Designated Record Set Guidance

January 6, 2003

The purpose of this guidance is to identify groups of records called "designated record sets" that persons served have the right to access and amend.

Definitions

Designated record set means:

1) A group of records maintained by or for health care provider, that is:
   a) The medical records and billing records about individuals maintained by or for a covered health care provider; or
   b) Used, in whole or in part, by or health care provider to make decisions about individuals.
2) For purposes of this definition, the term record means any item, collection, or grouping of information that includes protected health information and is maintained, collected, used, or disseminated by or for health care provider.

Individually identifiable health information is information that is a subset of health information, including demographic information collected from an individual, and:

1) Is created or received by a health care provider; and
2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and
   a) That identifies the individual; or
   b) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

Protected health information ***(PHI)***:

1) Includes individually identifiable health information that is:
   a) Transmitted by electronic media;
   b) Maintained in the internet, extranet, leased lines, dial-up lines, private networks and those transmissions that are physically moved from one location to another using magnetic tape, disk or compact disk media; or
   c) Transmitted or maintained in any other form or medium.
2) Excludes individually identifiable health information in:
   a) Education records covered by the Family Educational Right and Privacy Act, as amended, 20 U.S.C. 1232g including records described at 20 U.S.C. 1232g(a)(4)(B)(iv) as follows:
      i) Of students who are 18 years or older or are attending post-secondary educational institutions,
      ii) Maintained by a physician, psychiatrist, psychologist, or recognized professional or paraprofessional acting or assisting in that capacity,
      iii) That are made, maintained, or used only in connection with the provision of treatment to the student, and
      iv) That are not available to anyone, except a physician or appropriate professional reviewing the record as designated by the student.
   b) Employment records held by a health care provider in its role as employer.

Process Notes[1] means notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during

[1] The HIPAA Privacy Regulations refer to "Process Notes" as "Psychotherapy Notes."

a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the individual's medical record. Psychotherapy notes exclude medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date.

What type of information should be considered as Designated Record Sets?

1) Health information created and/or maintained by a health care provider for the purpose of making decisions about individuals. The following health information should be considered when specifying designated record sets:
   a) Medical Records –
      i) Specify what constitutes the medical record in your organization (e.g., paper records stored in medical record folders maintained in Health Information Management Department; active medical records utilized by health care staff prior to client discharge).
      ii) Includes both paper and electronic versions
   b) Financial Records –
      i) For the following, specify if the Designated Record Set is the automated system or a report produced by an automated system.
         (1) Financial Responsibility Form
         (2) Demographic Data Sheet
         (3) Emergency Medical Care Plan Form
         (4) Financial Appeals
         (5) Insurance Benefits Form
   c) "Working" Records – (NOTE: If not summarized elsewhere then, "working records" used to make decisions about a person served need to be considered as part of the Designated Record Set.)
      i) Raw test data from psychological tests
      ii) Audiotapes (e.g., dictation tapes, taped sessions with consumers/family that would not be considered psychotherapy notes)
      iii) Videos/photographs of patients used for teaching purposes
      iv) Telemedicine
      v) Coding Worksheets
      vi) X-ray film
      vii) Working notes summarized and dictated into the medical record

2) Health information specifically created and/or maintained by Business Associates when acting on behalf of your organization, as specified in a Business Associate Agreement.
   a) For example, billing records maintained by a private billing service
   b) Do not include duplicative information that is also maintained by the health care provider

What type of information should NOT be in a Designated Record Set?

1) Health information that is not used to make decisions about individuals or information that the person served does not have a right of access based on state or federal law. Some examples follow.
   a) Process Notes or Psychotherapy Notes (as defined) ***(HIPAA Regulations conflict with Virginia Human Rights Regulations which allow persons served to have***

access to these notes. Therefore in Virginia Process or Psychotherapy Notes must be part of the Designated Record Set.)

b) Copies of reports/documentation/forms wherein the originals are maintained in an 'official' record maintained by the organization
   i) Copies produced from original records maintained by the organization should be limited and should not be disclosed outside the health care provider.
   ii) Copies of health information that are maintained in more than one location must be protected but only the original document should be included in a designated record set.
   iii) If the same protected health information is maintained in more than one location, the health care provider is required to produce the information only once.
c) Quality Improvement records/Utilization Review
d) Risk Management records
e) Research documentation (Note: When protected health information is created or obtained by a covered health care provider/researcher for a clinical trial, the Privacy Rule permits the patient's access rights in these cases to be suspended while the clinical trial is in progress, provided the research participant agreed to this denial of access when consenting to participate in the clinical trial.)
f) Information compiled in reasonable anticipation of, or for use in civil, criminal, or administrative action or proceeding (e.g., Incident Reports - used to identify problems and implement corrective action)

Example of Designated Record Set Matrix (DRSM)

DRSM – Access & Amend	DRSM – Access Only	Not Part of DRSM
Paper Medical Record in Health Information Department		
Process Notes kept by the originator (must obtain authorization to use these notes for anything other than supervision or training)		
Third-party information in Medical Record		Video/Audio Tapes used for training
MIS data and automated medical record		Raw data from psychological assessments if information is available in summary form
Financial Records		
Third-party information in Financial Records		Quality improvement records unless the records are used to make decisions about a case
		Risk management records unless the records are used to make decisions about a case
		Utilization management records unless the records are used to make decisions about a case and is not summarized in the Medical Record Chart.
		Research documentation during the research if the person served agrees to suspend their right to access during the research
		Incident Reports
		Investigations of incidents or sentinel events