



CALIFORNIA CANCER REGISTRARS ASSOCIATION
www.ccraregistrars.org

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To: CCRA Members and other Registry Professionals

Subject: HIPAA Question and Answer Document

Please find enclosed a HIPAA frequently asked questions (FAQ) document developed for your information and use. These FAQs have been prepared for educational purposes for registrars in regard to HIPAA Privacy Rule implementation and its impact upon hospital reporting of cancer. The individuals who have prepared these FAQs believe the information to be accurate but emphasize that this is a new law and is subject to interpretation. This document should be used for informational purposes only. Contact your own facility's HIPAA representative/officer for implementation policies specific to your facility.

This document was revised on April 16, 2003.

Frequently Asked Questions and Answers About the HIPAA Privacy Rule Regarding Hospital-based Cancer Registry Operations

1. When does the HIPAA Privacy Rule become effective?

The final Privacy Rule, which was approved August 14, 2002, becomes effective April 14, 2003.

2. 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 This includes most hospitals, clinics, and private practice physicians.

¹45 CFR 160.103

3. Are hospitals and in some cases, physicians still required to report cancer cases to the state cancer registry?

Yes. Public health reporting under the authority of state law is specifically exempted from the Privacy Rule regulations.¹ Cancer reporting law requires hospitals and physicians to report cancer patient information in most states.

¹45 CFR 154.512(b)(1)(i)

4. 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:

(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

5. Is a Business Associate agreement required when a physician provides treatment and follow-up information to a hospital cancer registry without patient consent?

No. 45 CFR 164.506 (c) (4) permits the disclosure of protected health information if both covered entities has or had a relationship with the patient. Additionally, "a health care provider that has a direct treatment relationship with an individual is not required by the Privacy Rule to obtain an individual's consent prior to using and disclosing information about him or her for

treatment, payment, and health care operations" (Federal Register, August 12, 2002, 45 CFR Parts 160 and 164, page 53211).

6. Is a Business Associate agreement required when two covered entities exchange treatment and follow-up information without patient consent?

No. 45 CFR 164.506 (c) (4) permits the disclosure of protected health information if both covered entities has or had a relationship with the patient. Additionally, "a health care provider that has a direct treatment relationship with an individual is not required by the Privacy Rule to obtain an individual's consent prior to using and disclosing information about him or her for treatment, payment, and health care operations" (Federal Register, August 12, 2002, 45 CFR Parts 160 and 164, page 53211)

7. When the hospital cancer registry reports to the state cancer registry, is an accounting of disclosures of protected health information required for the following: new case reports, follow-up records, correction records, deletion records, pathology only cases, tumor board/cancer conference only cases and consultation only cases?

Yes, either the hospital cancer registry or another department within the hospital must keep an accounting. 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

¹45 CFR 164.528

8. Are reporting facilities required to permit access to confidential patient records by state cancer registry staff for the purposes of assuring the completeness and accuracy of cancer reporting?

Yes, if state law permits the state cancer registry to perform these studies.

9. Is a hospital-based cancer registry required to keep an accounting of disclosures for protected health information released to researchers?

HIPAA Privacy Rules for release of protected health information for research purposes are different from the above-described permissions for mandatory cancer reporting. See your HIPAA privacy officer for research release policies.

10. Can a covered entity request and obtain x-ray reports, specimen slides, and medical records for a specific patient from another covered entity for the purpose of cancer conference/tumor board presentations without patient consent?

Yes. Cancer Conferences/Tumor Boards are forums that provide a multidisciplinary team approach for diagnosing and staging cancer patients and recommending treatment options. These activities fall under treatment and health care operations.

45 CFR 164.506 (c) (4) permits the disclosure of protected health information if both covered entities has or had a relationship with the patient. Additionally, "a health care provider that has a direct treatment relationship with an individual is not required by the Privacy Rule to obtain an individual's consent prior to using and disclosing information about him or her for treatment, payment, and health care operations" (Federal Register, August 12, 2002, 45 CFR Parts 160 and 164, page 53211)

11. Can an American College of Surgeons (ACoS) approved cancer registry contribute data to the ACoS National Cancer Data Base?

Yes, if a business associate agreement for this activity is in place. For more information, contact the American College of Surgeons, Commission on Cancer at www.facs.org.

12. Is a Business Associate agreement required when an independent contractor (vendor) performs cancer reporting activities for a covered entity?

Yes. 45 CFR 164.502 (e) permits disclosure of protected health information to a business associate. A business association occurs when the right to use or disclose the protected health information belongs to the covered entity, and another person is using or disclosing the protected health information (or creating, obtaining and using the protected health information) to perform a function or activity on behalf of the covered entity.

13. Our hospital-based cancer registry contracts with the regional or state cancer registry to help abstract and report our cases. Do we need to have a Business Associate agreement with the regional or state cancer registry?

No. The Privacy Rule requires business associate agreements with entities that carry out health care functions on behalf of the covered entities. State and regional cancer registries are acting on behalf on the state when they provide on-site abstracting and reporting services, not the covered entity.

14. Is a covered entity required to mention in their privacy notice, the disclosure of protected health information for cancer reporting?

Yes. The Privacy Notice must contain language relating to required disclosures of protected health information, one of which is to the regional cancer registry, a public health authority.

45 CFR 164.520 (1) (B)

OFFICIAL FEDERAL GOVERNMENT HIPAA WEB SOURCES

1. <http://www.hhs.gov/ocr/hipaa/>

Contents:

Office for Civil Rights - HIPAA
 Medical Privacy - National Standards to Protect the Privacy of Personal Health Information
 What's New - Updated 3/13/03 with New FAQs, New FAQs Search Tool and The Address for Submitting Requests for Preemption Exception Determinations.
 Background and General Information
 Privacy Regulation
 Technical Assistance
 News 2002
 News 2001
 News 2000
 Other Relevant Sites

2. <http://www.hhs.gov/ocr/hipaa/privacy.html>

Contents:

Office for Civil Rights - HIPAA
 Medical Privacy - National Standards to Protect the Privacy of Personal Health Information
 OCR Guidance Explaining Significant Aspects of the Privacy Rule - December 4, 2002

3. <http://www.hhs.gov/ocr/hipaa/finalreg.html>

Contents:

Final Modifications to Privacy Rule
 Final Modifications to the Privacy Rule, Federal Register, August 14, 2002
 [Text / PDF]
 Privacy Rule
 October 10, 2002 Complete Privacy Rule Text, as modified
 Complete Regulation Text for Privacy Rule (Parts 160 and 164), as modified (05/31/02, 08/14/02), -
 Unofficial version [PDF = 2.5M]
 (The Office of the Federal Register publishes the official version of all federal regulations in the Code of
 Federal Regulations (CFR).)
 Correction of Effective and Compliance Dates, Federal Register, 2/26/01
 [Text / PDF]
 Technical Corrections to the Rule, Federal Register, 12/29/00 [Text / PDF]
 Rule in PDF Format, 12/28/00 -- Zipped [2.6M]
 or in 8 parts: Part 1 | Part 2 | Part 3 | Part 4 | Part 5 | Part 6 | Part 7 | Part 8
 Rule in Text Format, 12/28/00 -- Zipped [725K]
 or in 8 parts: Part 1 | Part 2 | Part 3 | Part 4 | Part 5 | Part 6 | Part 7 | Part 8
 Rule in HTML Format, 12/28/00 -- Part 1 | Part 2 | Part 3 | Part 4 | Regulation Text Only

OTHER PERTINENT WEB SITES

American College of Surgeons (www.facs.org)

North American Association of Central Cancer Registries (www.naacrr.org)