e-health law perspectives
"Disease Management and Formulary Compliance Programs Under the HIPAA Privacy Rule."

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A. The HIPAA Privacy Rule Framework Applied

Much cutting edge care integration is currently taking place in the disease management industry. Disease management is seen by many as helping to bridge the mini Berlin Walls that categorize many of the health systems clinical activities. Disease management organizations are frequently using HIPAA protected health information ("PHI") to match interventions, including pharmaceutical interventions, to appropriate cases. The HIPAA privacy rule that became effective on April 14th (and will be enforced in 2003) does not, however, give a "blank check" to such programs.

The HIPAA privacy rule governs how covered entities, notable health plans (HMOs, other health insurers and ERISA plans) can use or disclose PHI (patient identifiable health and health payment information). It also dictates how entities providing services to providers or plan (their so-called "business associates") may use or disclose the PHI acquired from the covered entities.

Generally the rule allows customary or mainstream activities conducted by providers or health plans to take place under the authority of a general consent -- the ***Section 506 consent.*** Providers will seek such consents from their patients at the time of treatment (or confirm that one has previously been executed). Health plans may acquire such a consent at the time of enrollment (or otherwise) but they are not forced to get the paper executed -- the rule gives them credit for it.

The privacy rule allows protected health information ("PHI") to be used or disclosed for programs that might be deemed to be disease management programs when conducted directly or indirectly by covered entities on the strength of this consent (actual or implied). However, the rule does not categorically bless such programs.

- **First**, the rule requires that the program fit within the scope of the "treatment" or "healthcare operations" which the Section 506 consent has allowed.
- **Second**, it requires that the use or disclosure of PHI pass through a screen as to whether it is ***marketing*** or not.
- **Third**, if the program constitutes marketing, it must take one of the forms the rule provides.

- **Fourth** if the use or disclosure of PHI which is deemed marketing does not fit one of the acceptable forms, the provider or health plan using or disclosing the data must turn to the patient or enrollee for a Section 508 authorization.

  It is important to note the implications of the fourth step. The final privacy rule is strongly biased against releases of PHI in instances where a Section 508 authorization would be required. The cost of securing such releases and the onerous nature of the content suggests that most activity which require such authorizations will be discontinued over time. Thus, the compliance task facing most organizations conducting disease management is to do so under the authority of the Section 506 consent because the program does not have a marketing component or, if it does, to fit it into one of the marketing forms that does not require a Section 508 authorization.

  Aside from the issue of whether a disease management program can access data under the rule, there is also an issue as to the scope of the access. Access in the treatment context is, for providers, unfettered as to application of the minimum necessary requirement. However, disease management organizations seeking records from a provider, as the business associate of a health plan, would not enjoy that latitude if obtaining those records in either the treatment or health care operations context.

B. DISEASE MANAGEMENT AND DRUG COMPLIANCE AS "TREATMENT"

The final rule is not stingy as to what constitutes "treatment." "Treatment" includes "the coordination or management of health care." However, it only includes such coordination or management when it is done by a health care provider or "by a health care provider with a third party." Thus, where it is not marketing, use and disclosure of PHI in the context of the disease management conducted by providers may take place without a Section 508 authorization. Moreover, disclosures to disease management vendors, acting for a provider, would also not require patient authorization. However, release to third parties not acting with a provider is not as clearly facilitated.

The preamble suggests that "outreach programs" (a non-judgmental term for many disease management techniques?) can be either treatment or health care operations, depending first on whether their target is a population or an individual patient and second, even if individual patient targeted, whether it is an activity performed on behalf of a health plan or on behalf of a provider. Thus, the preamble reserves the "treatment" label to those outreach activities that are both focused on an individual and undertaken on behalf of a provider. This is frustrating to disease management organizations which acknowledge their client to be the health plan but see their activities as being more individualized than the "health care operations" label supports.

Disease management organizations are thus caught between a rock and a hard place. For sound reasons they have traditionally not seen themselves as providers. Professional liability and state prohibitions on the corporate practice of medicine are among the reasons to continue to avoid that label. On the other, they would like the unfettered access to PHI which providers receive in the context of treatment. Moreover, they believe that their outreach to patients on behalf of health plans is at least supportive of the treatment of those persons and less administrative than the activities characterizing health care operations.

Prescription drug compliance programs face similar issues. The Preamble make clear that a pharmacy's furnishing a patient with customized prescription drug information about the risks, benefits and conditions of use of an agent would be considered treatment. Disclosures could also be made to third parties acting for the provider in this regard.

However, many compliance programs are undertaken by third parties acting not at the behest of a provider but as a business associate of a health plan. These third parties face the same issues as the disease management organizations. The Preamble said that DHHS could not "state a general rule regarding whether such activities constitute treatment." Thus, disclosures for such purposes have issues today that did not exist prior to April of this year.

C. Disease Management as "Health Care Operations"

The use and disclosure of PHI for "health care operations" is richly defined. While "treatment" is captured in a paragraph, "health care operations" accounts for nearly a column and a half of text in the final rule. Within this vast array are several phrases which capture many disease management functions at least where such functions are "population based":

- activities related to improving health ;
- activities related to reducing health costs;
- protocol development;
- case management;
- care coordination;
- contacting providers and patients about treatment alternatives; and
- related functions that do not include treatment.

Many of these examples were apparently added to the final rule in the context of eliminating the term disease management from the definition of treatment and eschewing the utility of the term "disease management" in both the "treatment" and "healthcare operations" contexts. The industry may, however, find the DHHS response constraining insofar as the thrust is "population based" activity and "treatment" is specifically disclaimed. Many of the programs for which PHI is sought address specific populations but provide monitoring and other functions that may cross the Rubicon into treatment.

D. The "Marketing" Caveat

Disease management, pharmacy compliance and other programs also struggle against the constraint of the final rule's limitations on marketing. If the PHI is used for a communication "a purpose of which" is to encourage the recipients to purchase or use the product or service, then the marketing rules must be complied with.

Those rules give the covered entity or the third party "marketer" two choices. First, the covered entity or its agent could get the patient or enrollees approval for the release/use of the PHI in the form of a Section 508 authorization. Second, they could conform the "marketing" communication to the methods available under Section 514 of the rule.

Section 514 permits marketing to take place without the onerous Section 508 authorization if the covered entity uses or discloses the PHI in a face-to-face encounter with the individual. Section 514 also permits PHI to be used or disclosed for the marketing of products or services of nominal value.

If the services or products are not of nominal value or the marketing is not going to take place in a face-to-face encounter, the covered entity (or its business associate making the communication for it) must make the communication in a manner that identifies the covered entity as the party communicating, discloses direct or indirect remuneration for the communication and, in most instances, offer an opt-out from further communications.

If the covered entity is using or disclosing PHI to target the communication based on health status or condition, that communication must also explain to the individual why he/she has been targeted and how the service or product relates to the health of the individual.

The preamble left open the debate as to whether educational materials provided to enrollees are marketing or not. The use or disclosure of PHI to provide educational materials to patients may be "treatment" or "operations" "depending on the circumstances and who is sending the material." More importantly, the Preamble says that DHHS cannot "in the abstract" determine whether such activities constitute marketing under this rule."

E. Where does this leave us?

PHI can still be used and disclosed for disease management or other compliance purposes without a special Section 508 authorization if the covered entity makes that disclosure (or uses it) for treatment or health care operations purposes. Thus, many compliance programs will be reexamined to bring them within the ambit of a covered entity's treatment or health care operations purposes. At the same time, the covered entity or any third party acting on a covered entity's behalf will want to make sure that, if the compliance program has a marketing aspect to it, that a Section 508 consent is obtained or, preferably, the communication makes the disclosures dictated by Section 514.

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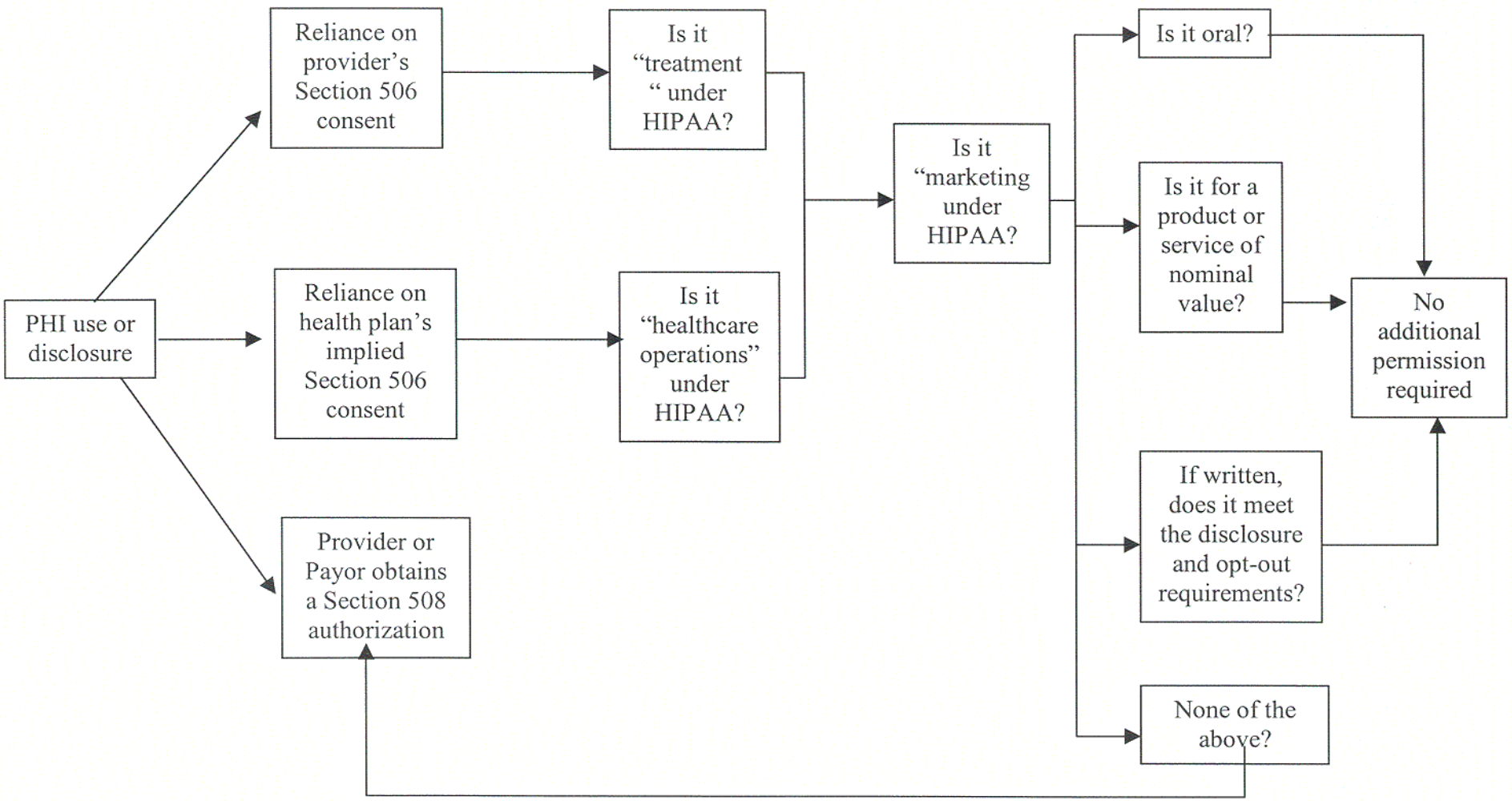
Compliance Programs & Disease Management HIPAA Options



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