of an individual may not be conditioned upon the individual's willingness to authorize the use or disclosure of his/her PHI for unrelated purposes.[14] In the context of clinical trials, that principle is not applicable, because the receipt of treatment in a clinical trial is voluntarily elected by the individual, and the clinical trial necessarily entails the use of PHI. Thus, a covered "health care provider may condition the provision of research-related treatment on provision of an authorization for the use or disclosure of [PHI] for such research..."[15] But where the same PHI will be used for both treatment-related research and other research, HHS wanted separate authorizations to help ensure that individuals understand that they could decline to allow their PHI to be used for the non-treatment related research while still receiving the clinical trial treatment by providing the conditioned authorization.[16]

Over the course of the past decade, HHS learned that its separate authorization requirement was impeding certain research. Researchers complained that requiring separate forms for corollary research activities is inconsistent with current informed consent practice under the "Common Rule" governing human research subject protections,[17] and creates unnecessary

documentation burdens.[18] There were also indications that research subjects found the separate authorization forms confusing and might be deterred by them from participating in a clinical trial. This affected researchers' ability to recruit clinical trial subjects whose PHI obtained during the trial could be placed in a databank for analysis not directly related to the trial.

HHS responded to these concerns by relaxing the requirement for separate "treatment-conditioned" and "unconditioned" authorizations for research purposes. The Final Rule permits such authorizations to be combined, so long as the compound authorization (i) clearly differentiates between the conditioned research and the unconditioned research; and (ii) clearly enables the individual to decline the use and disclosure of his or her PHI for the unconditioned research activities while agreeing to such use and disclosure for the conditioned research. The single authorisation must be designed so that the individual's consent to allow the unconditioned research is an affirmative *opt-in* consent; it is not permissible to use a combined authorization that only allows the individual the option to *opt out* of the unconditioned research activities (*e.g.*, "check here if you do *not* want your PHI provided to a databank").

The Final Rule provides for some flexibility in designing a compound research authorization for this purpose. For example, a compound authorization for use and disclosure of PHI for a clinical trial involving treatment as well as for use of the PHI for creating a databank could provide:

- A check-box for the individual to have the choice to opt in to the databank component, with just one signature line for the whole authorization;
- Two signature lines, one for consent to use of the PHI for the clinical trial and another for consent to the databank component; and
- A check-box to opt in to the databank component, with just one signature line, but with detailed information about the databank component presented in a separate brochure or information sheet that is incorporated by reference into the authorization form (even if not physically attached to the form).[19]

In addition, because an individual must be adequately informed of his/her right to revoke a HIPAA authorization at any time, a compound research authorization of this type must make clear how the individual can revoke the authorization for one activity (e.g., the databanking component) without affecting the authorization for the other activity. If a compound authorization fails to do that, an individual's revocation of it must be deemed to apply to the *entire* authorization. Only if the individual provides written clarification that states explicitly that the revocation applies only to a portion of the compound authorization may any other portion be considered to remain valid.[20]

Future Research

In issuing the Final Rule, HHS also relaxed another requirement it had imposed under the Privacy Rule: that an authorization for the use or disclosure of PHI for research purposes be "study-specific."[21] This requirement—i.e., that the authorization describe the specific research for which the PHI will be used and/or disclosed—has proven problematic for researchers who seek to use clinical trials as an opportunity to collect PHI, such as individual blood or tissue samples, for placement in a databank to preserve for later use in future research. In these instances, the scope and nature of future research is not always known at the time data collection occurs. Thus, HHS's view that a research authorization must be "study-specific" has frequently precluded the use of previously collected samples, as it may be very difficult to re-contact clinical trial participants to obtain their authorization for use of the samples in later research by the time the parameters of such later research have been determined.

HHS has now revised its position on this point. Under the Final Rule, an authorization for the disclosure and use of PHI for future "unspecified" research may be valid, so long as the authorization is sufficiently descriptive 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.[22] For example, an authorization might state that "your medical records may be used in future research on the causes and treatment of diabetes and related conditions." This aligns the Privacy Rule with the general understanding for informed consents under the Common Rule.

Marketing

As noted, marketing is another activity for which the use or disclosure of PHI by a HIPPA covered entity or business associate generally requires an individual authorization. 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."[23] A HIPAA-covered entity may not use PHI to make any such communication without an authorization, unless the communication (i) is made during a face-to-face encounter

with an individual; or (ii) consists of a promotional gift of nominal value provided by the covered entity.[24]

As promulgated in 2002, the Privacy Rule excluded from the term "marketing" communications made for three particular purposes, *even if the covered entity was paid by a third party to make a communication*. Those purposes were: (i) describing a health-related product or service that is provided by, or included in a plan of benefits of, the covered entity; (ii) providing treatment to the individual; or (iii) for case management or care coordination for the individual, or directing or recommending alternative treatments, therapies, health care providers, or settings of care to the individual.[25] In the HITECH Act, Congress overrode this exclusion in part, by prohibiting a covered entity from using PHI to make any of the three above-described types of communications without an individual authorization if the covered entity is paid to make the communication.[26] Congress provided only one exception to this new prohibition, allowing covered entities to be paid a "reasonable" fee to make a communication that "describes only a drug or biologic that is currently being prescribed for the recipient of the communication."[27] In other words, a covered entity may accept payment for marketing purposes only to provide refill reminders—and then only for payment up to a "reasonable amount."

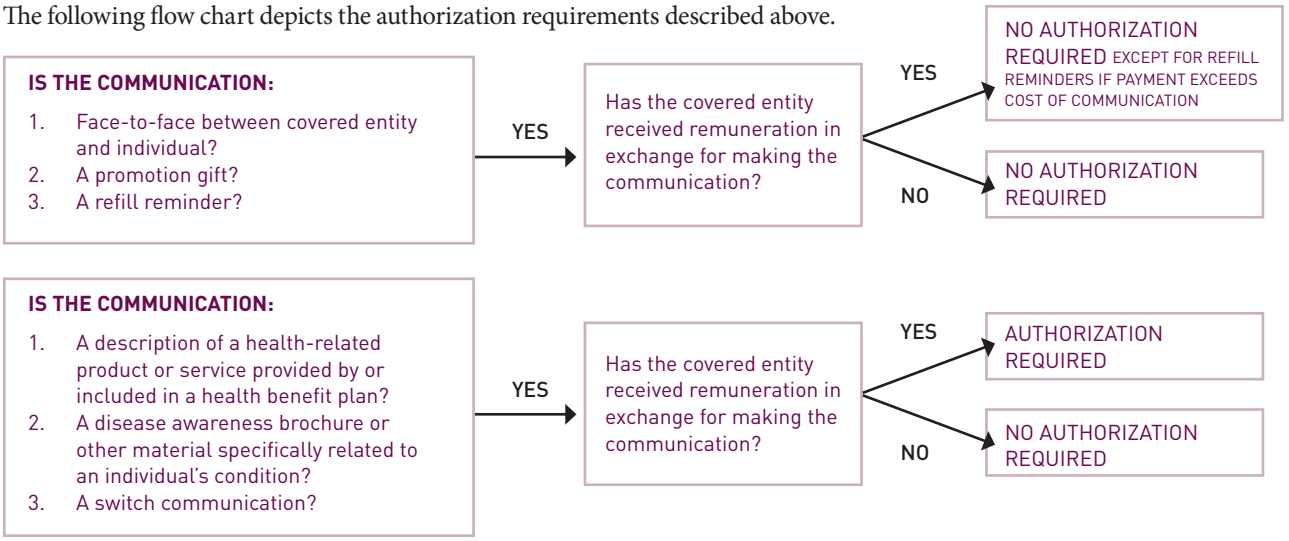
Although the HITECH Act is ambiguous as to what might be deemed a "drug or biologic that is currently being prescribed" for an individual, in issuing the Final Rule, HHS clarified that it interprets the phrase to include generic equivalents of a specifically named branded drug, not just that branded drug, and also, with respect to self-administered drugs or biologics, all aspects of a drug delivery system (*e.g.*, insulin pumps).[28] HHS also indicated that it intends to provide future guidance to answer questions about what the phrase might cover.

With respect to the condition that, to rely on the refill reminder exception, a covered entity may receive only a fee "reasonable" in amount, the Final Rule states that "any financial remuneration received by the covered entity in exchange for making the communication [must be] *reasonably related* to the covered entity's cost of making such a communication."[29] According to HHS, costs that are "reasonably related" to making such a communication are those which cover only the covered entity's costs of labor, supplies, and postage to make the communication.[30] HHS considers any remuneration a covered entity receives as a profit, or that otherwise creates an incentive to make the communication, not to be "reasonably related" to the covered entity's cost for making the communication.[31] For example, if a pharmaceutical manufacturer paid a pharmacy an amount sufficient to cover only the pharmacy's cost of drafting, printing, and mailing refill reminders, no authorization would be required, but if the manufacturer provided the pharmacy an additional amount to encourage the pharmacy's continued willingness to send such communications, authorizations would be required.

In issuing the Final Rule, HHS also clarified that:

- The term "financial remuneration" does not include non-financial benefits, such as in-kind benefits, provided to a covered entity in exchange for making a communication about a product or service.[32] For example, a pharmaceutical or medical device company could provide a set of written materials to a covered

The following flow chart depicts the authorization requirements described above.



entity to facilitate communications about the company's products, so long as there is no financial payment for actually sending the communications.

- The financial remuneration a covered entity receives from a third party will trigger the authorization requirement only if the remuneration is provided in exchange for the covered entity making a communication that encourages individuals to purchase or use *the third party's* product or service.[33] Thus, a covered entity could be remunerated to communicate with patients about its *own* services, even if those services may involve the use of the third party's products, so long as the communication does not specifically promote the third party's products.

Conclusion

For the pharmaceutical and medical device industries, the Final Rule both knocks down certain barriers (on the research side) and erects others (on the marketing side). In both contexts, subtle elements may determine whether certain programs and activities are permissible under the Final Rule. Careful examination of all options, in consultation with legal counsel, may make a significant difference in the extent to which a desired outcome involving PHI can be achieved.

1. "PHI" in this context includes, with very limited exceptions, any information relating to an individual's health that is created or received by a health care provider, health plan, employer, or "health care clearinghouse" and either identifies or reasonably could be used to identify the individual. 45 C.F.R. § 160.103.
2. Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules; Final Rule, 78 Fed. Reg. 5566 (January 25, 2013).
3. A HIPAA "business associate" is a person (individual or entity) who, other than as a member of the workforce of a particular covered entity, performs healthcare functions "on behalf of such covered entity," or provides legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, or financial services for the covered entity, in circumstances requiring access to PHI. 45 C.F.R. § 160.103.
4. Medical device companies that bill insurers for their products and services generally meet the health care provider definition of a "covered entity;" pharmaceutical companies very rarely are "covered entities." (The employee health plans sponsored by any of these companies, however, are HIPAA covered entities).
5. Standards for Privacy of Individually Identifiable Health Information, 45 C.F.R. Part 160 and Part 164, Subparts A and E.
6. 42 U.S.C. § 17935(d).
7. 78 Fed. Reg. at 5606.
8. *Id.* at 5607.
9. *Id.* at 5606.
10. *Id.* at 5697 (to be codified at 45 C.F.R. § 164.502(a)(5)(ii)(B)(*2*)(*ii*)).
11. *Id.* at 5607.
12. This limitation was intended to prevent covered entities from coercing individuals into signing an authorization for a use or disclosure that is not necessary to carry out the services that the covered entity provides to the individual. See *id.* at 5609.
13. 45 C.F.R. § 164.508(b)(3)(i).
14. Other than in the clinical research context, the Privacy Rule requires that a HIPAA authorization expressly state that the provision of treatment or health care benefits to an individual may not be conditioned on the individual's signing of the authorization. *Id.* § 164.508(c)(2)(ii)(A).

15. *Id.* § 164.508(b)(4)(i).
16. *See* 78 Fed. Reg. at 5609.
17. 45 C.F.R. Part 46, Subpart A.
18. 78 Fed. Reg. at 5609.
19. *Id.* at 5611. With respect to the latter option, if the brochure or information sheet includes required elements of the authorization (or informed consent), then the brochure or information sheet must be made available to potential research participants before they are asked to sign the consent/authorization document (unless the authorization document itself includes the required elements). *Id.*
20. *Id.*
21. *See* Standards for Privacy of Individually Identifiable Health Information; Final Rule, 67 Fed. Reg. 53182, 53226 (Aug. 14, 2002).
22. *See* 78 Fed. Reg. at 5612-13.
23. 45 C.F.R. § 164.501.
24. *Id.* § 164.508(a)(3)(i).
25. *See* 78 Fed. Reg. at 5592.
26. 42 U.S.C. § 17936(a)(2).
27. *Id.* § 17936(a)(2)(A).
28. 78 Fed. Reg. at 5596.
29. *Id.* at 5696 (to be codified at 45 C.F.R. § 164.501) (emphasis added).
30. *Id.* at 5597.
31. *Id.*
32. *Id.* at 5596.
33. *Id.*