



# HIPPA Privacy Rule Policies

<b>Policies and Procedures</b>	Policy # 17	
<b>USES AND DISCLOSURES OF LIMITED DATA SETS</b>		
APPROVED BY:	ADOPTED:	
	REVISED: 07122017	
SUPERCEDES POLICY: NEW	REVIEWED: 07122017	

## Purpose

To describe how LifeMed ID may create and use or disclose Limited Data Sets as set forth in this policy and in accordance with state and federal privacy laws, HIPAA Regulations and LifeMed ID’s contracts with its customers.

## Policy

It is the policy of LifeMed ID to use and disclose Limited Data Sets for Research, public health, and Health Care Operations in accordance with state and federal privacy laws, HIPAA Regulations and LifeMed ID’s contracts with its customers.

LifeMed ID will only use or disclose a Limited Data Set if LifeMed ID obtains satisfactory assurance in the form of a Data Use Agreement or Business Associate Agreement, that the recipient will only use or disclose the Protected Health Information (PHI) for limited purposes.

All workforce members must comply with this policy. Violations of this policy will result in disciplinary action based on the seriousness of the offense or other factors. Disciplinary action may include written warning, suspension, or termination.

## Definitions

“Customer” is an entity from which LifeMed ID receives PHI subject to a Business Associate Agreement (or other written agreement with the entity) in compliance with the HIPAA Regulations and approved by LifeMed ID’s legal counsel.

“Data Use Agreement” is an agreement that establishes:

- a. The permitted uses and disclosures of the Limited Data Set by the recipient, consistent with the purposes of the Research, and which may not include any use or disclosure that would violate the HIPAA Privacy Rule if done by a Covered Entity or a Business Associate,
- b. Limits who can use or receive the data, and
- c. Requires the recipient to agree to the following:
  - i. Not to use or disclose the information other than as permitted by the Data Use Agreement or as otherwise required by law,





- ii. To use appropriate safeguards to prevent the use or disclosure of the information other than as provided for in the Data Use Agreement,
- iii. To report to the LifeMed ID any use or disclosure of the information not provided for by the Data Use Agreement of which the recipient becomes aware,
- iv. To ensure that any subcontractor, to whom the recipient provides the Limited Data Set agrees to the same restrictions and conditions that apply to the recipient with respect to the Limited Data Set; and
- v. Not to identify the information or contact the individual.

“Limited Data Set” means health information from which specified identifiers have been removed; information in a Limited Data Set is protected, but may be used for research, public health and health care operations without the individual's Authorization;

A Limited Data Set is PHI that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual:

- a. Names;
- b. Postal address information, other than town or city, State, and 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; and
- p. Full face photographic

For definitions of other capitalized terms or phrases, please refer to: *HIPAA-HITECH Privacy and Security Glossary*.

## Procedures

1. Creation of Limited Data Sets. To the extent permitted by its contracts with customers, LifeMed ID or its Subcontractors may create and disclose Limited Data Sets in accordance with this policy. All of the identifiers listed in the *Limited Data Set Checklist* (included herein) must be removed before the information is deemed to qualify as a Limited Data Set.
2. Purpose of Disclosure. Limited Data Sets may be disclosed only for the purposes of research, public health, or health care operations.
3. Recipients of Limited Data Sets. Information in a Limited Data Set may be disclosed only to a recipient, approved by LifeMed ID in consultation with the Privacy Officer, which has given satisfactory assurance, by signing a Data Use Agreement.





- a. If LifeMed ID becomes aware that the recipient is violating the Data Use Agreement, the LifeMed ID Privacy Officer will take one of the following actions:
  - i. Terminate the Data Use Agreement (immediately or after giving the recipient an opportunity to cure, consistent with the terms of the Data Use Agreement); and/or
  - ii. Report the problem to LifeMed ID's legal counsel.
4. Accounting of Disclosures. Disclosures of information in a Limited Data Set are not required to be included in the Accounting of Disclosures. Refer to: *Privacy Policy #11: Accounting of Disclosures*.

## Documentation

This version of the policy, together with any forms and other documentation created or obtained in accordance with the policy, will be retained by LifeMed ID for a period of at least 6 years plus the current year from the date of creation or the date when last in effect, whichever is later.

## Additional Material

### Limited Data Set Checklist:

Health information is deemed to constitute a Limited Data Set if all of the following elements have been removed with regard to

1. The individual,
2. The individual's relatives,
3. The individual's employer, and
4. The individual' household members:
  - a. Names,
  - b. Street address or post office box,
  - 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,
- 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, and
- p. Full face photographic images and comparable images.



## Regulatory Authority

### 45 C.F.R. §164.514 Other requirements relating to uses and disclosures of protected health information.

(e) **(1) Standard:** *Limited data set.* A covered entity may use or disclose a limited data set that meets the requirements of paragraphs (e)(2) and (e)(3) of this section, if the covered entity enters into a data use agreement with the limited data set recipient, in accordance with paragraph (e)(4) of this section.

**(2) Implementation specification:** *Limited data set:* A limited data set is protected health information that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual:

- (i) Names;
- (ii) Postal address information, other than town or city, State, and zip code;
- (iii) Telephone numbers;
- (iv) Fax numbers;
- (v) Electronic mail addresses;
- (vi) Social security numbers;
- (vii) Medical record numbers;
- (viii) Health plan beneficiary numbers;
- (ix) Account numbers;
- (x) Certificate/license numbers;
- (xi) Vehicle identifiers and serial numbers, including license plate numbers;
- (xii) Device identifiers and serial numbers;
- (xiii) Web Universal Resource Locators (URLs);
- (xiv) Internet Protocol (IP) address numbers;
- (xv) Biometric identifiers, including finger and voice prints; and
- (xvi) Full face photographic images and any comparable images.

**(3) Implementation specification:** *Permitted purposes for uses and disclosures.*

- (i) A covered entity may use or disclose a limited data set under paragraph (e)(1) of this section only for the purposes of research, public health, or health care operations.
- (ii) A covered entity may use protected health information to create a limited data set that meets the requirements of paragraph (e)(2) of this section, or disclose protected health information only to a business associate for such purpose, whether or not the limited data set is to be used by the covered entity.



#### **(4) Implementation specifications: Data use agreement**

*(i) Agreement required. A covered entity may use or disclose a limited data set under paragraph (e)(1) of this section only if the covered entity obtains satisfactory assurance, in the form of a data use agreement that meets the requirements of this section, that the limited data set recipient will only use or disclose the protected health information for limited purposes.*

*(ii) Contents. A data use agreement between the covered entity and the limited data set recipient must:*

*(A) Establish the permitted uses and disclosures of such information by the limited data set recipient, consistent with paragraph (e)(3) of this section. 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 requirements of this subpart, if done by the covered entity;*

*(B) Establish who is permitted to use or receive the limited data set; and*

*(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;*

*( 3 ) Report to the covered entity 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 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.*

*(iii) Compliance.*

*(A) A covered entity is not in compliance with the standards in paragraph (e) of this section if the covered entity knew of a pattern of activity or practice of the limited data set recipient that constituted a material breach or violation of the data use agreement, unless the covered entity took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful:*

*(1) Discontinued disclosure of protected health information to the recipient, if feasible.;*

*(B) A covered entity that is a limited data set recipient and violates a data use agreement will be in noncompliance with the standards, implementation specifications, and requirements of paragraph (e) of this section.*



## References

### Internal

1. Privacy Policy #11, Accounting of Disclosures

### External

1. Omnibus Final Rule: <http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=a1031c979126e6440b522063b7bba578&rqn=div5&view=text&node=45:1.0.1.3.78&idno=45%20>