

Understanding the Marketing Restrictions of HIPAA

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HIPAA's Restrictions on Marketing Activities:

- **THE AUTHORIZATION REQUIREMENT:** The general rule is that covered entities must obtain an individual's authorization before using or disclosing protected health information ("PHI") for marketing purposes. 45 CFR 164.514(e)

**The Myriad of Exceptions to
the
Authorization Requirement:
Do the Exceptions Swallow
the Rule?**

HIPAA's Definition of "Marketing"

- HIPAA 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." 45 CFR 164.501

Proposed rule referenced "health and non-health items and services"; final rule deleted the reference.

Three Exceptions to the Definition of “Marketing”

- In general, activities which constitute treatment, payment, and health care operations (TPO) are excepted from the definition of marketing.
 - Thus, covered entities may use and disclose PHI for TPO without securing an authorization (*i.e.* pursuant to a consent).

First Exception

- **Communications made by a covered entity for the purpose of describing its network, the scope of services it provides, and the services for which it pays.**

Second Exception

- **Communications “tailored” by the provider to the circumstances of a particular individual for treatment purposes or furthering the individual’s care.**
 - **Includes activities such as referrals, prescriptions, recommendations, and other communications that address how a product or service may relate to the individual’s health.**

Third Exception

- **Communications made by the provider or health plan to an individual in the course of managing the treatment of that individual or for recommending alternative treatments, therapies, providers, or settings of care.**
 - **Permits covered entities to discuss products or services in the course of managing an individual's care or providing treatment.**

More Exceptions . . .

- Three “marketing” situations are excluded from the authorization requirement. 45 CFR 164.514(e)
 - i.e., these activities fall within the definition of “marketing” but involve specific situations wherein an authorization is not required.

- **FIRST SITUATION: Face-to-face communications with the individual**
 - e.g. physician tells patient about product or service during office visit
- **SECOND SITUATION: Communications involving products or services of “nominal value” (note: “nominal value” not defined in the rule)**
 - e.g. coupon, rebate, toothbrush, etc.

- **THIRD SITUATION:**
Communications involving health-related products or services of the covered entity or of a third party, provided that the communication:
 - (a) identifies the covered entity as the “marketer”; and
 - (b) reveals whether the covered entity receives any remuneration from a third-party for making the communication; and

- (c) tells the individual how to opt-out of future communications; and
- (d) if PHI was used to “target” an individual about a particular product or service, discloses why the individual was chosen and how the product or service could benefit him/her. PLUS . . .

- **The covered entity determines, prior to making the targeted communication, that the product or service “may be beneficial to the health of the type or class of individual targeted.”**

**With all these new
restrictions, should a
covered entity give up
“targeted” marketing????**

NO!

- **HIPAA creates new opportunities for marketing. Covered entities need to figure out how to take advantage of these opportunities.**
- **How aggressive does your organization want to be? Factors to consider:**

Balance the competing interests

- On the one hand, PHI-based marketing is more cost effective than mass mailing and has a higher return on investment because the targeted market has a known need.
- On the other hand, PHI-based marketing could be perceived as invasive. This depends on the sensitivity of the health condition of the targeted market (i.e. AIDS or STD vs. allergies or smoking)

Consider common law and state law restrictions

- **Example: Weld v. CVS Pharmacy, Inc., et. al, C.A. No. 98-0897, Suffolk Superior Court, Boston, MA**
 - Privacy-based class action lawsuit filed in 1998, still pending
 - Plaintiffs alleged breach of privacy by CVS in connection with pharmacy mailing program regarding refill reminders, product information, etc.

How to minimize exposure for marketing activities

- **Develop a policy on the use of PHI in your organization's marketing program**
 - Document your marketing decision-making process: why you targeted them and how the product/service will benefit them (document the clinical reasons for concluding the benefit)

How to minimize exposure for marketing activities (cont.)

- Monitor the implementation of the policy
- Consider using only permission-based marketing programs
 - topic-based permission (e.g. heart disease)
 - points-based permission (e.g. membership program)

Conclusion

- TBA