

4. Limited Data Set for Protected Health Information (PHI)	
PURPOSE	This policy explains the process of creating Limited Data Sets for PHI to protect patient privacy.
POLICY	4.1. Polk County will recognize that PHI can be provided in a limited data set in certain circumstances. (§164.514(e))

PROCEDURES

Limited Data Sets

Polk County may use PHI to create a limited data set, or disclose PHI to a Business Associate to create a limited data set. Polk County may use or disclose a limited data set or disclose a limited data set when a current data set agreement is in place only for the purposes of research, public health or health care operations, when the need for the limited data set has been documented.

Limited Data Set

§164.514(e)

A limited data set is protected health information that excludes the following direct identifiers of the patient or of relatives, employers, or household members of the individual:

- a. Names.
- b. Postal address information, other than town or city, state, and full zip code.
- c. Telephone numbers.
- d. Fax numbers.
- e. Electronic mail addresses.
- f. Social Security numbers.
- g. Medical record numbers.
- h. Health plan beneficiary numbers.

- i. Account numbers.
- j. Certificate/license numbers.
- k. Vehicle identifiers and serial numbers, including license plate numbers.
- l. Device identifiers and serial numbers.
- m. Web Universal Resource Locators (URLs).
- n. Internet Protocol (IP) address numbers.
- o. Biometric identifiers, including finger and voice prints.
- p. Full face photographic images and any comparable images.

Data Use Agreement

§164.514(e)

Polk County may use or disclose a limited data set after obtaining satisfactory assurance, in the form of a data use agreement, that the limited data set recipient will only use or disclose the PHI for limited purposes. You should use the form, *Polk County Data Use Agreement*. This may be modified, but at a minimum, it must:

- a. Define the permitted uses and disclosures of the limited data set.
- b. Establish who is permitted to use or receive the limited data set.
- c. Provide that the limited data set recipient will:
 - C Not use or further disclose information other than as permitted by the *Data Use Agreement* or as otherwise required by law.
 - C 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 covered entity any use or disclosure of the information not provided by its *Data Use Agreement*.
 - C Ensure that any agents, including subcontractors to whom Polk County provides the limited data set agree to the same restrictions and conditions that apply to the limited data set recipient with respect to such information.
 - C Not identify the information or contact the individuals.

Violation of the Data Use Agreement

If you know of a pattern of activity or practice by the recipient of the limited data set that

constitutes a material breach or violation of the *Data Use Agreement*, you must take reasonable steps to cure the breach or end the violation. If Polk County is not able to do so, you must:

- C Discontinue disclosure of the limited data set to the recipient.
- C Report the problem to the Secretary of the Department of Health and Human Services.

A covered entity that violates a data use agreement is in noncompliance with the Privacy Rule, and must be reported to the Secretary.

FREQUENTLY ASKED QUESTIONS

What is a limited data set?

A limited data set has crucial identifying information removed from the data in order to protect a patient's privacy. In order to maintain this privacy, a limited data set **cannot** include any of the following:

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

When is a limited data set used?

A limited data set is used for research, public health, or for health care operations. Research may include any collective work done by a university, institution, or public health department to gain a greater understanding of a health issue. For example:

- C A medical school may use a limited data set to study the effects of a particular medication on people over 60 years old who have high blood pressure and diabetes.
- C The Department of Health may use a limited data set to determine outbreaks of the West Nile Virus.
- C Administrators may use data sets to develop procedures to implement new security policies.

Who can receive limited data sets?

A limited data set can be shared with a contracted Business Associate, or anyone engaged in research, public health, or health care operations. A limited data set use agreement must be completed by anyone who makes a request, except for contracted Business Associates.

What is a Business Associate?

A Business Associate is any organization or individual with whom Polk County works in the course of conducting business. This may include a laboratory that conducts tests for your patients, or a billing agency that bills patients and insurance companies. For purposes of this policy, Business Associates may see PHI. Use caution in making this determination.

Note: Business associates require contracts. For more information about the Business Associate Contract Form, see Policy 14: *Business Associates*.

What is a data use agreement?

A limited data set use agreement is a contractual document between Polk County and the organization or individual who wants to use a limited data set for research, public health, or health care operations. The data use agreement is meant to provide a reasonable assurance that the organization obtaining the limited data set will not violate the use and disclosure terms of the agreement. The limited data set use agreement must establish the permitted and required uses and disclosures:

- C Establish who is permitted to use or receive the limited data set.
- C Requires that the recipient not use or further disclose the information other than as permitted by the agreement or required by law.
- C Require appropriate safeguards to protect other uses and disclosures not allowed by agreement.
- C Require reports to the covered entity of any inappropriate use or disclosure.
- C Ensure that agents and subcontractors of the Business Associate also agree to the same restrictions and requirements.
- C Not identify patient contact information.

What do I do if someone violates the data use agreement?

If there is a violation of the data use agreement by the Business Associate or other approved organization, you must do all of the following:

- C Immediately report the problem to Polk County's Privacy Officer.
- C Terminate Polk County's relationship with the organization immediately and discontinue the disclosure of the limited data set to the recipient.
- C Report the problem to the Secretary of the Department of Health and Human Services.

AUTHORITY

45 CFR §164.514(e) (2002)