
Title:	DPH Privacy and Security Manual
Chapter:	IV. Client Rights Policies, Designated Record Sets
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Purpose

The purpose of the Division of Public Health (DPH) designated record sets policy is to address the DPH privacy requirements and criteria for identifying categories of records that will become Designated Record Sets (DSRs). This policy is in compliance with the [DHHS Policy and Procedure Manual, Section VIII, Security and Privacy](#), that establishes the NC Department of Health and Human Services (DHHS) privacy Designated Record Set requirements.

Policy Scope:

- ***HIPAA covered health care components***
- ***Internal Business Associates***

Background

Allowing clients the right to access and amend their individually identifiable health information (IIHI) facilitates an open and cooperative relationship between clients, their health care providers, and health plans and provides clients the opportunity to know what health information may be used to make decisions about them.

The client's right to request access, amendment, and copies of his/her personal health information are limited to that information that is maintained in Designated Record Sets, as determined by the Division.

Policy

All workgroups within the DPH that have been designated as Covered Health Care Components and "internal Business Associates," must define their categories of records that are "Designated Record Sets," which are considered the only personal health information records to which clients have a right to request access, amendment, and copies.

Designated record sets are any item, collection, or grouping of IIHI that is maintained, collected, used, or disseminated by or for a health plan or health care provider. These record sets include medical records, billing records, and other records used to make decisions about clients.

DPH is ***not required*** to allow clients access to Designated Record Sets if a licensed health care professional determines that access to such information would not be in the best interest of the client or another individual, and such determination is documented.

DPH is ***not required*** to amend, at a client's request, any information in a record that the Division knows to be true and accurate.

Designated Record Sets

A Designated Record Set is a description of health and/or business information that can be maintained in one or many areas within the Division.

The term *record* means any item, collection or grouping of information that includes individually identifiable health information and is maintained, collected, used or disseminated by or for a health plan or health care provider.

Designated Record Sets are categories of records maintained by the Division covered components that are used, in whole or in part, to make health and financial decisions about clients, such as:

- Medical records and/or financial records of individual clients, maintained by or for a covered health care provider
- Employee health records that are maintained separately from personnel records
- The enrollment, payment, claims adjudication and case or medical management record systems maintained by or for a health plan.

External Business Associate Records

Records created and/or maintained by a Division External Business Associate for services rendered to the Division must be considered when evaluating documentation for Designated Record Sets. The Division is responsible for identifying their External Business Associates and for ensuring that a Business Associate Agreement is in place when required, as defined in [DPH Privacy Policy, Business Associates](#).

Health information specifically created and/or maintained by External Business Associates, when acting on behalf of the Division, is subject to the same client right provisions to request access to or amendment of such information in accordance with the Business Associate Agreement. Copies of information that are also maintained by a health care provider or health care plan should not be included in the Business Associate's Designated Record Set.

Internal Business Associate Records

Internal Business Associates who maintain individually identifiable health information are subject to the requirements of this policy in identifying Designated Record Sets. This is accomplished by joint agreement between the Division and its Internal Business Associate(s).

Implementation

Evaluation of Documentation

The Division has developed a process to evaluate the documentation maintained by the Division to determine those groups of records that should be categorized as “Designated Record Sets.”

The DHHS HIPAA Office has distributed the following guidance, which the DPH Privacy Office used to help define designated record sets: [Guidance for Identifying Designated Record Sets under HIPAA](#), prepared by the NCHICA Designated Record Sets Subcommittee Privacy and Confidentiality Focus Group and Approved for Public Distribution, August 1, 2002. The DPH Privacy Office has used this guidance to evaluate what documentation should be considered as Designated Records Sets.

The DPH Privacy Office has gathered information from the applicable DPH workgroups to make this assessment. This information includes:

- Documentation type (e.g., medical record)
- Basic content (e.g., assessments, reports, examinations)
- Location of the documentation (e.g., Medical Record Department)
- Contact person (e.g., Privacy Officer)
- Paper/Electronic documentation (e.g., paper)
- Documentation contains IIHI (e.g., yes)
- Documentation is used to make decisions about the client (e.g., yes)
- Comments that identify any information included in a designated record set that the client would not have a right to access to or amend.

The information is evaluated to determine whether it is to be classified as and included in a Designated Record Set. Next, the evaluation determines which records should be included or excluded before considering the records further as Designated Record Sets, as described below.

Inclusions

The Division assesses its documentation requirements to identify those records that meet the intent of this policy. Minimally, the following categories of records are being considered as Designated Record Sets:

- Medical Records
- Financial and Business Records (eligibility, claims, remittances, statements)
- Enrollment Records
- Payment Records
- Claims Adjudication Records

Documentation such as raw test data and laboratory reports that could be maintained by various programs in the Division agency are considered “working records” and should be evaluated as to the benefit to clients to access and amend. Reports developed from “working records” that are filed in the medical record should be evaluated with the record as a whole and not as separate documentation.

Exclusions

The benefits of access to information that is not used in making decisions about a client is limited and is outweighed by the burdens of locating, retrieving and providing access to such information. Such information may be found in many types of records that include significant information not relevant to the client, as well as information about other persons. The right of access does not extend to those records maintained for reasons other than for making decisions about clients.

Administrative and oversight records that are maintained by the Division require independent evaluation to determine whether or not they should be considered a Designated Record Set.

The following are examples of documentation that may be excluded from being defined as a designated record set:

- Quality Improvement Reports
- Copies of reports/documentation already designated
- Oversight activities
- Research documentation
- Appointment or surgical schedules
- Risk Management records (including incident reports).

Documentation of Designated Record Sets

The Division must maintain the documentation that supports the Division’s assessment of its records for determination of its Designated Record Sets. Documentation may be maintained electronically or on paper. Such information must be kept current and available for reference should a client request access to his/her medical and/or financial records. Documentation must be maintained for at least six years.

The Division has developed a [Designated Record Set Template](#), which is based on the DHHS template. This form is used to document the Designated Record Sets for each DPH Covered Components. The DPH Privacy Office retains copies of the completed DRS forms by date for six years.

Division of Public Health Designated Record Determination

The following procedures and Designated Record Set determination is in compliance with the HIPAA Privacy Rule and should be considered whenever staff receives requests from clients or their legal representatives, for access, amend, or copy information that the Division might have access to or maintain about them.

Applicability of Designated Record Sets within DPH

The following DPH workgroups have been designated as Covered Health Care Components and internal Business associates:

- **Covered Health Care Components**
 - State Laboratory of Public Health
 - Children’s Developmental Services Agencies (state operated)

- **Internal Business Associates**
 - Administrative, Local, and Community Support Section – HSIS Business Liaison
 - Administrative, Local, and Community Support Section – Medicaid Liaison and Reimbursement
 - Administrative, Local, and Community Support Section – Information Technology
 - Women’s and Children’s Health Section – Children’s Special Health Services
 - State Center for Health Statistics – pending final determination

The HSIS Business Liaison has also been identified as a business associate of the local health departments, for whom it performs Medicaid billing services.

The following table shows the requirements for defining designated record sets for these workgroups:

DPH Workgroup	Designation	Maintains DSRs	Client Right to Access, Amend, Copy	Procedure/Rational
State Laboratory of Public Health	Covered Health Care Component	Yes	No	<p>The State Laboratory maintains laboratory test results and associated administrative information about the tests requested by health care providers. CLIA and NC Administrative Code restrict access to these records except by the “authorized sender” of the specimen, as defined by NC Administrative Code.</p> <p>All requests from clients and/or their personnel representatives are referred to the health care provider who ordered the test and submitted the sample to the State Laboratory. The provider is the “authorized submitter” and all individual access to the laboratory records for an individual is through the health care provider.</p>
Children’s Developmental Services Agencies	Covered Health Care Component	Yes	Yes	HIPAA specifically excludes records governed by FERPA from being designated record sets. The CDSA's are subject to FERPA and are excluded from HIPAA privacy requirements. FERPA and IDEA define client access rights and the records to which clients have access. These definitions and client rights procedures are defined in the <i>ITP</i> .
Medicaid Liaison and Reimbursement	Internal BA of Division of Medical Assistance	No	No	Medicaid Liaison and Reimbursement performs cost analysis on behalf of DMA. The workgroup does not maintain unduplicated health information about individual clients and is not involved in making decisions about them.
Children’s Special Health Services	Internal BA of Division of Medical Assistance	Yes	Yes	With the DHHS Office of the Controller provides prior approval (authorization) for Medicaid for mobility devices. Prior approval is a decision about the client.

DPH Workgroup	Designation	Maintains DSRs	Client Right to Access, Amend, Copy	Procedure/Rational
				<p>CSHS provides medical review of existing DME provider records and supporting medical information to authorize or disallow medical necessity for mobility devices. A medical authorization documenting the decision is created via Purchase of Medical Care Services system based on review of medical necessity. This authorization is sent to the provider.</p>
HSIS Business Liaison	Internal BA of State Lab and CDSA's and external BA of the local health departments	Yes	Yes	<p>With the Division of Information Resources Management, provides billing services for the covered health care providers.</p>

DPH Workgroup	Designation	Maintains DSRs	Client Right to Access, Amend, Copy	Procedure/Rational
State Center for Health Statistics	TBD pending AG review – Internal BA of Division of Medical Assistance	No	No	Performs cost analysis and data aggregation services for DMA. . The workgroup does not maintain unduplicated health information about individual clients and is not involved in making decisions about clients.
Information Technology	Internal BA for DPH covered health care components and internal BAs	No	No	Workgroup provides data processing and network support functions and does not maintain records nor make decisions about clients.

Procedure for Defining Designated Record Sets Within DPH

The applicable DPH workgroups defined in the above table must document their Designated Record Sets.

Workgroups that are business associates of other department workgroups and for other DHHS agencies should work with the agency or workgroup for whom they perform functions to determine who maintains the original records and what procedures will be established for clients to request access to them. DPH workgroups should also consult the DPH Privacy Office for additional guidance of identifying designated record sets.

The DPH Privacy Office has worked with the applicable DPH workgroups to complete the following:

- Identify and document Designated Records Sets to which clients have a right to request access, amendment, and copies using the [Designated Record Set Template](#).
- Record the following information about the record on the worksheet:
 1. Documentation type (e.g., medical record, billing record, laboratory test results)
 2. Basic content contained in the record (e.g., patient billing statements, submissions)
 3. Purpose
 4. Documentation contains IIHI (yes or no)
 5. Documentation is used to make decisions about clients (yes or no)
 6. Record Owner (who is responsible for maintaining the record)
 7. Contact person (who to contact with questions about the designated record set)
 8. Location (where the record is stored)
 9. Media (e.g., paper, electronic)

10. Client Access (procedures for client to request access to record set)
 11. Comments (any additional information regarding the record set).
 12. The Privacy Office retains a copy of the Designated Record Sets defined for each applicable workgroup in the [DPH Designated Record Set Definition](#) worksheets.
 13. If applicable, a copy of this documentation is also provided to the covered health care components or external covered entities for which you are providing services. Copies must be kept for at least six years.
- The DPH Privacy Office reviews the Designated Record Set determinations on a periodic basis or as needed if additional records are added or if the composition and access methods to the records change. Each affected DPH workgroup also notifies the DPH Privacy Official of any changes to the Designated Record Sets.

Client Request to Access Designated Record Sets

Clients served by the DPH Covered Health Care Components and Business Associates do not access DPH Designated Record Sets directly through the Division. Access, as documented in the [DPH Designated Record Set Definition](#) worksheets, is via the direct provider of service. DPH provides a form, [Request for Accessing/Inspecting/Copying Health Information](#), which could be used by a client to formally request access and for the DPH workgroup to document the reasons for referring the request to the direct service provider.

For relevant documents:

[Designated Record Set Template](#)

[DPH Designated Record Set Definition](#)

[Request for Accessing/Inspecting/Copying Health Information](#)

These documents can be accessed on the DPH HIPAA website at <http://www.schs.state.nc.us/hipaa/>.

References: DHHS Directive Number III-11; DHHS Policy and Procedure Manual, Section VIII, Security and Privacy, DPH HIPAA Compliance Statement, DPH Client Rights Privacy Policy, Rights of Clients, 45CFR 164-524; 45CFR 164-526, 45, Clinical Laboratory Improvement Amendments of 1988 (CLIA), 493.1109, 10A 42A 0.0002 and 0.0005

For questions or clarification on any of the information contained in this policy, please contact the DPH Privacy Office at HIPAA.DPH@ncmail.net.