



NORTH AMERICAN ASSOCIATION OF CENTRAL CANCER REGISTRIES

FREQUENTLY ASKED QUESTIONS AND ANSWERS ABOUT CANCER REPORTING AND THE HIPAA PRIVACY RULE

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Betsy Kohler, MPH, CTR

Maureen MacIntyre, BSN, MHSA

Maria J. Schymura, PhD

Executive Director:

Holly L. Howe, PhD
2121 West White Oaks Drive
Suite C
Springfield, Illinois 62704-6495
(217) 698-0800 Ext. 2
(217) 698-0188 Fax
hhowe@naaccr.org

<http://www.naaccr.org>

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 a 'Public Health Authority' under HIPAA?

Under HIPAA, a 'Public Health Authority' refers to "an agency or authority of the United States, a State or territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate."¹ "...Such agencies are authorized by law to collect or receive such information for the purposes of preventing or controlling disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions."² Central cancer registries are considered public health authorities because state laws mandate their duties.

¹ 45 CFR 164.501

² 45 CFR 164.512

3. What is a 'Covered Entity' under HIPAA?

A 'Covered Entity' is a health care plan, a healthcare clearinghouse, or a health care provider who transmits any health information in electronic form for financial and administrative transactions. A 'health care provider' is "a provider of medical or health services, and any other person who furnishes, bills or is paid for health care in the normal course of business."¹

¹ 45 CFR 160.103

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4. Is it a violation of HIPAA for a covered entity to report information about cases of cancer to the state cancer registry?

No. Reporting information about cases of cancer in accordance with the requirements of state authorizing statutes and regulations is permitted by HIPAA. The Privacy Rule contains a specific provision authorizing covered entities to disclose protected health information as required by law.¹ In fact, penalties for failure to comply with state reporting are specified in state law and often consist of significant fines.

¹45 CFR 164.512(a)(1)

5. Since HIPAA is federal, will it override the state laws?

No. HIPAA does not obstruct any state law that supports or mandates the reporting of diseases or injury for public health purposes.

6. Is there specific legal documentation that supports the requirement to release cancer patient information to any agency?

Individual state laws and regulations document cancer reporting requirements. Central registries should consult their state laws and regulations regarding release of cancer patient information.

7. What, if any, are the consequences of not cooperating with state cancer registry requests for new cancer case information?

HIPAA does not obstruct any state law that supports or mandates the reporting of diseases or injury for public health purposes. Penalties for failing to comply with state reporting are specified in the state law and often consist of significant fines.

8. Does HIPAA require covered entities to obtain written authorization from the individual before reporting protected health information to the state cancer registry?

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.¹

¹45 CFR 164.512(a)(1)

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9. How does HIPAA impact the data collection of non-reportable/benign diseases (i.e. benign brain, CIN III, Co-morbid conditions)?

HIPAA does not obstruct any state law that supports or mandates the reporting of any disease.

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10. Are private practice physicians still required to report new cancer cases?

Yes, in compliance with state reporting regulations. The central cancer registry has a reportable list that identifies which cancers are reportable, and all reportable cancers should be reported, as required by state law.

11. Will private practice physicians and hospitals be permitted to continue to provide follow-up and treatment information to hospital cancer registries without patient authorization?

Yes. Although private practice physicians and hospitals are health providers, and thus covered under the provisions of the HIPAA privacy regulations,¹ they may continue to provide cancer patient follow-up and treatment information to hospital cancer registries without patient authorization when both the physician and the hospital has or had a relationship with the patient.

Under the HIPAA Final Privacy Rule, private practice physicians and hospitals may disclose confidential patient information to hospitals for the purpose of treatment, payment and **health care operations** (emphasis added) (quality assessment/improvement is considered a health care operation). A business associate agreement is not required between a hospital and physician for such purposes (emphasis added).

Section 164.506(c)(4), states, in relevant part, that

"A Covered Entity may disclose protected health information to another covered entity for health care operations activities of the entity that receives the information, if each entity either has or had a relationship with the individual who is the subject of the protected health information being requested, the protected health information pertains to such relationship, and the disclosure is:

(i) For a purpose listed in paragraph (1) or (2) of the definition of health care operations Section 164.501 of the Privacy Rule defines health care operations and Paragraph (1) of the definition provides, in relevant part:

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(1) Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, **population-based activities related to improving health** (emphasis added) or reducing health care costs, protocol development, case management and case coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment.

Paragraph (2) of the definition provides, in relevant part:

(2) Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers, training of non-health care professionals, accreditation, certification, licensing, or credentialing activities.

Thus, as hospital cancer registries collect treatment and follow-up data in compliance with state law and for the purpose of “population-based activities related to improving health” this is a permitted disclosure without requirement of patient authorization. It may also be noted that many hospital cancer registries collect this information for “conducting quality assessment and improvement activities”, for “reviewing the competence or qualifications of health care professionals”, for “conducting training programs” and for “accreditation, certification, licensing, or credentialing activities”. All of these are specifically permitted in paragraphs (1) and (2) shown above.

Note that Section 164.506(c)(4) specifically provides for the ability of one covered entity to provide an individual's PHI to another covered entity, if the receiving covered entity “has or had” a relationship with the individual. This specific reference to the past tense is important since it means that a covered entity's ability to obtain information about a patient need not be “cut-off” if the patient no longer has a direct relationship with the covered entity.

While exchange of treatment and follow-up information is permitted without patient authorization under the provisions described above, an accounting of disclosure must still be maintained.

¹45 CFR 160.103

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12. What if a patient does not want follow-up information to be collected?

State-mandated cancer reporting typically does not require patient informed consent nor can individuals elect to be removed from reporting. In a state which allows the collection of follow-up cancer data for public health purposes, it can be collected regardless of consent from a patient.

13. Once HIPAA is in place, will pathology labs be able to continue to send new cancer case information to the state cancer registry?

Yes. Public health reporting under the authority of state law is specifically exempted from HIPAA rules

14. If the government-authorized public health entity is not located in the same state as the covered entity, is it still ok under HIPAA to provide the data?

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."^{1,2}

¹ FR p. 82525

² 45 CFR 164.512

15. Are covered entities required to determine whether the information about cases of cancer reported to the state cancer registry 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.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 state cancer registry pursuant to state law and regulations.²

¹ 45 CFR 164.502(b)(1)

² 45 CFR 164.502(b)(2)(v)

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Holly L. Howe, PhD
2121 West White Oaks Drive
Suite C
Springfield, Illinois 62704-6495
(217) 698-0800 Ext. 2
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16. 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 state cancer registry?

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The Privacy Rule requires covered entities to verify a requester's identity before disclosing protected health information.¹ 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.² The Privacy Rule also requires covered entities to verify the requester's authority.³ A covered entity that reasonably relies on a written statement of the legal authority under which the information is requested will fulfill this requirement.⁴ To assist covered entities in meeting the verification requirements, the state cancer registry may elect to provide a written statement to cancer reporting facilities with the aforementioned information.

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Maria J. Schymura, PhD

¹45 CFR 164.514(h)(1)(i)

²45 CFR 164.514(h)(2)(ii)(C)

³45 CFR 164.514(h)(1)(i)

⁴45 CFR 164.514(h)(2)(iii)(A)

17. Are covered entities required to sign "business associate agreements" with regional or state cancer registries that perform on-site abstracting and cancer data reporting?

HIPAA requires business associate agreements with entities that carry out health care functions on behalf of covered entities, but state and regional registries are acting on behalf of the state when they provide on-site abstracting and reporting services, not the covered entity. Therefore, they are not business associates.

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Suite C
Springfield, Illinois 62704-6495
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18. Does HIPAA apply to the use or disclosure of information about cancer cases after it has been reported to the state cancer registry?

No. The Privacy Rule applies to disclosure of protected health information by covered entities as required by law; state cancer registries are not covered entities. However, state cancer registry authorizing legislation typically includes strict limits on use and disclosure of reported information.

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19. 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 state cancer registry?

Yes. The Privacy Rule requires covered entities to provide an accounting of disclosures of protected health information.¹ The accounting must include for each disclosure:

- The date of the disclosure
- The name of the entity or person who received the protected health information and, if known, the address of such entity or person
- A brief description of the protected health information disclosed
- A brief statement of the purpose of the disclosure that reasonably informs the individual of the basis for the disclosure or, in lieu of such statement, a copy of a written request for a disclosure under §164.502(a)(2)(ii) or 164.512, if any.¹

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Treasurer

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Representatives-at-Large:

¹45 CFR 164.528

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