Disclosures of PHI to the FDA
HIPAA Policy: Privacy 08

Summary: Explains the rules governing the disclosure of PHI to the Food and Drug Administration.

Affected Individuals: Staff at HIPAA covered entities; patients at HIPAA covered entities

1.0 PURPOSE

The purpose of this policy is to aid the University of Mississippi (UM) employees in making reports to the Food and Drug Administration (FDA) in a manner that is compliant with the Health Insurance Portability and Accountability Act (HIPAA).

2.0 SCOPE

The UM Disclosures of Protected Health Information (PHI) to the Food and Drug Administration Policy applies to any UM employee required to report to the FDA.

3.1 STANDARDS

It is the policy of UM that disclosures to the FDA, in most cases, can be made without an authorization from the patient. This type of disclosure should be made only to a person subject to the jurisdiction of the FDA with respect to a FDA-regulated product or activity for which that person has responsibility. The information should be used for the purposes of public health activities only, such as activities related to the quality, safety, or effectiveness of a FDA-regulated product or activity.

Examples of these purposes include but are not limited to the following:

- Collecting or reporting adverse events (or similar activities regarding food or dietary supplements), product defects or problems (including problems with the use or labeling of a product) or biological product deviations;
- Tracking FDA-regulated products;
- Enabling product recalls, repairs, replacement, or lookback (including locating and notifying persons who have received products that have been withdrawn, recalled or are the subject of lookback); and
- Conducting post-marketing surveillance.

All disclosures reported to the FDA are subject to accounting requirements of the HIPAA. For this reason, a record will be kept of all PHI reported pursuant to this FDA disclosure policy.

All reports made to a FDA-regulated person or entity, for the purposes of public health activities, will be documented, so that UM can account for these disclosures.

4.0 CONTACT INFORMATION

For questions about the UM Disclosures of PHI to the FDA Policy or for more information, call the Office of General Counsel at 662-915-7014.