

HOGAN & HARTSON HEALTH LAW ADVISORY

January 16, 2001

HIPAA STANDARDS FOR USE OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION FOR MARKETING AND FUNDRAISING

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) authorized the Secretary of Health and Human Services to promulgate rules governing the use of individually identifiable health information in certain transactions if Congress failed to enact legislation in this area by August 1999. Congress missed this deadline, and on December 28, 2001, the Department of Health and Human Services ("HHS") published in the Federal Register its final rule establishing standards for protecting the privacy of individually identifiable health information.

In general, the rule requires covered health care providers to obtain patient consent before using or disclosing the protected health information of any individual for treatment, payment or certain "health care operations." Health care providers that do not have a direct treatment relationship with the patient (e.g., laboratories, physicians called for a consultation) and health plans may use or disclose protected health information for treatment, payment, and health care operations, provided that the provider or health plan has included these activities in the "Notice" of information practices that it has published and distributed to patients and enrollees. Except for a few activities that are listed in the regulation, such as public health reporting, no other use or disclosure may be made without specific patient authorization.

Under the final rule, health plans, health care clearinghouses, and health care providers ("covered entities") are prohibited from using or disclosing protected health information for marketing without specific patient authorization. The regulation, in effect, establishes two separate categories of marketing communications and rules governing the form of patient authorization required for each type. In addition, the regulation distinguishes "marketing" communications from the care management and benefits coordination activities that a health plan or health care provider may engage in the course of providing treatment or coordinating health benefits coverage and payment for an individual. The regulation also creates new rules for fundraising activities by certain not-for-profit entities. This advisory will briefly summarize each of these new regimes in turn.

MARKETING BY THIRD PARTIES

The regulation defines "marketing" as a "communication about a product or service a purpose of which is to encourage recipients of the communication to purchase or use the product or service." Any disclosure of patient information, including a list or roster of a provider's patients, to a third party for marketing is explicitly prohibited by the rule without the specific authorization of each patient. The authorization form must specify the purpose of the disclosure, the information to be disclosed and the third party recipients. The availability of treatment and payment cannot be conditioned on signing of such an authorization; and the authorization cannot be in the same form in which the patient provides consent for information to be used in providing treatment. The authorization must have an expiration date, and be revocable by the patient at any time.

The covered entity must keep a list of all of the third parties to whom the patient's information has been disclosed under such an authorization, and the patient has the right to obtain a list of all of those disclosures.

MARKETING BY COVERED ENTITIES

The final regulation accommodates the fact that health plans and providers also may engage in marketing activities and that their patient lists may sometimes be an acceptable source of contacts. For communications by health plans and providers directly to patients, the regulation identifies very precise content and format requirements that must be met by any such communication, including a specific requirement that the covered entity provide an "opt-out" from all further marketing communications from the covered entity. Provided that the covered entity complies with these detailed new rules, these marketing communications by a covered entity may be encompassed by the consent or authority that the covered entity has for performing "health care operations."

In order for a covered entity (whether a health plan or a provider) to engage in this kind of marketing of its own services or products, or those of a third party, the communication must (a) occur in a face-to-face setting with the patient, or (b) must pertain to products of a "nominal value." For any written marketing communication, each of the following requirements must be met:

1. The covered entity must be identified as the party making the communication
2. The communication must disclose whether the covered entity has received or will receive direct or indirect remuneration for making the communication; and
3. Except when the communication is contained in a newsletter or pamphlet sent to a broad cross-section of patients or enrollees, contain instructions describing how the individual may opt out of receiving future such communications.

These regulations do not authorize the covered entity to furnish its patient list to a third party for its marketing purposes. Depending on the facts of the specific situation, any marketing communication by a covered entity that does not meet these narrow requirements would be a use or disclosure of protected health information in violation of the regulation, and would subject the covered entity to the civil and criminal penalties of the statute.

In addition, if a covered entity proposes to use patient information to selectively target its communication to individuals based on their health status or condition, the following requirements also must be met:

1. The covered entity must make a determination prior to making the communication that the product or service being marketed may be beneficial to the health of the type or class of individual targeted; and
2. The communication must explain why the individual has been targeted and how the product or service relates to the health of the individual; and
3. The covered entity must make reasonable efforts to ensure that individuals who decide to opt out of receiving future marketing communications are not sent such communications.

As noted above, any marketing communication by a covered entity that did not include this information, would be an impermissible use or disclosure of the patient information.

CARE MANAGEMENT AND BENEFITS COORDINATION

Under the regulation, the consent that the patient signs at the doctor's office or hospital covers "treatment" and "payment," which are defined to include various activities that providers and health plans perform in trying to ensure that patients receive medically appropriate care and that the care that is delivered is covered under the particular health benefits plan in which the patient is enrolled. Sometimes, the communications necessary to accomplish this may resemble "marketing" in that they concern specific products or the services of specific providers that are being recommended to the individual. Subject to the provision discussed below, the regulation acknowledges this fact by excluding from the definition of "marketing" the following types of communications:

1. A communication made by a covered entity for the purpose of describing the entities participating in a health care provider network or health plan network, or for the purpose of describing if and the extent to which a product or service (or payment for such product or service) is provided by a covered entity or included in a plan of benefits; or
2. Communications tailored to the circumstances of a particular individual and that are made by a health care provider to an individual as part of the treatment of the individual, and for the purpose of furthering the treatment of that individual; or
3. Communications made by a health care provider or health plan to an individual in the course of managing the treatment of that individual, or for the purpose of directing or recommending to that individual alternative treatments, therapies, health care providers, or settings of care.

A communication of any of these three types is not marketing only if (1) the communication is made orally, or (2) the communication is in writing and the covered entity does not receive direct or indirect remuneration from a third party for making the communication. Under the regulation, a communication that does not meet these narrow criteria to be considered part of the arrangements for treatment and benefits administration, it is "marketing" and, if the communication is made by a covered entity, it must comply with the regulation's requirements regarding content and form (discussed above), and must provide for an opt-out of future marketing communications. And if the communication is made by a third party, the patient's specific authorization must have been obtained in advance for use of the protected health information in making the communication.

FUNDRAISING

The regulation acknowledges the fact that some covered entities are not-for-profit entities that must engage in fundraising in order to support their basic activities. Patients and former patients often are receptive and respond generously to fundraising requests. The regulation does not treat these activities as "marketing," but as a special, very limited use of certain information permitted under separate, specific rules governing the "health

care operations" of the not-for-profit entity. To be permissible as "fundraising" the communication must meet all of the following criteria:

1. The covered entity (its business associate) or an institutionally related foundation must make the communication;
2. Only demographic information relating to an individual, and dates of service (not information about health or health care) may be used or disclosed for fundraising;
3. The information may be used to raise funds only for the benefit of the covered entity that has authority to use the information for treatment, payment, and health care operations with respect to the individual;
4. Any fundraising materials sent to the individual must include a description of how the individual may opt out of receiving any further fundraising communications; and
5. The covered entity must make reasonable efforts to ensure that individuals who decide to opt out of receiving future fundraising communications are not sent such communications.

As noted above, any use or disclosure of patient demographic information for fundraising activities that does not comply with these requirements would be a prohibited use or disclosure of protected health information under the regulation. If the covered entity did not obtain the specific authorization of the patient for such non-conforming fundraising activities, the use or disclosure of the information in the fundraising activity would be subject to civil and/or criminal sanctions under HIPAA.