



Frequently Asked Questions About HIPAA and Cancer Reporting Rev. 05/13/2003

These FAQs were prepared by the Minnesota Department of Health¹ to inform cancer reporting facilities and health practitioners about HIPAA.

1. What is the HIPAA Privacy Rule?

In 1996 the U.S. Congress passed a law requiring, among other things, uniform federal privacy protections for individually identifiable health information. This law is called the Health Insurance Portability and Accountability Act of 1996, or "HIPAA." The U.S. Department of Health and Human Services recently issued final regulations implementing the privacy provisions of HIPAA. These regulations are called the "Privacy Rule." Copies of the HIPAA Privacy Rule, as well as helpful explanatory materials, may be found at the HHS Office of Civil Rights website: <http://www.hhs.gov/ocr/hipaa/>.

2. What is the Minnesota Cancer Surveillance System?

The Minnesota Cancer Surveillance System (MCSS) is a population-based registry of data about cancer cases in Minnesota. It was created by the Minnesota legislature in 1987. It is located in the Minnesota Department of Health (MDH). The MDH is a "Public Health Authority" under 45 CFR 164.501 because it is the Minnesota state agency "that is responsible for public health matters as part of its official mandate." Under Minnesota's authorizing legislation, cancer reporting facilities and health care providers are legally required to report information about cancer cases to the MCSS. Many facilities abstract information about cancer cases and report it to the MCSS as complete abstracts; other facilities, which do not have an in-house cancer registry, report cancer cases via pathology reports.

3. Is it a violation of HIPAA for a covered entity to report information about cases of cancer to the MCSS?

No. Reporting information about cases of cancer in accordance with the requirements of the MCSS authorizing statute and rule is permitted by HIPAA. The Privacy Rule contains a specific provision authorizing covered entities to disclose protected health information as required by law. See 45 CFR sec. 164.512(a)(1), Minnesota Statutes 144.671 – 144.69, and Minnesota Rules Chapter 4606.

1. This information is based on material prepared for members of the North American Association of Central Cancer Registries by individuals active in national, state, regional and hospital cancer registry organizations in consultation with legal counsel and with information provided by US federal officials involved in interpretation and implementation of the HIPAA Privacy Rule.

4. If the covered entity is not located in Minnesota, is it permissible under HIPAA to provide the data to the MCSS?

Yes, it is not prohibited. In fact, the definition of a “public health entity” was broadened in the section “Uses and Disclosures for Public Health Activities,” which states specifically “... We broaden the scope of allowable disclosures ... by allowing covered entities to disclose protected health information not only to U.S. public health authorities but also, 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.” (See FR p. 82525 and 45 CFR 164.512)

5. Does HIPAA require covered entities to obtain written authorization from the individual before reporting protected health information to the MCSS?

No. The provision of the Privacy Rule authorizing disclosure of protected health information as required by law is an exception to the requirement for written authorization. See 45 CFR sec. 164.512 (a)(1).

6. Are covered entities required to determine whether the information about cases of cancer reported to the MCSS is the “minimum necessary” information required to be disclosed?

No. The Privacy Rule does include a general requirement that covered entities make reasonable efforts to limit the disclosure of protected health information to the minimum necessary to accomplish the intended purpose of the disclosure. See 45 CFR sec. 164.502(b)(1). However, there is a specific exception to this requirement for disclosures that are required by law, such as the reporting of information about cases of cancer to the MCSS pursuant to Minnesota statutes and rules. See 45 CFR sec. 164.502(b)(2)(v).

7. What information is required for a covered entity to meet the Privacy Rule's verification requirements with respect to reporting information about cases of cancer to the MCSS?

The Privacy Rule requires covered entities to verify a requester's identity before disclosing protected health information. See 45 CFR sec. 164.514(h)(1)(i). In the case of disclosure to a person acting on behalf of a public official, a covered entity that reasonably relies on a written statement on appropriate government letterhead that the requester is acting under the government's authority will fulfill this requirement. See 45 CFR sec. 164.514(h)(2)(ii)(C). The Privacy Rule also requires covered entities to verify the requester's authority. See 45 CFR sec. 164.514(h)(1)(i). A covered entity that reasonably relies on a written statement of the legal authority under which the information is requested will fulfill this requirement. See 45 CFR sec. 164.514(h)(2)(iii)(A). To assist covered entities in meeting the verification requirements, the MDH has provided a written statement to cancer reporting facilities with the aforementioned information.

8. Are covered entities required to sign “business associate agreements” with the MCSS when it performs on-site abstracting and cancer data reporting?

No. HIPAA requires business associate agreements with entities that carry out health care functions on behalf of covered entities, but the MCSS is acting on behalf of the state when it provides on-site abstracting and reporting services, not the covered entity. Therefore, it is not a business associate.

9. Does HIPAA apply to the use or disclosure of information about cancer cases after it has been reported to the MCSS?

No. The Privacy Rule applies to disclosure of protected health information by covered entities as required by law. It does not apply to subsequent use or disclosure by non-covered entities, such as the MCSS. However, the MCSS' authorizing legislation includes strict limits on use and disclosure of reported information. See M.S. § 144.69, 144.658, and M.S. Chapter 13.

10. Are covered entities required to provide individuals upon request with an accounting of any protected health information that the entity has disclosed about them to the MCSS?

Yes. The Privacy Rule requires covered entities to provide an accounting of disclosures of protected health information. See 45 CFR 164.528. However, MDH² has concluded that HIPAA permits a covered entity to account for these disclosures in a general, not patient-specific, manner. When disclosing individual protected health information (PHI) to the MCSS, a covered entity may keep a general log of disclosure rather than noting each disclosure in the individual patient records (see example below). This conclusion is based on review of HIPAA privacy rule and guidance from the Centers For Disease Control and Prevention (CDC) and the U.S. Department of Health and Human Services (DHHS).

The required accounting of disclosures may be accomplished in different ways. Typically, the covered entity must keep an accounting of each disclosure by date, the information disclosed, the identity of the recipient, and the purpose of the disclosure. However, 5 CFR 164.528(b)(3) does not require this type of log for multiple disclosures for the same purpose. According to the CDC and DHHS,

“Where the covered entity has, during the accounting period, made multiple disclosures to the same recipient for the same purpose, the Privacy Rule provides for a simplified means of accounting. In such cases, the covered entity need only identify the recipient of such repetitive disclosures, the purpose of the disclosure, and describe the PHI routinely disclosed. The date of each disclosure need not be tracked. Rather, the accounting may include the date of the first and last such disclosure during the accounting period, and a description of the frequency or periodicity of such disclosures. For example, the vast amount of data exchanged between covered entities and public health authorities is made through ongoing, regular reporting or inspection requirement.”³

Example:

A covered entity routinely reports all cases of cancer it diagnoses or treats to the MCSS. The covered entity would not need to annotate each patient’s record whenever a routine public health disclosure is made. An accounting of such disclosures to a requesting individual would only need to identify the public health authority receiving the PHI (MDH/MCSS), the PHI disclosed (cancer cases), the purpose for the disclosure (required for cancer surveillance), the periodicity (monthly) if applicable, and the first and last dates of such disclosures during the accounting period (e.g., May 1, 2003 to June 1, 2003).

2. *Disclaimer of Legal Advice:* This is the Minnesota Department of Health’s (MDH) analysis of how a covered entity may account for public health disclosures to the MCSS and still be in compliance with the Health Insurance Portability and Accountability Act (HIPAA, privacy rules, 45 CFR 160 and 164). This is not legal advice and you should not rely on it as legal advice. Consult with a lawyer for legal advice.

3. April 11, 2003 Vol. 52/Early Release *MMWR*: HIPAA Privacy Rule and Public Health; Guidance from CDC and the U.S. Department of Health and Human Services, <http://www.cdc.gov/mmwr/pdf/other/m2e411.pdf>.