

**LOUISIANA STATE UNIVERSITY
HEALTH CARE SERVICES DIVISION
BATON ROUGE, LA**

POLICY NUMBER: 7509-20

CATEGORY: HIPAA Policies

CONTENT: Limited Data Set
- Limited Data Set Request and Data Use Agreement – Attachment A

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INQUIRIES TO: **LSU HCSD**
Compliance Section
Post Office Box 91308
Baton Rouge, LA 70803
Telephone: 225-354-4840

Note: Approval signatures/titles are on the last page

LOUISIANA STATE UNIVERSITY HEALTH CARE SERVICES DIVISION

Limited Data Set

I. SCOPE

This policy is applicable to all workforce members of the LSU Health Care Services Division facilities, including employees, physician/practitioner practices, vendors, agencies, business associates and affiliates.

II. PURPOSE

To provide guidance to the health care facilities and providers affiliated with the LSU System in the following areas:

- To outline the process for reviewing and responding to requests for limited data sets.
- To provide guidance on how to create a limited data set.
- Define requirements of a Data Use Agreement for use and disclosure of a limited data set.

III. POLICY

All LSU System health care facilities and providers may use and disclose PHI in a limited data set as described in this policy.

IV. DEFINITIONS

1. **Protected Health Information (sometimes referred to as “PHI”)** – for purposes of this policy means individually identifiable health information held or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper, or oral. It includes demographic data that relates to that relates to:
 - a) The individual’s past, present, or future physical or mental health or condition;
 - b) The provision of health care to the individual; or
 - c) The past, present, or future payment for the provision of health care to the individual, and that identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual. PHI includes many common identifiers such as name, address, birth date, social security number, etc.

2. **Designated Record Set** –is a group of records maintained by or for the Facility that is:

- The medical records and billing records about individuals maintained by or for the Facility; or
- Any records used, in whole or part, by or for the Facility to make decisions about individuals.
- Any record that meets this definition of Designated Record Set and which are held by a HIPAA Business Associate of the Facility are part of the Facility’s Designated Record Set.

- The term *record means* any item, collection, or grouping of information that includes PHI and is maintained, collected, used or disseminated by or for the Facility.
- The term *record* also includes patient information originated by another health care provider and used by the Facility to make decisions about a patient.
- The term *record* includes tracings, photographs, videotapes, digital and other images that may be recorded to document care of the patient.

3. Psychotherapy Notes – means notes recorded by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint or family counseling session and that are separated from the rest of the individual’s record. Psychotherapy notes does not include: 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.

4. Privacy Officer – Person designated by the facilities and clinics as the Privacy Officer.

5. Limited Data Set –A subset of protected Health Information (PHI) that excludes the direct identifiers listed in “Creating Limited Data Sets” portion of this policy.

V. PROCEDURE

Creating Limited Data Sets

1. The Facility 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.
2. Limited data sets may only be used or disclosed:
 - a. For the purpose of research, public health, or health care operations.
 - b. To another covered entity for purposes of health care operations.
 - c. To any health care provider for purposes of health care operations.

d. By a business associate for purposes of creating a limited data set for the Facility, another entity listed above, or the business associate.

3. 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 of the patient:

- Names
- Postal address information, *other than* town or city, State, and zip code
- Telephone numbers
- Fax numbers
- Electronic mail addresses
- Social Security numbers
- Medical record numbers (including prescription numbers and clinical trials numbers)
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web Universal Resource Locators (URLs)
- Internet Protocol (IP) address numbers
- Biometric identifiers, including finger and voice prints
- Full face photographic images and any comparable images

The Facility may assign a code or other means of record identification to allow information de-identified under this section to be re-identified by the entity, provided that:

- (1) The code or other means of record identification is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual; and
- (2) The Facility does not use or disclose the code or other means of record identification for any other purpose, and does not disclose the mechanism for re-identification.

The Federal Information Processing Standard (FIPS) 198 "Keyed-Hash Message Authentication Code" (HMAC) does not qualify as an appropriate method for de-identifying information under Federal privacy requirements; however, the HMAC methodology may be used to create a limited data set.

4. Accounting of Disclosures of PHI in a Limited Data Set. No accounting of disclosures is required with respect to disclosures of PHI within a limited data set.

Requests for Limited Data Sets

1. **Minimum Necessary Applies.** The minimum necessary standard applies to requests for limited data set information. For example, date of birth should only be disclosed where a requestor and the facility 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 specifies the particular data elements required, the facility can rely on a requested disclosure as the minimum necessary. See Policy on the Minimum Necessary Standard for Use and Disclosure of PHI for additional requirements for relying on information requested as meeting the minimum necessary standard.

 2. **Data Use Agreement Required.**
 - a. Recipients of a limited data set must sign a Data Use Agreement outlining the approved use of the limited data set. The Facility must obtain satisfactory assurance, in the form of a Data Use Agreement that meets the requirements of the HIPAA Privacy Rule that the recipient will only use or disclose the PHI for the limited purpose.
 - b. A Data Use Agreement may be combined into one document with a Business Associate Contract.

 3. **Data Use Agreement Contents.** The Data Use Agreement between the Facility and the recipient of the limited data set must:
 - a. Establish the permitted uses and disclosures of such information by the limited data set recipient, as stated above; [**“List in detail the permitted uses and disclosures of information included in the limited data set by the limited data set recipient. In no case may the permitted uses and disclosures exceed the limitations set forth in Item 2 under ‘Procedure’.”**]
 - b. Prohibit the limited data set recipient to use or further disclose the information in a manner that would violate the HIPAA Privacy Rule.
 - c. Establish who is permitted to use or receive the limited data set; and
 - d. Provide that the limited data set recipient will:
 - i. Not use or further disclose the information other than as permitted by the Data Use Agreement or as otherwise required by law.
 - ii. Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the Data Use Agreement.
 - iii. Report to the Facility’s Privacy Officer any use or disclosure of the information not allowed by its Data Use Agreement of which it becomes aware;
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- iv. 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
 - v. 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.
4. The Limited Data Set Request and Data Use Agreement Form must be reviewed, approved or denied by the HIM director or designee, with input from the Privacy Officer.
5. If only a limited data set is released to a Business Associate for healthcare operation purposes, then a Data Use Agreement suffices and a Business Associate Agreement is not necessary.

Fee Schedule

1. The requestor of a limited data set may be asked to compensate the Facility for resource expenditures related to the request.
2. The Facility may establish a fee schedule to compensate for the use of personnel, time, software, hardware, and supplies for:
 - a. Reviewing requests for limited data sets (Application Fee);
 - b. Generating the limited data set; and
 - c. Other specified activities related to the production and delivery of the limited data set.

The Facility should consider establishing a basis for fees related to the production of a limited data set. The fee should capture costs related to personnel time, computer usage, and supplies. In the event the initial review results in an approval to create the limited data set, a determination of the cost to produce the data set should be made and communicated to the requestor.

Improper Use or Disclosure of Limited Data Sets

1. The Facility is not in compliance with the HIPAA Privacy Rule if it knows 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, unless the facility takes reasonable steps to cure the breach or end the violation, and if such steps are unsuccessful:
 - a. Discontinues disclosure of PHI to the recipient; and
 - b. Reports the problem to the Secretary of the Department of Health and Human Services (DHHS).
2. The Facility is not in compliance with the HIPAA Privacy Rule if the Facility receives a limited data set and violates the Data Use Agreement.

3. If there is an impermissible use or disclosure of any limited data set, the Facility must treat it as a potential breach and perform a risk assessment to determine if breach notification is required. In analyzing such an improper use, the Facility must consider the possibility of the limited data set being re-identified as a factor in determining if the incident is a reportable breach.

Responsibilities

The Facility is responsible for ensuring that requests for and disclosure of limited data sets are handled consistently. The HIM Director or designee, or in some cases, the Project Lead is to be responsible for:

1. Obtaining a signed Data Use Agreement from the recipient of the limited data set to protect the information.
2. Notifying requestors in writing of approved and denied requests for limited data sets.
3. Routing approved requests to the facility designated personnel or business associate for processing.
4. Documenting the delivery of the limited data set to the approved recipient.
5. Approving the request for de-identified information.
6. Reviewing and denying or approving all requests for limited data sets for research purposes and documenting a waiver of the authorization for the purposes of the research.
7. Creating limited data sets from PHI as described in section Creating Limited Data Sets above.

Revision History

February 20, 2015

- Added “or in some cases, the Project Lead” to the Responsibilities section.

REFERENCES:

45 C.F.R. § 164.514(e)

Limited Data Set Request and Data Use Agreement

For Facility Use Only: Date Request Received: _____

Instructions: Carefully review and complete this Request for a Limited Data Set of PHI and Data Use Agreement. Submit an *original* copy of this document to [Name of Facility] Privacy Officer at [Street Address, City, State, Zip Code]. If you have any questions about how to complete this request, or the Data Use Agreement requirements, contact the Privacy Officer at the above address or [Telephone number; E-mail address]. [Name of Facility] reserves the right to approve, approve with modifications, or deny this request. [Name of Facility's] Privacy Officer will notify you, in writing, of our decision. Please complete this entire document to facilitate review of your request. Thank you.

REQUEST FOR LIMITED DATA SET

A. We (as identified below in section G) request to use and receive a Limited Data Set of Protected Health Information (PHI) from [Name of Facility] for the following purpose(s):
Check all that apply:

1. Research – *specify intended uses and disclosures of the Limited Data Set:*

2. Public Health – *specify intended uses and disclosures of the Limited Data Set:*

3. Health Care Operations – *specify intended uses and disclosure of the Limited Data Set:*

Attachment A continued

B. We request the following data from [*Name of Facility*] and have determined that this information is the minimum necessary PHI needed for the purpose(s) identified above in section A:

1. Type of Data or Records Requested:

2. Dates of Service for the Data or Records:

3. Data or Records to Exclude, if any:

4. Additional Data or Record Parameters:

5. Requested Record Layout or Format:

6. Other Requirements:

DATA USE AGREEMENT

- C. Requesting Party. *Please check box below:*
1. We are current members of the [Name of Facility's] workforce and have signed the facility's Confidentiality Agreement and agree to the parameters of this Data Use Agreement.
 2. We are NOT members of the [Name of Facility's] workforce and agree to the parameters of this Data Use Agreement.
- D. We understand as recipients of a Limited Data Set from [Name of Facility] I/we will adhere to the following Data Use Agreement requirements:
1. We understand that the information included in the Limited Data Set is considered to be protected health information (PHI) under the Health Insurance Portability and Accountability Act (HIPAA) and any use or disclosure of PHI is regulated by HIPAA, and other Federal and State laws and regulations.
 2. We will only use or disclose the information in this Limited Data Set as described in section A of this document.
 3. We understand this Data Use Agreement does not authorize or permit me/us to use or further disclose the information that would violate any Federal, State, or local laws and regulations.
 4. Only those listed in section H of this document are permitted to use or receive the Limited Data Set.
 5. We will use appropriate safeguards to prevent use or disclosure of the information other than as provided by this Data Use Agreement.
 6. We will report to [Name of Facility's] Privacy Officer any use or disclosure of the information not provided for by this Data Use Agreement of which I/we become aware.
 7. We will ensure that any agents, including subcontractors, to whom I/we provide the Limited Data Set to agree to the same restrictions and conditions that apply to us [the Limited Data Set recipient(s)] with respect to the Limited Data Set.
 8. We will not identify the information or contact any of the individuals (patients, patient's family members, employers, or household members) identified or otherwise included in the Limited Data Set.
 9. We will not attempt to link any information in the Limited Data Set with personally identifiable records from any other source.

Attachment A continued

10. We will not (nor will I/we permit others to) copy, sell, rent, license, lease, loan, or otherwise grant access to the data covered by this Data Use Agreement to any other person or entity.
 11. At the conclusion of the use of the Limited Data Set We agree to destroy all copies of the Limited Data Set, unless otherwise provided for in this Agreement.
- E. We understand that if [*Name of Facility*] becomes aware of a pattern of activity or practice of mine/ours, as recipients of the Limited Data Set, that constitutes a material breach or violation of this Data Use Agreement, [*Name of Facility*] must take reasonable steps to cure the breach or end the violation, as applicable, and, if such steps are unsuccessful [*Name of Facility*] will:
1. Discontinue disclosure of protected health information to us; and
 2. Report the problem to the Secretary of the Department of Health and Human Services.
- F. Covered Entity as Recipient of Limited Data Set. If the recipient of the Limited Data Set is [*Name of Facility*] or another covered entity as defined in the HIPAA Privacy Rule and the recipient violates this Data Use Agreement, the recipient will be in noncompliance with the HIPAA Privacy Rule's standards, implementation specifications, and requirements for use and disclosure of a Limited Data Set. If we are a covered entity and are found to be noncompliant with the HIPAA Privacy Rule, I/we understand we may be subject to civil or criminal penalties.
- G. We understand that [*Name of Facility*] may charge reasonable fees for creating and delivering Limited Data Sets and [*Name of Facility*] will notify us of these fees in advance.

REQUESTOR/RECIPIENT INFORMATION

H. We are the requestor(s) and recipient(s) of the Limited Data Set identified in this document and agree to provisions of this Data Use Agreement (*If necessary, use a separate page to identify all names of individuals or organizations requesting or receiving the Limited Data Set information, and attach to this document*):

1. Name:

Title:

Organization:

Address:

Telephone:

Fax:

E-mail:

Signature: _____

Date: _____

2. Name: _____

Title: _____

Organization:

Address:

Telephone: _____

Fax: _____

E-mail: _____

Signature: _____

Date: _____

FOR FACILITY USE ONLY

Review decision. *Check one:*

1. ___ Request Denied
2. ___ Request Approved
3. ___ Request Approved with the following modification:

Fees Due to [*Name of Facility*], if applicable:

1. Amount Due:

\$ _____

2. Date Fees Collected:

Signature: _____

Date: _____

Title: _____

Department: _____

[NO PLACE TO LIST INTENDED USES OF LIMITED DATA SET]

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