HIPAA is already law

HIPAA was passed by the Clinton administration in 1996, but enactment was delayed until April 12, 2001 at which date the Bush administration passed HIPAA into law. Covered entities have two years to comply (April 14, 2003). Smaller health plans are afforded an extra year to comply (April 14, 2004). However, all covered entities (that are not yet HIPAA compliant) were required to file a HIPAA compliance by October 15, 2002.

HIPAA sets national minimum standard

Historically, state statutes set forth by a state’s department of health or other public health authority governs cancer registries reporting activities. States vary considerably on the stringency of health privacy law; therefore HIPAA seeks to establish a minimum standard. Think of HIPAA as a floor (rather than a ceiling) of national standards.

If current state laws are stricter than HIPAA regulations, then state law overrides HIPAA. Conversely, if HIPAA is stricter than existing state regulations, then HIPAA presides.

It is not always readily apparent which is applicable (state law or HIPAA). American Health Information Management (AHIMA) has published a useful “preemption decision form” to aid in the process. There are other good decision grids available online in various health law and health privacy web sites. However, it is only a guideline and not intended as definitive answer for determining preemption. Your facility’s Legal Department should be consulted to conclude preemption issues.

HIPAA why does it keep changing?

The health care industry has responded to HIPAA with testimony and comments detailing the impact of HIPAA on the healthcare process. It was never the intention of HIPAA to interfere with patient access to care or relationships with healthcare provider(s). The U.S. Department of Health and Human Services (DHHS) realizes that there may be inadvertent consequences as HIPAA is put into practice as with many complex pieces of legislation. Therefore, DHHS introduces new regulations and modifications to the legislation as it was originally written by congress. These changes begin as a Notice of Proposed Rule Modification (NPRM). The NPRM is published and a comments period - usually 30 days - offers the opportunity for comment or questions about the proposed changes. There were 11,000 comments received in response to the last NPRM’s considered in the most recent ““Final Rule”. Through the NPRM process, HIPAA continues to reduce unintended impact to the healthcare process. A ““Final Rule”” was published August 14, 2002 and is the current set of HIPAA standards. In the years ahead, there will surely be more ““Final Rules”” as HIPAA matures.
HIPAA who is in charge?

The U.S. Department of Health and Human Services is directed by congress to oversee the implementation of HIPAA. DHHS authorizes the HIPAA “Final Rule” as published in the Federal register. The DHHS Office for Civil Rights (OCR) is the body that will enforce the privacy and security portions of HIPAA. DHHS has directed Centers for Medicare and Medicaid (CMS) to enforce the transaction Code Set Rules of HIPAA.

OCR regularly provides official “Guidance” on their web site as a response to frequently asked questions. Additionally DHHS publishes fact sheets and other resource materials on their web site http://www.hhs.gov/news. Both are easily accessible and up-to-date information sources.

HIPAA reduced

There are many sections, subsections, parts and regulations of HIPAA. This paper is focused on privacy and security issues relating to the cancer registry function. With that in mind, HIPAA may be thought of in three distinct topics.

- Continuity of Insurance Coverage.
- Fraud and Abuse Prevention
- Administrative simplification (privacy and security)

Part 160 – (160.101-160.312) pertains mainly to the administrative simplification provisions seek to unify and simply the claims process by setting national standards for electronic healthcare transactions (but also applies to paper transactions). This is directed at the billing and insurance claims process.

Part 164 – (164.102-164.534) is thought of as the security and privacy portion of HIPAA and seeks to protect personal health information (PHI) of patients and their rights to protect their privacy. For the most part, the cancer registry function is concerned with this part of HIPAA. Specifically, follow-up functions of a registry can collide with patient rights that are protected under HIPAA.

HIPAA Frequently Asked Questions

- Is a business agreement needed to be HIPAA compliant?
- Is my registry/facility a covered entity (CE)?

How does HIPAA affect:
- The exchange of data within the reporting facility?
- The exchange of data within and outside of the state?
- Patient follow-up operations?
- Obtaining PHI from external physicians?
- Patient follow-up?

Under the current August 14, 2002 “Final Rule”, many of the cancer registry functions are being carried out under the “operations” umbrella of HIPAA regulations known as “...consent for uses and disclosures to carry out treatment, payment or healthcare operations....” (T/P/O). (164.506, (a)(2) and (3) of 45CFR). “Operations” include “...quality assessment and improvement activities” and “population-based activities relating to improving health or reducing health care costs”. This allows hospitals and physicians to disclose PHI, including first course of treatment and follow-up to each other for specified healthcare operations, provided that both covered entities have a relationship with the patient. Patient follow-up many years after treatment (or encounter) remains an area that needs further clarification by OCR in future modifications to the “Final Rule”.

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HIPAA “Accounting of Disclosure” concerns

HIPAA guarantees a patient’s right to know to whom his or her PHI has been disclosed without their consent. To meet this HIPAA requirement a CE must maintain an “accounting of disclosure” which is essentially a record (kept for the most recent six years of disclosures) of “what, where, when, to whom and for what purpose” any PHI was disclosed without patient consent. This includes data submissions to state and central cancer registries that are covered under law and to researchers conducting special studies. It has been suggested that “accounting of disclosure” requirements could be designed into the software used in registry reporting. There are already many competitors working in tandem with CEs and DHHS to develop software to address HIPAA compliance.

HIPAA business associate agreement

Until HIPAA regulations are revised with more clarifications and protections, some CE’s are opting to enter into a business associate agreement (BA) that restricts the business associate to further exchange PHI beyond purposes and regulations delineated in HIPAA. The American College of Surgeons Commission on Cancer is pursuing business associate relationships with hospitals so that it may continue to receive data for the National Cancer Data Base.

If your state law requires the submission of annual follow-up, you and your physicians are protected from penalties or violations of the privacy rule when requesting follow up PHI. However, many states require only incidence (first time) reporting of cancer cases. Even under existing state law protections, it would seem a prudent measure to enter into a business associate agreement with medical staff and off site treating physicians as a safety net if the release of PHI is ever challenged. A sample Business Associate agreement authored by Office for Civil Rights may be downloaded at the OCR web site [http://www.hhs.gov/ocr/hipaa/contractprov.html](http://www.hhs.gov/ocr/hipaa/contractprov.html)

HIPAA navigation tools

Since HIPAA is and will continue to be an evolving body of regulations, it is a good practice to keep a current “Final Rule” and applicable 45 CFR for reference. This can be downloaded free of charge at [http://www.access.gpo.gov/nara/cfr/index.html](http://www.access.gpo.gov/nara/cfr/index.html). Other essential web addresses for valuable sources of concise and up to date HIPAA information are:

OCR [http://www.hhs.gov/ocr/hipaa/contractprov.html](http://www.hhs.gov/ocr/hipaa/contractprov.html),
DHHS [http://www.os.dhhs.gov/ocr/hipaa/](http://www.os.dhhs.gov/ocr/hipaa/) and

Guidance in sample forms and models that may prove helpful in the field:
North American Association of Central Cancer Registries (NAACCR) Model letter for physicians to release of PHI (Consent from OCR FAQ sheet) available at [http://www.naaccr.org/Training/files/ModelLetterforCentralCancerRegistriestosendtoReportingFacilities.pdf](http://www.naaccr.org/Training/files/ModelLetterforCentralCancerRegistriestosendtoReportingFacilities.pdf) This is a blanket letter that could be provided to physicians reluctant to release follow-up PHI for concerns of violating HIPAA.

American Health Information Association (AHIMA) sample preemption decision form at: [http://library.ahima.org/xpedio/groups/public/documents/ahima/pub_bok1_010548.html](http://library.ahima.org/xpedio/groups/public/documents/ahima/pub_bok1_010548.html) This form is helpful in understanding whether HIPAA or state law applies to a specific situation. However, your Legal Department is the ultimate guide.
HIPAA legislative avenues

Identify and write to your state legislator to influence the process. The following web site can assist in identifying and contacting (email, post and phone) your local and state representatives. http://www.house.gov/MemStateSearch.html Additionally, AHIMA link http://www.ahima.org/dc/guide.doc, “Guidebook for effective interaction with Federal and State Governments” is an excellent source for model letters and language formats for corresponding with legislative entities.

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HIPAA Resources

If you are in a Commission on Cancer approved program, contact Greer Gay at the CoC <GGay@facs.org> or (312) 202-5439. If not, contact your privacy officer at your facility. They should have access to the information on HIPAA that affects follow-up.

Department of Health and Human Services (DHHS)
http://www.hhs.gov/ocr/hipaa/
http://www.hhs.gov/ocr/hipaa/contractprov.html

Federal Register

Office of Civil Rights (OCR)

Department of Health and Human Services (DHHS)
http://www.os.dhhs.gov/ocr/hipaa/

Centers for Medicare and Medicaid (CMS)
http://cms.hhs.gov/hipaa/

North American Association of Central Cancer Registries (NAACCR)

American Health Information Management Association (AHIMA)
http://library.ahima.org/xpedio/groups/public/documents/ahima/pub_bok1_010548.html
http://www.ahima.org/dc/guide.doc

U.S. House of Representatives’ Lookup
http://www.house.gov/MemStateSearch.html


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