



**FREQUENTLY ASKED QUESTIONS (FAQS)
RECEIVED BY THE COC RELATED TO HIPAA**

Can my hospital continue to submit data to the National Cancer Data Base? Yes

August 14 Rules and Regulations, **Federal Register** Vol. 67, no. 157.

The College is entering into Business Associate (BA) agreements with hospitals in order for the College to provide a service to the hospital, namely, quality assessment/improvement related to cancer treatment through the National Cancer Data Base.

Under the terms of the BA Agreement, hospitals may disclose protected health information (PHI) to the College and the College agrees to protect and safeguard such information.

Can I as a registrar and an agent for the hospital, continue to get treatment and follow-up information from other hospitals and physicians not on the medical staff at my hospital? - Yes

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

Based on our interpretation of the Final Privacy Rule, issued on August 14, 2002, follow-up with a cancer patient is permissible under Section 164.506(c)(4), which 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 or
- (ii) For the purpose of health care fraud and abuse detection or compliance."

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 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.

We consider the College's activities related to the National Cancer Data Base to be for quality assessment and improvement purposes, including outcomes evaluation. Such activities are specifically included in paragraph (1) of the definition of health care operations quoted 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 had (past tense) 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 for quality assessment and improvement purposes need not be "cut-off" if the patient no longer has a direct relationship with the covered entity.

Example of Follow-Up, a Hypothetical Situation:

Our interpretation of Section 164.506(c)(4) may be applied in the following hypothetical situation:

Hospital 1 has a BA Agreement with the College. Patient Smith sees Dr. A at Hospital 1 for cancer treatment. Dr. A discloses information about Patient Smith to Hospital 1 and Hospital 1 gives the information to the College under the BA Agreement.

Patient Smith moves away and is now being treated by Dr. B, affiliated with Hospital 2. Hospital 2 may or may not have a BA Agreement with the College. Dr. B may disclose follow-up information received from Patient Smith to Hospital 1 and/or Hospital 2, since the covered entities (both the physicians and the hospitals) have or had a relationship with Patient Smith, the PHI pertains to that relationship, and the information is being disclosed for the quality assessment and improvement activities of Hospital 1 and/or 2.

Can Cancer Conferences Continue? - Yes

August 14 Rules and Regulations, Federal Register Vol. 67, no. 157.

Cancer conferences are critical to the cancer approval's program. These conferences serve as means to improve the quality of care a cancer patient receives at that program. The regulations recognize the need for such activities, specifically - quality improvement/assurance and accreditation (Section 160.103, p. 53248) - and particularly so in the definition of the relationship between the program (the covered entity) and the business associate (the College).

Cancer conferences serve as a means for quality improvement/assurance. The Department of Health and Human Services (DHHS) designed the final HIPAA regulations to be "sufficiently flexible to accommodate the various circumstances of any covered entity.... (Specifically) A covered entity's policies and procedures may and should allow the appropriate individuals within an entity to have access to protected Health Information (PHI) as necessary to perform their jobs with respect to the entity's covered functions" (p. 53197). The Cancer Committee should define what information will be included on the agenda, who can/cannot attend conference and for what purpose the cancer conference serves relative to treatment, quality improvement, and approvals.

"The minimum necessary standard is not intended to impede essential treatment, payment, or health care operations activities of covered entities. Nor is the Rule intended to change the way covered entities handle their difference with respect to disclosure of PHI. The Department recognizes that, in some cases, an individual's entire medical record may be necessary for payment or health care operations purposes, including disease management purposes." (p. 53197).

What Protected Health Information Is Sent to the NCDB? A limited data set, pending existence of a business associate agreement.

The data transmitted to the NCDB meet the Standards for a Limited Data Set as defined in Section 164.514(e), pp. 53270-53271, **Federal Register, Vol. 67** (157), 8/14/2002. A covered entity may use or disclose a limited data set if the covered entity enters into a data use agreement with the limited data set recipient (e) (1) for the purpose of health care operations (e) (3) (in this instance, quality improvement and accreditation) if the following requirements are met (e) (2). The rule specifies the removal of the following direct identifiers to qualify for a Limited Data Set: 1) Name, 2) Street Address, 3) Phone/Fax numbers, 4) e-mail address, 5) Social Security Number, 6) Certificate/license number, 7) Vehicle identifiers, 8) URLs and IP addresses, 9) full face photos, etc., 10) Medical record numbers, 11) Health beneficiary numbers, 12, Other account numbers, 13) Device identifiers/serial numbers, and 14) Biometric identifiers. These data may be collected locally, and in some states transmitted to the State Registry, but none of these items are sent to the NCDB (See Chap. IX, Required Status Table (Item # Order). In **Standards for Cancer Registries, Data Standards and Data Dictionary, 7th ed, Record Layout Version 10**, ed., D. Hulstrom, Springfield, IL, North American Association of Central Cancer Registries, pp. 107-118).

What if my institution refuses to sign the Business Associate Agreement with the College?

The Business Associate Agreement allows the College to schedule and perform cancer program surveys at facilities currently approved by the Commission on Cancer as well as programs applying for initial approval, include facility data in the NCDB data base, and provide participating facilities with an analysis of their own data and aggregated comparative data on outcomes for the purpose of quality improvement.

A facility that has not signed the Business Associate Agreement within 6 months of notification will be identified as a facility that no longer wishes to participate in the Commission on Cancer Approvals Program. A warning letter will be sent at the 6-month interval, which will provide the facility with an additional 30 days to sign the BA agreement or be removed from the Approvals Program. A final letter notifying the facility that they have been removed will be sent to the facility administrator with copies provided to the cancer committee chair, Cancer Liaison Physician, cancer registrar, and Cancer Liaison State Chair. The Approval status can be reinstated if the facility signs the Business Associate Agreement within 30 days of the date of the final notification letter.

Programs that are currently approved as well as new programs must sign the Business Associate Agreement before scheduling a survey date.

Why must I send cancer committee minutes to the surveyor prior to the Survey? Will this be permissible under HIPAA?

The Commission on Cancer is an organization that performs activities such as quality assurance and improvement and approval functions for a covered entity, as the Commission is the recognized grantor of that status for cancer programs. Cancer Program Standards, 2004 specify that cancer committee minutes be provided to the surveyor prior to the on-site visit.

Cancer committee minutes provide documentation of multiple areas of program activity and are needed for advance review so that the surveyor can adequately prepare for the survey visit and accurately assess program activity.

The Business Associate agreement signed by each approved program allows cancer committee minutes to be provided to the surveyor prior to the on-site visit.