

# Fundraising and Marketing

**Elizabeth C. Stone, J.D.**

University of Wisconsin-Madison  
Office of Administrative Legal Services

**Rebecca Hutton, J.D., M.S.**

HIPAA Privacy Officer  
University of Wisconsin-Madison

**Beth DeLair, R.N., J.D**

HIPAA Privacy Officer  
University of Wisconsin Hospitals and Clinics Authority



# University of Wisconsin Health Organized Health Care Arrangement

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- University of Wisconsin-Madison
- University of Wisconsin Hospital and Clinics Authority (“UWHC”)
- University of Wisconsin Medical Foundation (“UWFMF”)
- University Health Care and University Care Clinics (“UHC” and “UCC”)

# Marketing – General Definition

## (§ 164.501)

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- A communication about a product or service that encourages recipients to purchase or use the product or service (of the covered entity or third party)
  - Intent of the communication is not relevant (67 F.R. 53,186)
  - Promoting health in a general manner is NOT marketing
    - e.g. mailings promoting health fairs or support groups, providing information about new diagnostic tools, reminding women to get annual mammograms (67 F.R. 53,189)
  - Communications about government and government-sponsored programs are NOT marketing (67 F.R. 53,189)

# Marketing – General Definition

## (§ 164.501)


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- An arrangement between a covered entity (CE) and any other entity whereby the CE discloses PHI, in exchange for direct or indirect remuneration, to enable the other entity to promote its own products or services
  - Intended to close loophole whereby another entity could market its own products under guise of being business associate proposing treatment alternatives (67 F.R. 53,188-189)

# Marketing – Exceptions (§164.501)

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1. Description of a health-related product or service (or payment for such) that is provided by, or included in a plan of benefits of, the covered entity.
  - Entities participating in provider/plan network
  - Replacement of/enhancements to health plan
    - e.g. continuation coverage
    - Does NOT extend to “excepted benefits” or other types of insurance (67 F.R. 53,187)
  - Value-added items or services (“VAIS”) (67 F.R. 53,187)
    - Must be health-related
    - Must truly “add value” – not available to general public



# Marketing – Exceptions

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2. Communications regarding treatment of the individual
  - e.g. prescriptions, referrals to specialist
  - remuneration does not transform treatment communication into marketing (67 F.R. 53,187)
3. Communications made for case management/care coordination, or to direct alternative treatments, therapies, health care providers, or settings to the individual



# Marketing – Exceptions

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- Purpose of the exceptions: “to facilitate those communications that enhance the individual’s access to quality health care.” (67 F.R. 53,186)

# Marketing Authorizations

## (§ 164.508(a)(3))

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- A covered entity must obtain authorization to use/disclose PHI for marketing UNLESS the communication is in the form of:
  - A face-to-face communication by the CE to an individual (e.g. samples); or
  - A promotional gift of nominal value provided by the CE (e.g. pens bearing brand name).
- If the marketing involves direct or indirect remuneration to the CE from a 3<sup>rd</sup> party, the authorization must state this fact.





# Bottom Line

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Covered entity must obtain authorization to use/disclose PHI for marketing unless the communication

1. Describes a health-related product/service/benefit provided by the CE;
2. Involves treatment of the individual;
3. Relates to case management/care coordination for the individual;



## Bottom Line (continued)

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4. Is a face-to-face communication by the CE to the individual; or
5. Is a promotional gift of nominal value provided by the CE.

# Miscellaneous

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- HIPAA allows use of PHI to generate mailing list to use to seek authorizations for marketing (65 F.R. 82,491)
- Disclosures to, and uses/disclosures by, Business Associates are governed by above rules
- Commentary: DHHS intends to offer more specific guidance on marketing (67 F.R. 53,189)
- HIPAA marketing provisions do not amend or modify other federal or state laws that may prohibit certain marketing-type transactions (67 F.R. 53,167)
  - e.g. anti-kickback statute, Stark laws

# Fundraising

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- Final Rule: §164.514(f)(1) A covered entity may use, or disclose to a business associate or to an institutionally related foundation, the following PHI for the purpose of raising funds for its own benefit, without authorization. . .
  - Demographic information related to the individual; and
  - Dates of health care provided to the individual

# Related Preamble

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- 65 FR 82718 Permissible fundraising activities include appeals for money, sponsorship of events etc. . . .(but) do not include royalties or remittances for the sale of products to third parties.
- 65 FR 82546 “Institutionally related foundation” means a foundation that:
  - Qualifies as a non-profit foundation under 501(c)(3) of IRS code
  - Has in its charter statement of charitable purposes an explicit linkage to the covered entity



# Preamble Continued

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- 65 FR 82718 Demographic information includes:
  - Name
  - Address and other contact information
  - Age
  - Gender
  - Insurance information
- Demographic information does not include information about the illness or treatment.

# Implementation Requirements

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- §164.520(b)(1)(iii)(B) if a covered entity intends to fundraise (with or without an authorization), it must include such a statement in its Notice of Privacy Practices
- Fundraising communications sent out without an authorization must include a description of how the individual may opt out of receiving further communications
  - A CE must make reasonable efforts to ensure that those who choose to opt out do not receive further fundraising communications.

# Fundraising and Health Care Operations

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- §164.501 Health care operations means. . . Consistent with the applicable requirement of 164.514. . . Fundraising for the benefit of the entity.
- Preamble 65 FR 82491 Health care operations include business management activities and general administrative functions, including:
  - Fundraising for the benefit of the covered entity to the extent permitted under 164.514; and
  - Uses and disclosures of PHI to determine from whom an authorization should be obtained, for example to generate a mailing list of individuals who would receive an authorization request.



# Summary and Discussion

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1. Fundraising, to the extent permitted without authorization under 164.514, is considered to be a business management or general administrative function type of health care operation
  - So, a CE can use demographic information and dates of services without an authorization.
    - Note\* Hybrid entities must designate internal fundraising as part of their health care component in order to use PHI for fundraising without an authorization.



# Summary Continued

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2. Final rule permits covered entities, as part of health care operations, to use PHI to develop mailing lists of patients from whom an authorization must be obtained for fundraising activities.

# Summary Continued

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## 3. Institutionally related foundations

- Are affected by HIPAA only when they receive PHI from covered entity
- Are not covered by HIPAA when they receive PHI from patient directly
- Can receive demographic information and dates of health care provided for fundraising from related covered entity without authorization.
- Cannot receive other PHI from a covered entity for fundraising unless the covered entity obtained an authorization.
  - Note\* although arguably not required, we recommend a BA like contract with institutionally related foundations.



# Summary Continued

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4. Business Associates that fundraise on behalf of covered entity:
  - Can receive demographic information and dates of services from the covered entity for fundraising without an authorization.
  - Cannot receive other PHI for fundraising without an authorization.

# Applying “Marketing” Rules

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- Letter to let patients know MD has left or moved
  - Does not meet definition of marketing because it describes service of the covered entity.
- General Letter promoting “Women's Health Month”
  - Does not meet definition of marketing because it describes services of covered entity.
- Provider who is paid by pharmaceutical company to send prescription reminders to patients
  - Does meet definition of marketing because it relates to treatment. Remuneration is irrelevant.

# Marketing Continued

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- Women's health screening: Disclosing PHI to sponsoring organization in exchange for money.
  - Is marketing because it is an arrangement whereby a CE receives remuneration for disclosing PHI to another covered entity, to enable that other entity to promote its products or services.
- Health Plan sends newsletter that includes ads for pharmaceuticals
  - Is marketing even if newsletter contains only general health-related information because it encourages recipients to purchase products.

# Marketing Continued

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- Using PHI in a brochure sent to other clinicians to promote training service
  - Is marketing because it is encouraging others to use a service.
- Letter to family re: memorial service
  - Is it marketing? Is there any way we can justify using PHI without an authorization?

# Applying Fundraising

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## 1. Non-diagnosis-targeted mailing—use only demographics

- No authorization needed
  - Ex: All patients seen in the last 3 months.
  - Ex: All patients under age 18 seen in the last 3 months

## 2. Diagnosis-targeted mailing

- Authorization needed
  - Ex: From a particular department (e.g. oncology) or related to a specific treatment (cancer) need authorization.



# Examples Continued

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## 3. Grateful patient approaches MD/clinician

- Initial information—not a “use” because patient is providing information
- Subsequent contact
  - No authorization if patient directly provides information
  - No authorization if diagnosis/treatment is not linked to patient

# Examples Continued

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## 4. Clinician identifies patients and contacts

### Foundation

- Generally, need an authorization before disclosing information to BA or institutionally related foundation;
- Do not need an authorization to identify potential donors to BA or institutionally related foundation for purposes of seeking authorization (“health care operation”)
  - Can only disclose demographic information
  - Clinician should ask patient about interest in donating/receiving fundraising communications prior to disclosing PHI to Foundation.

# Examples Continued

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## 5. Use of existing database

- Use of existing database by CE's and BA's/foundations post 4/13/03 is permitted without authorization if it contains only demographic information and dates of service, and other non PHI information (e.g. donor history).
  - EX: database contains information where they were last treated (e.g. transplant clinic).
  - EX: database contains information of what fundraising projects they have contributed to in the past (e.g. cancer center).