



MEMORANDUM

TO: Clients and Friends
FROM: Lawyers Alliance for New York
RE: Designating your organization as a hybrid entity under HIPAA rules
DATE: March 8, 2008

With the enactment of the Health Insurance Portability and Accountability Act ("HIPAA"), nonprofit organizations should be aware of the responsibilities they owe to their clients in safeguarding their personal information. This legal alert provides a brief overview of what it means to be a "covered" entity as well as a "hybrid" entity under HIPAA, and the different responsibilities that exist if classified as either. For your convenience, we offer a chart at the end of this document to help you determine if your organization operates activities regulated by HIPAA. Also discussed are the benefits of properly classifying an organization as a "hybrid" organization, and the necessary steps that should be taken to ensure this classification.

Organizations that offer multiple services to their clients may find that some of their services are regulated by the Health Information Portability and Accounting Act ("HIPAA"). Organizations offering HIPAA regulated activities are considered "covered"¹ entities (see chart). A multi-service organization that offers both "covered" and "non-covered" services to its clients has the option of designating itself as a hybrid entity², thus compartmentalizing its HIPAA obligations to just the portion of the organization that is HIPAA "covered". An organization that do not designate itself as a hybrid entity runs the risk that Health and Human Services ("HHS")³ will deem the entire organization a "covered entity", and extend HIPAA obligations to all programs – "covered" and "non-covered" alike.

To be considered a "hybrid entity", an organization must self designate the "covered" programs in writing, as health care components⁴ and then implement necessary safeguards⁵ to ensure that improper use or disclosure of information does not occur within the organization at large. For HIPAA purposes, the designated health care component of the hybrid organization is

¹ Reference the chart below to determine whether your services are HIPAA "covered" services.

² A hybrid entity is an organization that has a component that is a "covered" health care provider, and whose activities include both "covered" and "non-covered" functions.

³ HHS is the governmental agency that regulates HIPAA

⁴ 45 C.F.R. § 164.105(a)(2)(iii)(C) Health Care Components are departments or programs within the larger organization that engage in "covered" activities.

⁵ Physical (e.g. locked folder cabinets) and technological (e.g. firewalls, password protected files accessible only to necessary staff) safeguards.

considered separately from the larger organization. Therefore, protected health information⁶ derived from the activities/programs of the health care component can only be shared with the rest of the organization in accordance with HIPAA regulations.

According to HIPAA rules, once designated, a hybrid entity must maintain a written or electronic record of the designation, and retain the document for at least six (6) years from the date of the designation or the date when it was last in effect, whichever is later. The hybrid designation documentation is not filed with HHS⁷. Upon designation a hybrid entity should immediately set organizational policies and systems in place that implement HIPAA rules, especially the construction of the aforementioned safeguards. The set-up and implementation of these policies is critical because in the event that an HHS investigation or audit occurs, the organization will have the necessary documentation supplemented by complimentary policies indicating that the organization is, and has been acting as a hybrid entity.

Some of the steps an organization must take in order to designate itself as a hybrid entity are as follows:

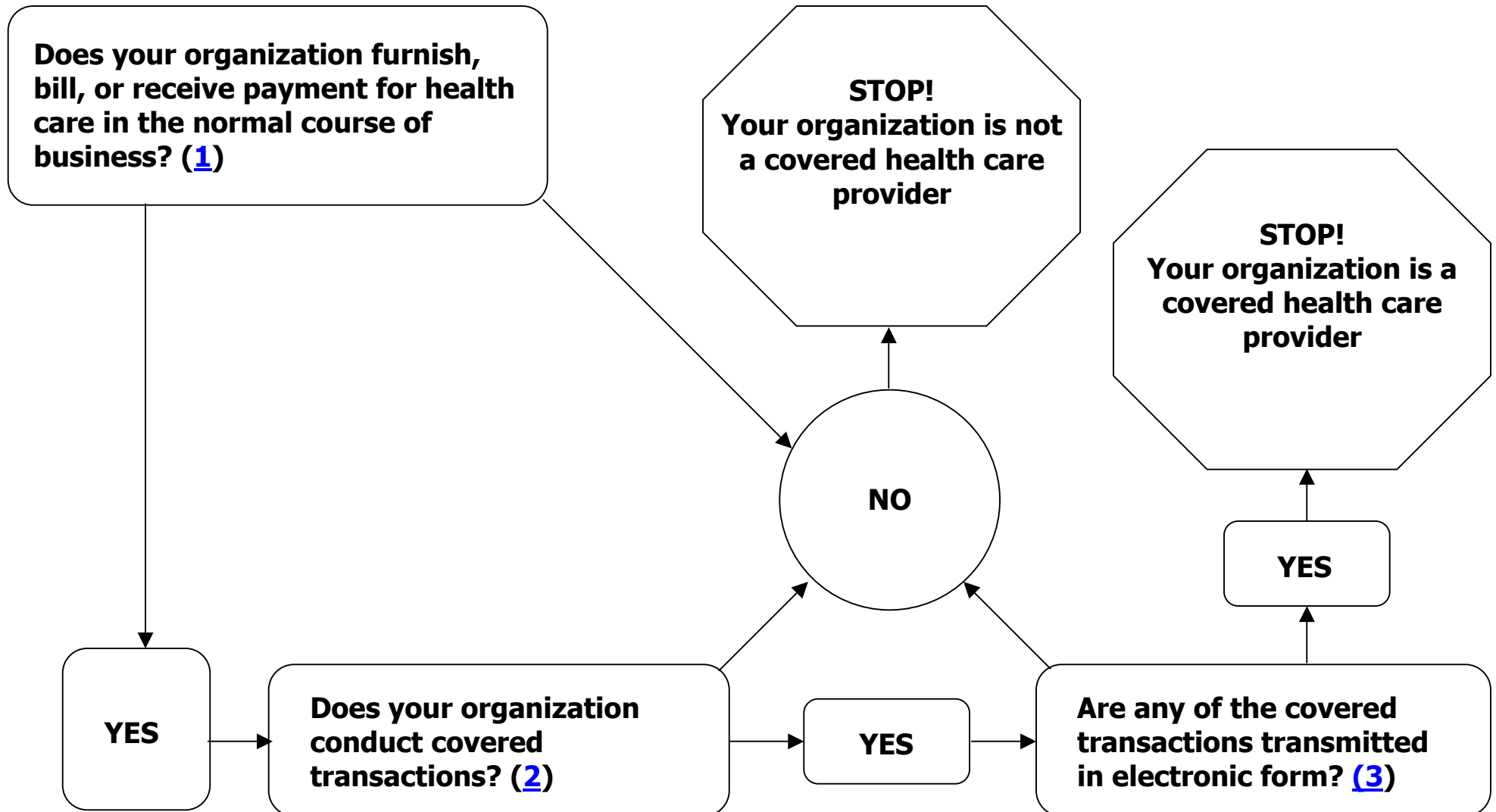
- Conduct an initial organizational assessment to determine if your organization is a “covered” entity, therefore falling within the auspices of HIPAA. Lawyers Alliance can provide the assistance necessary to make this determination.
- Determine which programs within the organization are “covered” and “non-covered” programs, and institute physical and technological safeguards that will prevent protected information from being improperly used and/or disclosed. This includes, but is not limited to, physically separating “covered” program offices/cubicles from “non-covered” program offices/cubicles; installing a firewall that prevents unauthorized access to electronic files of “covered” clients.
- Revise appropriate organizational policies, including but not limited to personnel policies and document destruction policies, to address the roles and responsibilities of staff members employed within the “covered” program to protect client information in accordance with HIPAA rules.
- Prepare a document that states the organization’s decision to designate itself as a hybrid entity. Within the document indicate which programs are “covered” and which ones are “non-covered” and date and file the document with other important organizational documents.

This alert is meant to provide general information only, not legal advice. HIPAA regulations contain specific requirements and details not included here. If further information is desired please contact Staff Attorney Viva Obioha at Lawyers Alliance for New York at (212) 219-1800 x 276 for further information.

⁶ Protected Health Information refers to individually identifiable health information created or received by a covered entity that relates to the past, present or future physical or mental health or condition of an individual, including information regarding the provision of payment of and payment for health care, that is transmitted or maintained in any form or medium.

⁷ According to HHS Office of Civil Rights Region X, the written or electronic instrument used in hybrid designation is never filed with HHS; rather it is an organizational document that should be filed with all other organizational policies.

Is your organization a covered health care provider?



1. Health care means: care, service, or supplies related to the health of an individual. It includes but is not limited to preventive, diagnostic, rehabilitative, maintenance, or palliative care and counseling, assessments, or procedures as they relate to the physical or mental conditions or functional status of an individual.

2. The following transactions are “covered transactions” as defined by Health and Human Services:

- i. *Claims*: Requests to obtain payment from a health plan¹ for health care or if there is no direct claim because reimbursement based contract then the transaction is the transmission of information for the purpose of reporting health care;
- ii. *Benefit eligibility inquiries*: Inquiries and/ or responses to a health plan to obtain information, about an enrollee’s eligibility to receive health care under the plan; coverage of health care under the health plan; benefits associated with the benefits plan;
- iii. *Referral authorization requests*: Response/requests for the review of health care to obtain an authorization for the health care; or a response/request to obtain authorization for referring an individual to another health care provider; or
- iv. *Health Care payment and Remittance advice*: Transmission of payment, information about the transfer of funds, payment processing information, explanation of benefits, and remittance of advice.

3. In electronic form means using electronic media, electronic storage media (e.g. hard/floppy disk, hard drive) including memory devices in computers (hard drives), and any removable/transportable digital memory medium, such as magnetic tape or disk, optical disk, or digital memory card. Transmission media include Internet and Intranet. Phone, faxes are NOT considered electronic media.

¹ A contracting governmental agency will serve as a “health plan” for purposes of reading this regulation.