DISCLOSURES FOR PUBLIC HEALTH ACTIVITIES

[*45 CFR 164.512(b)*]

Background **To view complete file click here**

The HIPAA Privacy Rule recognizes the legitimate need for public health authorities and others responsible for ensuring public health and safety to have access to protected health information to carry out their public health mission. The Rule also recognizes that public health reports made by covered entities are an important means of identifying threats to the health and safety of the public at large, as well as individuals. Accordingly, the Rule permits covered entities to disclose protected health information without authorization for specified public health purposes.

How the Rule Works

General Public Health Activities. The Privacy Rule permits covered entities to disclose protected health information, without authorization, to public health authorities who are legally authorized to receive such reports for the purpose of preventing or controlling disease, injury, or disability. This would include, for example, the reporting of a disease or injury; reporting vital events, such as births or deaths; and conducting public health surveillance, investigations, or interventions. See 45 CFR 164.512(b)(1)(i). Also, covered entities may, at the direction of a public health authority, disclose protected health information to a foreign government agency that is acting in collaboration with a public health authority. See 45 CFR 164.512(b)(1)(i). Covered entities who are also a public health authority may use, as well as disclose, protected health information for these public health purposes. See 45 CFR 164.512(b)(2).

A "public health authority" is an agency or authority of the United States government, a State, a territory, a political subdivision of a State or territory, or Indian tribe that is responsible for public health matters as part of its official mandate, as well as a person or entity acting under a grant of authority from, or under a contract with, a public health agency. See 45 CFR 164.501. Examples of a public health authority include State and local health departments, the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention, and the Occupational Safety and Health Administration (OSHA).

Generally, covered entities are required reasonably to limit the protected health information disclosed for public health purposes to the minimum amount necessary to accomplish the public health purpose. However, covered entities are not required to make a minimum necessary determination for public health disclosures that are made pursuant to an individual's authorization, or for disclosures that are required by other law. See 45 CFR 164.502(b). For disclosures to a public health authority, covered entities may reasonably rely on a minimum necessary determination made by the public health authority in requesting the

protected health information. See 45 CFR 164.514(d)(3)(iii)(A). For routine and recurring public health disclosures, covered entities may develop standard protocols, as part of their minimum necessary policies and procedures, that address the types and amount of protected health information that may be disclosed for such purposes. See 45 CFR 164.514(d)(3)(i).

Other Public Health Activities. The Privacy Rule recognizes the important role that persons or entities other than public health authorities play in certain essential public health activities. Accordingly, the Rule permits covered entities to disclose protected health information, without authorization, to such persons or entities for the public health activities discussed below.

- Child abuse or neglect. Covered entities may disclose protected health information to report known or suspected child abuse or neglect, if the report is made to a public health authority or other appropriate government authority that is authorized by law to receive such reports. For instance, the social services department of a local government might have legal authority to receive reports of child abuse or neglect, in which case, the Privacy Rule would permit a covered entity to report such cases to that authority without obtaining individual authorization. Likewise, a covered entity could report such cases to the police department when the police department is authorized by law to receive such reports. See 45 CFR 164.512(b)(1)(ii). See also 45 CFR 512(c) for information regarding disclosures about adult victims of abuse, neglect, or domestic violence.

- Quality, safety or effectiveness of a product or activity regulated by the FDA. Covered entities may disclose protected health information to a person subject to FDA jurisdiction, for public health purposes related to the quality, safety or effectiveness of an FDA-regulated product or activity for which that person has responsibility. Examples of purposes or activities for which such disclosures may be made include, but are not limited to:

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

  See 45 CFR 164.512(b)(1)(iii). The "person" subject to the jurisdiction of the FDA does not have to be a specific individual. Rather, it can be an individual or

an entity, such as a partnership, corporation, or association. Covered entities may identify the party or parties responsible for an FDA-regulated product from the product label, from written material that accompanies the product (know as labeling), or from sources of labeling, such as the Physician's Desk Reference.

- Persons at risk of contracting or spreading a disease. A covered entity may disclose protected health information to a person who is at risk of contracting or spreading a disease or condition if other law authorizes the covered entity to notify such individuals as necessary to carry out public health interventions or investigations. For example, a covered health care provider may disclose protected health information as needed to notify a person that (s)he has been exposed to a communicable disease if the covered entity is legally authorized to do so to prevent or control the spread of the disease. See 45 CFR 164.512(b)(1)(iv).

- Workplace medical surveillance. A covered health care provider who provides a health care service to an individual at the request of the individual's employer, or provides the service in the capacity of a member of the employer's workforce, may disclose the individual's protected health information to the employer for the purposes of workplace medical surveillance or the evaluation of work-related illness and injuries to the extent the employer needs that information to comply with OSHA, the Mine Safety and Health Administration (MSHA), or the requirements of State laws having a similar purpose. The information disclosed must be limited to the provider's findings regarding such medical surveillance or work-related illness or injury. The covered health care provider must provide the individual with written notice that the information will be disclosed to his or her employer (or the notice may be posted at the worksite if that is where the service is provided). See 45 CFR 164.512(b)(1)(v).

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Frequently Asked Questions

Q: Must a health care provider or other covered entity obtain permission from a patient prior to notifying public health authorities of the occurrence of a reportable disease?

A: No. All States have laws that require providers to report cases of specific diseases to public health officials. The HIPAA Privacy Rule permits disclosures that are required by law. Furthermore, disclosures to public health authorities that are authorized by law to collect or receive information for public health purposes are also permissible under the Privacy Rule. In order to do their job of protecting the health of the public, it is frequently necessary for public health officials to obtain information about the persons affected by a disease. In some cases they may need to contact those affected in order to determine the cause of the disease to allow for actions to prevent further illness.

The Privacy Rule continues to allow for the existing practice of sharing protected health information with public health authorities that are authorized by law to collect or receive such information to aid them in their mission of protecting the health of the public. Examples of such activities include those directed at the reporting of disease or injury, reporting deaths and births, investigating the occurrence and cause of injury and disease, and monitoring adverse outcomes related to food (including dietary supplements), drugs, biological products, and medical devices. See the fact sheet and frequently asked questions on this web site about the public health provision for more information.

Q: Does the public health provision of the HIPAA Privacy Rule require covered entities to make public health disclosures?

A: No. The Privacy Rule's public health provision permits, but does not require, covered entities to make such disclosures. This provision is intended to allow covered entities to continue current voluntary reporting practices that are critically important to public health and safety. The Rule also permits covered entities to disclose protected health information when State or other law requires covered entities to make disclosures for public health purposes. For instance, many State laws require health care providers to report certain diseases, cases of child abuse, births, or deaths, and the Privacy Rule permits covered entities to disclose protected health information, without authorization, to make such reports. See the fact sheet and frequently asked questions on this web site about the public health provision for more information.

Q: May covered entities disclose facially identifiable protected health information, such

as name, address, and social security number, for public health purposes?

A: Yes. The HIPAA Privacy Rule permits covered entities to disclose the amount and type of protected health information that is needed for public health purposes. In some cases, the disclosure will be required by other law, in which case, covered entities may make the required disclosure pursuant to 45 CFR 164.512(a) of the Rule. For disclosures that are not required by law, covered entities may disclose, without authorization, the information that is reasonably limited to that which is minimally necessary to accomplish the intended purpose of the disclosure. For routine or recurring public health disclosures, a covered entity may develop protocols as part of its minimum necessary policies and procedures to address the type and amount of information that may be disclosed for such purposes. Covered entities may also rely on the requesting public health authority's determination of the minimally necessary information. See the fact sheet and frequently asked questions on this web site about the public health and minimum necessary standards for more information.

Q: Does the HIPAA Privacy Rule's public health provision permit covered entities to disclose protected health information to authorities such as the National Institutes of Health (NIH)?

A: The definition of a "public health authority" requires that an agency's official mandate include the responsibility for public health matters. The mandate can be responsibility for public health matters, generally, or it can be for specific public health programs. Furthermore, an agency's official mandate does not have to be exclusively or primarily for public health. Therefore, to the extent a government agency has public health matters as part of its official mandate, it qualifies as a public health authority. For instance, various Department of Health and Human Service agencies, such as NIH and the Health Resources and Services Administration (HRSA), are authorized by law to assist the Secretary of Health and Human Services in carrying out the purposes of section 301 of the Public Health Service Act. Those agencies are public health authorities under the Rule, even if they have other non-public health mandates. To the extent a public health authority is authorized by law to collect or receive information for the public health purposes specified in the public health provision, covered entities may disclose protected health information to such public health authorities without authorization pursuant to the public health provision. See the fact sheet and frequently asked questions on this web site about the public health provision for more information.

Q: To whom may covered entities make public health disclosures regarding a product regulated by the Food and Drug Administration (FDA) when more than one person is identified on the product label?

A: Covered entities may identify persons responsible for an FDA-regulated product by using the product label, the literature that accompanies the product, or other sources of labeling, such as the Physician's Desk Reference. If multiple persons are named, covered entities may choose any of the persons named by these sources. See the fact sheet and frequently asked questions on this web site about the public health provision for more information.

Q: Is a covered entity permitted to disclose protected health information under the HIPAA Privacy Rule's public health provision when the link between an adverse event and a product regulated by the Food and Drug Administration (FDA) is only suspected?

A: Yes. In most instances when a covered entity makes an adverse event report to a person responsible for an FDA-regulated product, the covered entity will suspect, but not know, the product is the cause of the event. Determining whether the product is related to the adverse event almost always requires follow up with the covered entity which in turn may need further contact with the patient. FDA and product manufacturers receive a great deal of important information about the safety of regulated products from these reports. To limit such reports to those instances where the covered entity is convinced of the link between the product and the event would reduce the amount of useful safety, quality and effectiveness data available to the agency as well as to product manufacturers. This would limit significantly FDA's ability to protect the public health by helping to assure that only safe and effective products are marketed in the U.S. Accordingly, covered entities may disclose the minimum amount of protected health information that is reasonably necessary to report suspected adverse events associated with an FDA-regulated product. See the fact sheet and frequently asked questions on this web site about the public health and minimum necessary standards for more information.

Q: Does the HIPAA Privacy Rule's public health provision permit covered entities to disclose protected health information without authorization to a manufacturer of a product regulated by the Food and Drug Administration (FDA) for use by the manufacturer to assess the effectiveness of its marketing campaign?

A: No. The public health provision is intended to facilitate the flow of information that is essential to the FDA's public health mission. The provision does not permit covered entities to disclose protected health information to a manufacturer for the manufacturer's commercial purposes, or for any other non-public health purpose. For example, the Rule does not permit a covered entity to provide a drug manufacturer with a list of persons who prefer a different flavored cough syrup over the flavor of the manufacturer's product. Rather, this provision permits covered entities to disclose protected health information as necessary to continue current voluntary reporting of adverse events and similar reports that are necessary to ensure the quality, safety, or effectiveness of an FDA-regulated

product. For instance, a covered entity would be permitted to report a concern to a drug manufacturer that its cough syrup might be unsafe based on the belief that a difference in the taste could be due to drug tampering or a manufacturing problem. Likewise, a covered health care provider would be permitted to disclose protected health information to a drug manufacturer to report that the failure of a patient's medical condition to improve may be due to the drug's ineffectiveness. In making such a report, the covered entity may disclose the protected health information that is reasonably necessary to achieve the purpose of the report. See the fact sheet and frequently asked questions on this web site about the public health and minimum necessary standards for more information.

Q: Does the HIPAA Privacy Rule's public health provision permit covered health care providers to disclose protected health information concerning the findings of pre-employment physicals, drug tests, or fitness-for-duty examinations to an individual's employer?

A: The public health provision permits covered health care providers to disclose an individual's protected health information to the individual's employer without authorization in very limited circumstances. First, the covered health care provider must provide the health care service to the individual at the request of the individual's employer or as a member of the employer's workforce. Second, the health care service provided must relate to the medical surveillance of the workplace or an evaluation to determine whether the individual has a work-related illness or injury. Third, the employer must have a duty under the Occupational Safety and Health Administration (OSHA), the Mine Safety and Health Administration (MSHA), or the requirements of a similar State law, to keep records on or act on such information. For example, OSHA requires employers to monitor employees' exposures to certain substances and to take specific actions when an employee's exposure level exceeds a specified limit. A covered entity which tests an individual for such an exposure level at the request of the individual's employer may disclose that test result to the employer without authorization.

Generally, pre-placement physicals, drug tests, and fitness-for-duty examinations are not performed for such purposes. However, to the extent such an examination is conducted at the request of the employer for the purpose of such workplace medical surveillance or work-related illness or injury, and the employer needs the information to comply with the requirements of OSHA, MSHA, or similar State law, the protected health information the employer needs to meet such legal obligation may be disclosed to the employer without authorization. Covered health care providers who make such disclosures must provide the individual with written notice that the information is to be disclosed to his or her employer (or by posting the notice at the worksite if the service is provided there).

When a health care service does not meet the above requirements, covered entities may not disclose an individual's protected health information to the individual's employer without an authorization, unless the disclosure is otherwise permitted without authorization by other provisions of the Rule. However, nothing in the Rule prohibits an employer from conditioning employment on an individual providing an authorization for the disclosure of such information.