Memorandum

To: Local Health Agencies & Health Care Providers

From: Communicable Disease and Epidemiology Section

Re: HIPAA PRIVACY RULE AND REPORTING OBLIGATIONS

Implementation of the Health Insurance Portability and Accountability Act (HIPAA) has raised many questions regarding Montana’s disease reporting requirements and the obligations of laboratories and health care providers. With the advent of the new regulations, we recognize that many providers are still working through these issues as they strive to protect patient confidentiality and cooperate with public health efforts. State and local health departments share this concern and have similar safeguards to protect the information that is received as a result of reporting requirements.

To clarify how the HIPAA Privacy Rule interacts with state reporting requirements we’ve assembled a few fact sheets from the Health and Human Services’ Office of Civil Rights. The fact sheets are intended to address some of the most common questions and we hope that these official interpretations are useful in addressing any concerns that may exist.

In short:

The HIPAA Privacy Rule specifically allows covered entities to disclose protected health care information to public health authorities for the purpose of preventing or controlling disease, injury, or disability (45 CFR 164.512(b)). In other words, the HIPAA Privacy Rule allows the reporting of selected communicable conditions required by law. The authority of the state health department to mandate reporting requirements and methods is granted by statute (MCA 50-1-202(18)) and the related Administrative Rules of Montana authorized by this law.

The HIPAA Privacy Rule allows states to continue conducting public health surveillance activities on conditions of interest. In Montana, the rules require reporting of conditions of interest to the local county health department, who in return report to the state health agency.

Cooperation of laboratories, health care facilities and providers is essential to help ensure an adequate public health response to individual cases and outbreaks. Compliance with reporting efforts is also a legal obligation.

We hope this information addresses any concerns regarding information release and HIPAA. If any additional information is needed, please contact your local health department for clarification.
Do I need an authorization to report a communicable disease to a public health authority?

Question
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?

Answer
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.
Does the HIPAA Privacy Rule require covered entities to make public health disclosures?

**Question**

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

**Answer**

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.
May I disclose facially identifiable information, such as name and address, for public health purposes?

Question
May covered entities disclose facially identifiable protected health information, such as name, address, and social security number, for public health purposes?

Answer
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.
How does the HIPAA Privacy Rule reduce the potential for conflict with State laws?

Question
How does the HIPAA Privacy Rule reduce the potential for conflict with State laws?

Answer
The Privacy Rule is designed to minimize conflicts between Federal requirements and those of State law in the following ways:

· The Privacy Rule establishes a floor of Federal privacy protections and individual rights with respect to individually identifiable health information held by covered entities and their business associates. Covered entities may provide greater privacy rights to individuals and greater protections on such information. In addition, covered entities may comply with State laws that provide greater protections for individually identifiable health information and greater privacy rights for individuals.

· The Privacy Rule permits a covered entity to use or disclose protected health information if a State law requires the use or disclosure. See 45 C.F.R. 164.512(a).

· The Privacy Rule permits a covered entity to disclose protected health information to a public health authority who is authorized by law to collect such information for the purposes of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions. (See 45 C.F.R. 164.512(b) for all of the public health disclosures permitted by the Privacy Rule.) Thus, State laws that provide for the reporting of disease or injury, child abuse, birth or death, or for the conduct of public health surveillance, investigation, or intervention, likely will not conflict with the Privacy Rule. In the unusual case where there is a conflict, the State law would stand. See 45 C.F.R. 160.203(c). Because the Administrative Simplification Rules themselves exempt such State laws from preemption, a request for the Department of Health and Human Services (HHS) to issue a preemption exception determination is unnecessary and inappropriate.

· The Privacy Rule permits a covered entity to disclose protected health information to a health oversight agency for oversight activities authorized by law, such as audits and licensure activities. See 45 C.F.R. 164.512(d). Thus, State laws that provide for certain health plan reporting for the purpose of management or financial audits, program monitoring and evaluation, or the licensure or certification of facilities or individuals, likely will not conflict with the Privacy Rule. In the unusual case where there is a conflict, the State law would stand. See 45 C.F.R. 160.203(d). Because the Administrative Simplification Rules themselves exempt such State laws from preemption, a request for the Department of Health and Human Services (HHS) to issue a preemption exception determination is unnecessary and inappropriate.

Uses and disclosures for which consent, an authorization, or opportunity to agree or object is not required.

A covered entity may use or disclose protected health information without the written consent or authorization of the individual as described in §§ 164.506 and 164.508, respectively, or the opportunity for the individual to agree or object as described in § 164.510, in the situations covered by this section, subject to the applicable requirements of this section. When the covered entity is required by this section to inform the individual of, or when the individual may agree to, a use or disclosure permitted by this section, the covered entity’s information and the individual’s agreement may be given orally.

(a) Standard: uses and disclosures required by law.

(1) A covered entity may use or disclose protected health information to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.

(2) A covered entity must meet the requirements described in paragraph (c), (e), or (f) of this section for uses or disclosures required by law.

(b) Standard: uses and disclosures for public health activities.

(1) Permitted disclosures. A covered entity may disclose protected health information for the public health activities and purposes described in this paragraph to:

(i) A public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions; or, at the direction of a public health authority, to an official of a foreign government agency that is acting in collaboration with a public health authority;

(ii) A public health authority or other appropriate government authority authorized by law to receive reports of child abuse or neglect;

(iii) A person subject to the jurisdiction of the Food and Drug Administration:

(A) To report adverse events (or similar reports with respect to food or dietary supplements), product defects or problems (including problems with the use or labeling of a product), or biological product deviations if the disclosure is made to the person required or directed to report such information to the Food and Drug Administration;

(B) To track products if the disclosure is made to a person required or directed by the Food and Drug Administration to track the product;

(C) To enable product recalls, repairs, or replacement (including locating and notifying individuals who have received products of product recalls, withdrawals, or other problems); or
(D) To conduct post marketing surveillance to comply with requirements or at the direction of the Food and Drug Administration;

(iv) A person who may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading a disease or condition, if the covered entity or public health authority is authorized by law to notify such person as necessary in the conduct of a public health intervention or investigation; or

(v) An employer, about an individual who is a member of the workforce of the employer, if:

(A) The covered entity is a covered health care provider who is a member of the workforce of such employer or who provides a health care to the individual at the request of the employer:

(1) To conduct an evaluation relating to medical surveillance of the workplace; or

(2) To evaluate whether the individual has a work-related illness or injury;

(B) The protected health information that is disclosed consists of findings concerning a work-related illness or injury or a workplace-related medical surveillance;

(C) The employer needs such findings in order to comply with its obligations, under 29 CFR parts 1904 through 1928, 30 CFR parts 50 through 90, or under state law having a similar purpose, to record such illness or injury or to carry out responsibilities for workplace medical surveillance;

(D) The covered health care provider provides written notice to the individual that protected health information relating to the medical surveillance of the workplace and work-related illnesses and injuries is disclosed to the employer:

(1) By giving a copy of the notice to the individual at the time the health care is provided; or

(2) If the health care is provided on the work site of the employer, by posting the notice in a prominent place at the location where the health care is provided.

(2) Permitted uses. If the covered entity also is a public health authority, the covered entity is permitted to use protected health information in all cases in which it is permitted to disclose such information for public health activities under paragraph (b)(1) of this section.