Defining the Designated Record Set

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On December 28, 2000, the federal government published the Standards for Privacy of Individually Identifiable Health Information, more commonly referred to as the HIPAA privacy rule. The privacy rule was amended on August 14, 2002. The rule establishes the right of individuals to inspect, obtain a copy of, and request amendments to information about them in a designated record set. But what is a designated record set?

HIPAA Privacy Rule

Privacy Rule Standards

Section 164.524 of the privacy rule states that individuals generally have a right to inspect and obtain a copy of protected health information (PHI) about them in a designated record set.

In addition, section 164.526 of the rule states that individuals generally have a right to have a covered entity amend PHI about them in a designated record set.

Privacy Rule Definitions

The privacy rule (section 164.501) provides the following definitions for designated record set and PHI in order to clarify the access and amendment standards summarized in the previous paragraphs.

Designated record set is defined as a group of records maintained by or for a covered entity that is:

- the medical and billing records about individuals maintained by or for a covered healthcare provider
- the enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan, or
- information used in whole or in part by or for the covered entity to make decisions about individuals

Protected health information is defined as individually identifiable health information maintained in or transmitted by electronic media (Internet, extranet, leased lines, dial-up lines, private networks, magnetic tape, disks, or compact disk media). The definition specifically excludes education and employment records.

Privacy Rule Preamble

In addition to the definition of designated record set, the December 28, 2000, privacy rule preamble provides some additional guidelines.

The preamble states that for covered healthcare providers, designated record sets include, at a minimum, the medical and billing records about individuals maintained by or for the provider. The preamble also says that the minimum designated record set for health plans includes the enrollment, payment, claims adjudication, and case or medical management record systems of the plan. Additionally, the preamble states that designated record sets include any other group of records used in whole or in part, by or for a covered entity, to make decisions about individuals.

According to the preamble, records held by a business associate that meet the definition of designated record set are part of the covered entity's designated record set. However, the individual's rights to access, amend, and receive an accounting of

disclosures does not attach to the business associate's records if the business associate's information is the same as information maintained by the covered entity.

Although the privacy rule does not mention a clearinghouse's minimum designated record set specifically, the preamble notes that where clearinghouses are business associates of covered entities or maintain records that are used in whole or part to make decisions about individuals, clearinghouses may indeed have designated record sets.

The preamble emphasizes that individuals have a right to access and request amendments only to PHI in a designated record set. Therefore, information obtained during a phone conversation, for example, is subject to access only to the extent that it is recorded in the designated record set. The rule does not require a covered entity to provide access to all individually identifiable health information, because the benefits of access to information not used to make decisions about individuals is limited and is outweighed by the burdens of locating, retrieving, and providing access to such information.

The preamble also underscores the fact that covered entities often incorporate the same PHI in a variety of different data systems, not all of which will be used to make decisions about individuals. The preamble provides an example in which information systems used for quality control or peer review analyses may not be used to make decisions about individuals. In this example, the preamble says the information systems would not fall within the definition of designated record set. Furthermore, the preamble states that it does not require entities to grant an individual access to PHI maintained in these types of information systems.

The privacy rule and discussions in the preamble also make it clear that individuals do not have a right of access to:

- psychotherapy notes
- information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding
- PHI held by clinical laboratories if the Clinical Laboratory Improvements Amendments of 1988 (CLIA) prohibit such access
- PHI held by certain research laboratories that are exempt from the CLIA regulations (164.524)

CLIA regulations state that clinical laboratories may provide clinical laboratory test records and reports only to "authorized persons," as defined primarily by state law. When, according to state law, an individual is not an authorized person, this restriction effectively prohibits the clinical laboratory from providing an individual direct access to this information.

Individuals do not have access to PHI held by certain research laboratories that are exempt from the CLIA regulations. The CLIA regulations specifically exempt the components or functions of research laboratories that test human specimens but do not report patient-specific results for the diagnosis, prevention, or treatment of any disease, impairment, or assessment of the health of individual patients.

Section 164.524 of the preamble states that a general principle is that a covered entity is to provide access to PHI in accordance with the rule regardless of whether the covered entity created the information.

The rule defines, however, rare circumstances in which access to information contained within the designated record set can be denied. For example, access can be denied when, in the exercise of professional judgment, it is likely to endanger the life or physical safety of the individual or another person.

Other Federal Laws/Regulations

Other federal laws and regulations also give individuals the right to access their health information.

The Privacy Act of 1974, like the HIPAA privacy rule, gives individuals the right to access and request amendments to their records.[1] The act defines record as "any item, collection, or grouping of information about an individual that is maintained by an agency, including, but not limited to, his education, financial transactions, medical history, and criminal or employment history and that contains his name, or the identifying number, symbol, or other identifying particular assigned to the individual, such as a finger or voice print or a photograph."

The Medicare Conditions of Participation for State Long-term Care Facilities state that the resident or his or her legal representative has the right to access "all records pertaining to himself or herself" including current clinical records.[2] All

records is not defined, however.

The Confidentiality of Alcohol and Drug Abuse Patient Records regulation allows federally subsidized alcohol and drug abuse programs to give patients access to their own records, including the opportunity to inspect and copy any records that the program maintains about the patient.[3] The regulation defines records as "any information, whether recorded or not, relating to a patient received or acquired by a federally assisted alcohol or drug program."

The Occupational Safety and Health Administration (OSHA) requires that employers document certain employee injuries, including medical care provided in relation to those injuries. Employees and their designated representatives generally have access to such reports of injuries and related health records.[4]

The HIPAA privacy rule makes it clear that it is not intended to preempt other existing federal laws and regulations. Therefore, if an individual's rights of access are greater under another applicable federal law, the individual should be afforded the greater access.

State Laws

Many states have laws or regulations that give individuals the right to their health information. Some state laws may define health information more broadly than the privacy rule. Some states may not limit access and amendment to PHI in a designated record set. When state laws or regulations afford individuals greater rights of access, the covered entity must adhere to state law (section 45 CFR 160.201-160.205).

Discussion

The authors of the HIPAA privacy rule attempted to balance the difficulties faced by covered entities in providing individuals with all the information maintained about them with an individual's right to information. By using the term designated record set, the privacy rule attempts to relieve organizations of the need to retrieve information from telephone message pads, surgery schedules, appointment logs, and other databases in which individual health information might appear but that is not used to make care or payment decisions about the individual.

Yet, despite the definitions and discussions about the designated record set in the privacy rule, organizations struggle to decide what should and should not be considered their designated record set. The tables in this article attempt to provide covered entities with additional guidance. See "What's Included in the Designated Record Set" and "What's Outside the Designated Record Set," below for examples.

What's Included in the Designated Record Set

Designated Record Set	Examples
Medical record of covered providers	• The content of the chart in a paper-based provider office • The information defined as the legal health record in a computer-based record environment[5]
Billing record of covered providers	• The content of the patient account file in a paper-based provider office • The information defined as patient account data in a computer-based record environment
The enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan	The information defined as enrollment, payment, claims adjudication, and case or medical management information in a health plan information system

Other records used to make decisions about the individual	• A history and physical generated by a physician at a hospital and incorporated into the resident's record in a long-term care facility because it will be used to make decisions about the individual • Copies of reports generated by other providers and used to make decisions about the individual, even when such records are kept in a separate location or file folder • E-mail communications that an organization stores online and hasn't printed out in its otherwise paper-based health record
Records maintained by a business associate that meet the definition of designated record set that are not merely duplicates of information maintained by the covered entity to requests	Records maintained by record storage companies that have agreed to manage release of information rather than returning the records to the covered entity to respond

What's Outside the Designated Record Set

Outside the Designated Record Set	Examples
Health information generated, collected, or maintained for purposes that do not include decision making about the individual	• Data collected and maintained for research • Data collected and maintained for peer review purposes • Data collected and maintained for performance improvement purposes • Appointment and surgery schedules • Birth and death registers • Surgery registers • Diagnostic or operative indexes • Duplicate copies of information that can also be located in the individual's medical or billing record
Psychotherapy notes	The notes of a mental health professional about counseling sessions that are maintained separate and apart from the regular health record
Information compiled in reasonable anticipation of or for use in a civil, criminal, or administrative action or proceeding	Notes taken by a covered entity during a meeting with the covered entity's attorney about a pending lawsuit
CLIA	• Requisitions for laboratory tests • Duplicate lab results when the originals are filed in the individual's paper chart
Employer records	• Pre-employment physicals maintained in human resource files • The results of HIV tests maintained by the infectious disease control nurse on employees

	who have suffered needle stick injuries on the job
Individually identifiable health information maintained by organizations that are not covered entities as defined by HIPAA	Health records in a dental office that maintains all its records and billing systems manually
Business associate records that meet the definition of designated record set but that merely duplicate information maintained by the covered entity	Transcribed operative reports that have been transmitted to the covered entity
Education records	Records generated and maintained by teachers and teachers' aides employed by a school district in an institution for the developmentally disabled
Source data interpreted or summarized in the individual's medical or health record	• Pathology slides • Diagnostic films • Electrocardiogram tracings from which interpretations are derived

The privacy rule does not specifically address source data such as pathology slides, diagnostic films, and tracings. However, narrative throughout the preamble suggests that providing interpretations from source data would generally be acceptable. In most cases, individuals cannot interpret source data, so such data is meaningless. On the other hand, the interpretations of source data provide individuals with information needed to make informed decisions about their healthcare.

There may be times, however, when an individual has a legitimate need to access source data. When such a need arises, the covered entity will want to provide the individual with greater rights of access, allowing the individual access to or copies of the source data when possible.

Recommendations

The following are recommendations for managing designated record sets in your organization:

- Become familiar with federal and state laws and regulations that define what information individuals may access and amend
- Identify the records you believe individuals have the right to access and amend under state and federal laws and regulations
- Apply HIPAA's preemption standards where individuals' rights to access and amend are not the same under other federal or state laws and regulations
- Consult legal counsel when indicated
- Define your organization's designated record set in policy and procedure
- When an individual requests source data that is not considered part of the designated record set, provide the individual with access to or a copy of the source data when such access is possible, would not violate state or federal laws or regulations, and would not endanger the privacy, health, or safety of the individual or another individual

Notes

1. Privacy Act of 1974. 5 USC, Section 552A. Available at http://www.usdoj.gov/foia/privstat.htm.

2. Health Care Financing Administration, Department of Health and Human Services. "Conditions of Participation for State Long-term Care Facilities." *Code of Federal Regulations*, 2000. 42 CFR, Chapter IV, Part 483. Available at www.access.gpo. gov/nara/cfr/index.html

3. "Confidentiality of Alcohol and Drug Abuse Patient Records." 42 CFR, Part 2. Available at www.access.gpo.gov/nara/cfr/index.html.

4. Occupational Safety and Health Administration, Department of Labor. "Recording and Reporting Occupational Injuries and Illnesses." *Code of Federal Regulations*, 2002. 29 CFR, Chapter 17, Part 1904.35, Section 657.

5. Amatayakul, Margret et al. "Practice Brief: Definition of the Health Record for Legal Purposes." *Journal of AHIMA* 72, no. 9 (2001): 88A-H. Available at www.ahima.org/_journal/pb.html.

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"Standards for Privacy of Individually Identifiable Health Information; Final Rule." 45 CFR Parts 160 and 164. *Federal Register* 65, no. 250 (December 28, 2000). Available at http://aspe.hhs.gov/admnsimp.

"Standards for Privacy of Individually Identifiable Health Information; Final Rule." 45 CFR Parts 160 and 164. *Federal Register* 67, no. 157 (August 14, 2002). Available at http://aspe.hhs. gov/admnsimp.

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