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Marketing Under the 2013 HIPAA Omnibus Rule: New Requirements and Risks



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Overview

- Background on HIPAA Privacy Rule provisions
- HITECH Act mandates relating to marketing
- HHS implementation in Omnibus Rule
- Adheris legal challenge to HHS interpretation
- HHS responsive guidance

Background on HIPAA Privacy Rule and Marketing

- The HIPAA Privacy Rule generally prohibits a covered entity from using or disclosing protected health information (“PHI”) for marketing purposes.
- “Marketing” generally means making:
 - “a communication about a product or service that encourages recipients of the communication to purchase or use the product or service.” 45 C.F.R. § 164.501

Exceptions From the “Marketing” Definition

- “Marketing” does *not* include:
 - Face to face communications (including transmitting written brochures in person)
 - Provision of promotional gifts of nominal value (*e.g.*, branded pens, coffee cups, etc.)

Traditional Exceptions to the Authorization Requirement for Use of PHI for Marketing

- The Privacy Rule traditionally recognized that three types of “health care management/treatment” communications should not be subject to the marketing authorization requirement:
 - Describing a health-related product or service provided by or included in the benefits coverage of the covered entity making the communication;
 - Communications that encourage the use of a product or service but constitute “treatment”; and
 - Communications to manage care or to recommend alternative treatments, therapies, health care providers, or settings of care.

FCC and FTC Recognition of Permissible Health-Related Marketing Communications

- Both the Federal Communications Commission and the Federal Trade Commission regulate telemarketing, including calls encouraging use/purchase of health care products or services.
- In recognition of the Privacy Rule's exemption of "health care management/treatment" communications from the general marketing authorization requirement, the FCC and FTC exempted from their own prior written consent rules for autodialed/prerecorded telemarketing:
 - calls to describe a health-related product or service, *so long as*
 - such calls are made by a HIPAA covered entity or business associate.

HITECH Act Changes

- Congress was concerned about third parties (*e.g.*, pharmaceutical and medical device manufacturers) *paying* HIPAA covered entities to use PHI to make marketing communications about their products, including “healthcare management” communications.
- In the HITECH Act, Congress therefore newly required individual authorizations for the three types of “health care management/treatment” communications, *if the covered entity making the communication is paid to make the communication by the third party whose product or service is promoted.*

Exception: Refill Reminders

- Congress created one exception to the new “remunerated communications” authorization requirement, which essentially covers *refill reminders*.
- The HITECH Act “refill reminder” exception applies where:
 - a communication describes only *a drug or biologic that is currently being prescribed for the recipient of the communication; and*
 - any payment received in exchange for making the communication is “reasonable” in amount.

HHS Implementation: New “Marketing” Definition

- HHS implemented the HITECH Act by revising the definition of “marketing” to include a communication within any of the three health care management/treatment categories *if*:
 - there is *“direct or indirect payment from or on behalf of a third party whose product or service is being described” in exchange for making such communication,*
 - *unless* the communication is essentially just a refill reminder and the payment is “reasonably related to the covered entity’s cost of making the communication.”
- HHS said a payment would not be “reasonably related” if it exceeded the costs of labor, supplies and postage to make the communication.

Adheris Lawsuit: Challenge to HHS Interpretation

- In early September 2013, Adheris, Inc., which provides a refill reminder services and other therapy adherence message services, sued HHS to challenge its implementation of the HITECH Act “refill reminder” exception.
- Two legal claims:
 - 1) HHS’s interpretation violates the First Amendment by infringing on Adheris’ right of free speech
 - 2) HHS’s interpretation violates the Administrative Procedures Act because it is inconsistent with Congress’ HITECH Act intent
- Adheris sought a preliminary injunction to prevent HHS from enforcing the refill reminder requirements.

HHS Response to Adheris Claims

- In response to Adheris' lawsuit, HHS informed Adheris it would issue further guidance on "reasonable" financial remuneration.
- To avoid the court ruling on Adheris' motion for a preliminary injunction before Adheris could consider the guidance, HHS said it would postpone enforcing the refill reminder restrictions until November 7, 2013 (*i.e.*, by 45 days from the general Omnibus Rule compliance date).

HHS June 2013 Guidance: Basic Scope of “Refill Reminder” Exception

- The “refill reminder” exception applies only to communications about a *currently prescribed drug or biologic*.
- A “currently prescribed drug or biologic” includes:
 - generic equivalents of a drug being prescribed
 - where an individual is prescribed a self-administered drug, all aspects of the drug delivery system.
- Such a drug or biologic does *not* include:
 - new or alternative *formulations* (dosages, forms (liquid vs. pill), etc.) of a currently prescribed medicine
 - drugs *related* to the currently prescribed medicine

HHS Guidance: “Financial Remuneration”

- “*Financial remuneration*” means payment to a covered entity (or business associate, if applicable) from or on behalf of a third party whose product or service is being described.
- *Financial remuneration* does *not* include non-financial or in-kind benefits, such as:
 - Product brochures intended to be sent to patients
 - Message points to be used in calling patients about specific products or services

HHS Guidance: “Reasonable in Amount”

- Payments to cover the reasonable direct and indirect costs related to the communication, including *labor, materials, and supplies, as well as capital and overhead costs*
- If payments are to a business associate assisting a covered entity in carrying “refill reminder” communications: *up to the fair market value of the business associate’s services*

Factual Examples

- A pharmacy mails its diabetic patients information concerning the diabetic pumps used to administer their insulin
 - No authorization required, even if the pharmacy is paid by the manufacturer of the pumps, *provided the payment covers only the reasonable direct and indirect costs associated with the communications.*
- The pharmacy hires a vendor to assist in administering a medication adherence program that involves mailing adherence communications to patients about their currently prescribed drugs
 - No authorization required, even if the business associate is paid by the manufacturer of the drugs, *provided the payment does not exceed the fair market value of the business associate's services.*

Summary: When Is an Authorization Required?

TYPE OF COMMUNICATION	WITH REMUNERATION	WITHOUT REMUNERATION
Face-to-Face Between Covered Entity and Individual	No	No
Promotional Gift	No	No
Description of a Health-Related Product or Service Provided by or Included in a Health Benefit Plan	Yes	No
Disease Awareness Brochure or Other Material Specifically Related to an Individual's Condition	Yes	No
Switch Communications	Yes	No
Refill Reminders	No , so long as the remuneration is "reasonably related" to the cost of making the communication	No

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