



**POLICY AND REGULATIONS MANUAL
HIPAA ADMINISTRATIVE POLICY**

TITLE: USE AND DISCLOSURE OF LIMITED DATA SETS

PURPOSE: To: 1) outline the requirements for Use and Disclosure of PHI using Limited Data Sets, 2) provide guidance on how to create a Limited Data Set and 3) define requirements of a Data Use Agreement to be executed before a Limited Data Set is provided to authorized parties.

POLICY STATEMENT:

It is the policy of Harris County Hospital District (HCHD) to Use and Disclose Protected Health Information (PHI) from which certain direct identifiers have been removed to create a Limited Data Set, for the purposes of research, public health or healthcare operations when appropriate. HCHD facilities and providers will follow the enclosed guidelines for authorizing and creating Limited Data Sets to safeguard PHI and ensure compliance with the Health Insurance Portability and Accountability Act (HIPAA) privacy rule.

POLICY ELABORATION:

I. DEFINITIONS:

- A. **Business Associate** – A person or entity that provides certain functions, activities, or services for or to a Covered Entity involving the use and/or disclosure of PHI (e.g., claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, billing, benefit management, repricing, legal services, actuarial services, accounting services, consulting services, data aggregation services, management services, administrative services, accreditation services and financial services).
- B. **Covered Entity** – A health plan, a healthcare clearinghouse, or a healthcare provider that electronically transmits health information covered by the HIPAA Regulations.
- C. **Data Use Agreement** - An agreement between the covered entity and the limited data set recipient that establishes the permitted uses and disclosures of information within the limited data set.



- D. Healthcare Operations** - Any of the following activities of the covered entity that are related to covered functions:
1. Conducting quality assessment and improvement activities, including:
 - a. outcomes evaluation and development of clinical guidelines provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities;
 - b. Conducting population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination;
 - c. Contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment;
 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;
 3. Underwriting, premium rating, and other activities relating to the creation, renewal or replacement of a contract of health insurance or health benefits, and ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care (including stop-loss insurance and excess of loss insurance), provided that the requirements of § 164.514(g) are met, if applicable;
 4. Conducting or arranging for medical review, legal services and auditing functions, including fraud and abuse detection and compliance programs;
 5. Business planning and development, such as conducting cost-management and planning-related analyses to manage and operate the entity, including formulary development and administration, development or improvement of methods of payment or coverage policies; and
 6. Business management and general administrative activities of the entity, including, but not limited to:



**POLICY AND REGULATIONS MANUAL
HIPAA ADMINISTRATIVE POLICY**

- a. Management activities relating to implementation of and compliance with the requirements of this subchapter;
- b. Customer service, including the provision of data analyses for policy holders, plan sponsors or other customers, provided that protected health information is not disclosed to such policy holder, plan sponsor or customer.
- c. Resolution of internal grievances;
- d. The sale, transfer, merger or consolidation of all or part of the covered entity with another covered entity, or an entity that following such activity will become a covered entity and due diligence related to such activity; and
- e. Consistent with the applicable requirements of § 164.514, creating de-identified health information or a limited data set, and fundraising for the benefit of the covered entity.

E. Individually Identifiable Health Information (IIHI) – Information, including demographic information, that:

1. Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and
2. Relates to the past, present, or future physical or mental 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. Identifies the individual; or
 - b. There is a reasonable basis to believe the information can be used to identify the individual.

F. Protected Health Information (PHI) – Individually identifiable patient health information in any form, including demographic information, that is created or received by a healthcare provider, and relates to the patient's healthcare condition, provision of health care or payment for the provision of health care.



II. GUIDELINES FOR CREATING LIMITED DATA SETS

- A. HCHD may use PHI to create a Limited Data Set, or under a signed Business Associate contract, may disclose PHI to a Business Associate so that the Business Associate can create a Limited Data Set.
- B. Limited Data Sets may only be Used or Disclosed for the purposes of research, public health or Healthcare Operations, and only:
1. To another Covered Entity (health care provider, health plan, or health care clearinghouse) for purposes of Healthcare Operations.
 2. To any health care provider for purposes of Healthcare Operations.
 3. By a Business Associate for purposes of creating a Limited Data Set for the facility, another entity listed above, or the Business Associate.
- C. Limited Data Set - A Limited Data Set is PHI that excludes the following direct identifiers of the patient, or of the patient's relatives, employers or household members:
1. Names
 2. Postal address information, *other than* town or city, state, and ZIP Code
 3. Telephone numbers
 4. Fax numbers
 5. Electronic mail addresses
 6. Social Security numbers
 7. Medical Record numbers (including prescription numbers and clinical trial numbers)
 8. Health plan beneficiary numbers
 9. Account numbers
 10. Certificate/license numbers
 11. Vehicle identifiers and serial numbers, including license plate numbers
 12. Device identifiers and serial numbers
 13. Web Universal Resource Locators (URLs)
 14. Internet Protocol (IP) address numbers
 15. Biometric identifiers, including finger and voice prints, and
 16. Full face photographic images and any comparable images.



**POLICY AND REGULATIONS MANUAL
HIPAA ADMINISTRATIVE POLICY**

- D. HCHD departments will define and document procedures for creating Limited Data Sets within the guidelines described herein. These procedures will be made available to the Office of Privacy Administration upon request.
- E. Accounting of Disclosures of PHI in Limited Data Sets – Disclosures of PHI contained within a Limited Data Set are exempt from inclusion in the accounting of disclosures of PHI that may be requested by the patient or the patient’s representative.

III. REQUIREMENTS FOR PROCESSING LIMITED DATA SETS

A. Minimum Necessary

- 1. The Minimum Necessary standard applies to requests for Limited Data Set information. For example, PHI should only be disclosed where a requestor and HCHD agree that it is needed for the purpose of the request. In very limited circumstances, if the requestor provides an adequate description of the purposes of the Limited Data Set and specifics of the particular data elements required, the facility can rely on a requested Disclosure of a Limited Data Set as the Minimum Necessary information.
- 2. See Policy 3.11.302 Minimum Necessary Standard for Use and Disclosure of PHI for additional requirements for relying on information requested as meeting the Minimum Necessary standard.

B. Data Use Agreement (DUA)

- 1. HCHD must obtain satisfactory assurance, in the form of a Data Use Agreement as specified herein, that the recipient will only Use or Disclose the PHI for the limited purpose. Recipients of a Limited Data Set must complete and sign a Data Use Agreement outlining the approved uses of the Limited Data Set before receiving the requested data (The HCHD standard DUA is available on the HCHD intranet at: <http://home/departments/HIPAA/Forms/Forms.htm>).
- 2. In lieu of obtaining a Data Use Agreement, HCHD Workforce members who use or receive a Limited Data Set may sign the facility’s Confidentiality Agreement.



3. A Data Use Agreement may be combined into one document with a Business Associate Agreement.
- C. Required Content of a Data Use Agreement - The Data Use Agreement between the HCHD and the recipient of the Limited Data Set must:
1. Establish that the Uses and Disclosures of PHI by the Limited Data Set recipient will be for research, public health, or Health Care Operations;
 2. The Data Use Agreement may not authorize the Limited Data Set recipient to use or further disclose the information in a manner that would violate the privacy rule;
 3. Establish who is permitted to Use or receive the Limited Data Set; and
 4. Provide that the Limited Data Set recipient will:
 - a. Not Use or further Disclose the information other than as permitted by the Data Use Agreement or as otherwise required by law;
 - b. Use appropriate safeguards to prevent Use or Disclosure of the information other than as provided for by the Data Use Agreement;
 - c. Report to the HCHD Privacy Officer any Use or Disclosure of the information not allowed by its Data Use Agreement of which it becomes aware;
 - d. Ensure that any agents, including a subcontractor to whom it provides the Limited Data Set agrees to the same restrictions and conditions that apply to the Limited Data Set recipient with respect to such information; and
 - e. Not identify the information or contact any of the patients, or the patient's family members, employers, or household members whose PHI is included in the Limited Data Set.
- D. The Limited Data Set Request and Data Use Agreement is reviewed, approved or denied by HCHD's designated personnel including, but not limited to, individuals from Health Information Management, Research, Quality Management, Information Technology, Corporate Communications and other departments that receive or create requests for Limited Data Sets in the course of business. If the request is approved, each Data Use Agreement must be submitted to the Harris County Attorney's office for review prior to submitting to the requestor for signature and again before forwarding to the HCHD



President or designee for signature. (See HCHD Policy # 3.13: Signature Authority on Data Use Agreements for further information.)

E. Department Responsibilities

1. Requests for Limited Data Sets must be documented and may include:
 - a. Requestor's name, address, telephone numbers, title and organization or department;
 - b. Date of request;
 - c. Purpose of the request (i.e., research, public health or Healthcare Operations), including the intended Uses, any re-disclosures and who will use or have access to the Limited Data Set;
 - d. Names of all recipients of the Limited Data Set;
 - e. Record parameters or selection criteria – time period included, minimum number of patient records, type of patient records (such as by inpatient, outpatient, diagnosis, procedure, drug use or other criteria); and
 - f. Date the Limited Data Set is needed.
Examples of forms used to request Limited Data Sets include "Information Technology Report Request" and/or the "Health Information Management Chart Request Form." These forms are available on the HCHD Intranet at: <http://home/departments/HIPAA/Forms/Forms.htm> or on the Internet at: <http://www.hchdonline.com>.
2. It is the responsibility of the department receiving the request for a Limited Data Set to:
 - a. Assure the request form is complete;
 - b. Determine if the data set can be produced;
 - c. Complete the Data Use Agreement (the Office of Privacy Administration will provide assistance, if requested), have it reviewed by the County Attorney's office, submit the DUA to the requestor for signature and upon receipt of the signed copy forward it to the County Attorney's office for review before obtaining the signature of the HCHD President or designee;
 - d. Produce the data set or route the request to the department that will produce the Limited Data Set;
 - e. Assure the Limited Data Set is provided to the requestor; and



**POLICY AND REGULATIONS MANUAL
HIPAA ADMINISTRATIVE POLICY**

- f. Send the original signed Data Use Agreement to the HCHD Corporate Compliance Office to maintain for six years.

IV. FEE SCHEDULE

- A. The requestor of a Limited Data Set may be asked to compensate HCHD for resource expenditures related to the production of the Limited Data Set.
- B. HCHD may establish a fee schedule to compensate for the use of personnel time, software, hardware, and supplies for:
 1. Reviewing requests for Limited Data Sets (Application Fee); and
 2. Specified activities related to the production and delivery of the Limited Data Set including personnel time, computer usage, and supplies. When establishing fees for production of Limited Data Sets consideration should be given to any existing departmental or HCHD schedules and the fee schedule guidance provided in the Texas Public Information Act.
- C. In the event the initial review results in an approval to create the Limited Data Set, an estimate of the cost to produce the data set should be made and communicated to the requestor prior to creation of the Limited Data Set. Provision of the estimate should be documented including the cost, date, time and identity of the person providing the estimate.

V. LIMITED DATA SET VIOLATIONS

- A. If HCHD workforce members become aware of a pattern of activity or practice by the Limited Data Set recipient that constitutes a material breach or violation of the Data Use Agreement, such breach or violation must be reported to the HCHD Privacy Officer who shall take reasonable steps to cure the breach or end the violation, and, if such steps are unsuccessful:
 1. Discontinue Disclosure of PHI to the recipient; and
 2. Report the problem to the Secretary of the Department of Health and Human Services (DHHS).



**POLICY AND REGULATIONS MANUAL
HIPAA ADMINISTRATIVE POLICY**

- B. If HCHD receives a Limited Data Set and violates the Data Use Agreement, it is not in compliance with HIPAA privacy regulations. Members of the workforce who become aware of such violation must inform the Office of Privacy Administration.

REFERENCES/BIBLIOGRAPHY:

- 3.11.000, HCHD HIPAA Policy
- 3.11.105, Use and Disclosure of Protected Health Information for Treatment, Payment and Health care Operations
- 3.11.302, Minimum Necessary Standard for Use and Disclosure of Protected Health Information
- 3.11.401, Business Associates
- 3.13, Signature Authority on Data Use Agreements

OFFICE OF PRIMARY RESPONSIBILITY:

Office of Privacy Administration

ENDNOTES:

REVISION HISTORY:

Effective Date	Version	Approved by:
05/28/05	1.0	President & CEO