
**University of Wisconsin-Madison
Policy and Procedure**

Policy Number: 5.2
Policy Title: Creation of a Limited Data Set Under the HIPAA Privacy Rule
Effective Date: July 13, 2014
Last Revision Date: July 13, 2014
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I. Policy

A limited data set is protected health information that excludes direct identifiers. The UW HCC units may use or disclose a limited data set only for the purposes of public health activities, research, or health care operations. Such use or disclosure requires a data use agreement between the entity sharing or disclosing the limited data set and the recipient. This document describes how a limited data set may be created, and how it may further be used or disclosed under the Privacy Rule of HIPAA.

II. Definitions

- A. **Business Associate:** A person or entity not affiliated with UW-Madison that performs or assists in performing, for or on behalf of any unit in the UW-Madison Health Care Component, business support functions/services that involve the use of Protected Health Information.
- B. **Data Use Agreement:** An agreement between the entity that shares or discloses protected health information and recipient of the protected health information by which recipient agree only to use or disclose the protected health information for limited purposes as further described below.
- C. **Health Care Operations:** Any of a number of business and administrative activities, including
- Conducting quality assessment and improvement activities
 - Reviewing the competence or qualifications of health care professionals
 - Conducting training programs
 - Accreditation
 - Credentialing
 - Conducting or arranging for medical review, legal services and auditing functions
 - Business planning and development, and
 - Business management and general administrative activities

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Health care operations do not include research and many fundraising and marketing activities. See Privacy Policies # 3.5 “Uses and Disclosures of Protected Health Information for Marketing” and # 3.6 “Uses and Disclosures of Protected Health Information for Fundraising” for more information.

- D. Protected Health Information (“PHI”): Is health information or health care payment information, including demographic information, which identifies the patient or can be used to identify the patient. PHI does not include student records held by educational institutions or employment records held by employers.
- E. Public Health Activities: The activities of public health authorities who are legally authorized to receive protected health information for the purpose of preventing or controlling disease, injury, or disability. This would include, for example, the reporting of a disease or injury; reporting vital events, such as births or deaths; and conducting public health surveillance, investigations, or interventions.
- F. Public Health Authority: An agency or authority of the United States government, a State, a territory, a political subdivision of a State or territory, or Indian tribe that is responsible for public health matters as part of its official mandate, as well as a person or entity acting under a grant of authority from, or under a contract with, a public health agency.
- F. Research: A systematic investigation, include research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
- G. University of Wisconsin-Madison Health Care Component (“UW HCC”): Those units of the University of Wisconsin-Madison that have been designated by the University as part of its health care component under HIPAA. See Privacy Policy # 1.1 “Designation of UW-Madison Health Care Component” for a listing of these units.

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III. Procedures

A. Use or Disclosure of PHI to Create a Limited Data Set

1. A UW HCC unit may use or disclose a limited data set only for the purposes of research, public health activities, or health care operations.
2. A UW HCC unit may use PHI to create a limited data set, whether or not the limited data set is to be used by the UW HCC unit or disclosed to another entity or individual, without patient authorization.
3. A UW HCC unit may disclose PHI to a business associate in order to create a limited data set, whether or not the limited data set is to be used by the UW HCC unit or disclosed to another entity or individual, without patient authorization. Additional requirements apply before disclosing PHI to a business associate. (See Privacy Policy # 6.1 “Managing Arrangements of Business Associates with the University of Wisconsin-Madison”).

B. Procedures for Creating a Limited Data Set

A UW HCC unit may create a limited data set if the following direct identifiers of the patient or of relatives, employers, or household members of the patient, are removed:

1. Name
2. Postal address information, other than town or city, State and zip code
3. Phone numbers
4. Fax numbers
5. E-mail addresses
6. Social security number
7. Medical record number
8. Health plan beneficiary number

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9. Account numbers
10. Certificate/license numbers
11. Vehicle identifiers and serial numbers
12. Device identifiers and serial numbers
13. URLs
14. Internet protocol (IP) address numbers
15. Biometric identifiers (e.g., fingerprints)
16. Full face photographic and any comparable images

C. Data Use Agreements

1. The UW HCC unit may use or disclose a limited data set only if it obtains satisfactory assurance, in the form of a data use agreement, that the data recipient will only use or disclose the limited data set for specified purposes.
2. The data use agreement must:
 - a. Establish the permitted uses and disclosures of such information by the limited data set recipient, which may be for research, public health activities or health care operations only.
 - b. Establish who is permitted to use or receive the limited data set.
 - c. Provide that the limited data set recipient will:
 1. Not use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law;
 2. Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the data use agreement;

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3. Report to the UW HCC unit any use or disclosure of the information not provided for by its data use agreement of which it becomes aware;
4. 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
5. Not identify the information or contact the individuals.

D. Compliance

A UW HCC unit is not in compliance with this policy or with HIPAA regulations if the UW HCC unit knows of a pattern of activity or practice of the limited data set recipient that constitutes a material breach or violation of the data use agreement and the UW HCC unit fails to take reasonable steps to cure the breach or end the violation and, if such steps are, unsuccessful:

1. Discontinues disclosure of the PHI to the recipient; and
2. Reports the problem to the Secretary of the Department of Health and Human services.

IV. Documentation Requirements

The UW HCC unit will retain a copy of each data use agreement entered into with a limited data set recipient for at least six years from the date the data use agreement is terminated, and provide a fully executed copy of the data use agreement to the UW-Madison HIPAA Privacy Officer.

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V. Forms

Data Use Agreement for Disclosures of Limited Data Sets

VI. References

45 CFR 164.514(e) (HIPAA Privacy Rule)

VII. Related Policies

Policy Number 6.1 “Managing Arrangements of Business Associates with the University of Wisconsin-Madison”

VIII. For Further Information

For further information concerning this policy, please contact the UW-Madison HIPAA Privacy Officer or the appropriate unit HIPAA Privacy Coordinator or sub-Coordinator. Contact information is available within the “Contact Us” tab at hipaa.wisc.edu.

Reviewed By

UW-Madison HIPAA Privacy Officer
UW-Madison Office of Legal Affairs

Approved By

Interim HIPAA Privacy and Security Operations Committee