

HIPAA Privacy Policy #38
Creating Limited Data Sets

Effective Date: January 22, 2020	Refer to Privacy Rule Sections: 164.514
Authorized by: Equinox Board of Directors	Version #:

Policy: Equinox, Inc. may use and disclose Protected Health Information in a limited data set for the purposes of research, public health and health care operations as described in this Policy.

Procedures:

1. **Privacy Officer Responsibilities:** The Privacy Officer is responsible for ensuring that requests for, and disclosure of, limited data sets are handled consistently. Prior to disclosing a limited data set, the Privacy Officer shall be responsible for:
 - a. Obtaining a signed Data Use Agreement from the recipient for and disclosure of limited data set to protect the information;
 - b. Notifying requestors in writing of approved and denied requests for limited data sets;
 - c. Routing approved requests to the designated personnel or Business Associate for processing;
 - d. Documenting the delivery of the limited data set to the approved recipient;
 - e. Approving the request for a limited data set;
 - f. 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; and
 - g. Creating limited data sets from Protected Health Information as described in this Policy.
2. **Creating Limited Data Sets:**
 - a. Equinox, Inc. may use Protected Health Information to create a limited data set, or under a signed Business Associate agreement may disclose Protected Health Information to a Business Associate so that the Business Associate can create a limited data set, as set forth herein.
 - b. Limited data sets may only be used or disclosed:
 - i. For the purpose of research, public health, or health care operations;
 - ii. To another covered entity for purposes of health care operations;

- iii. To any health care provider for purposes of health care operations; and
- iv. By a Business Associate for purposes of creating a limited data set for Equinox, Inc., another approved provider listed above, or the Business Associate.

3. Limited Data Set:

- a. A limited data set is Protected Health Information that excludes the following direct identifiers of the patient, or of the patient's relatives, employers or household members:
 - Name
 - 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
 - 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
- b. A provider may assign a code or other means of record identification to allow information de-identified under this section to be re-identified by the provider, provided that:
 - i. The code or other means of record identification is not derived from, or related to, information about the patient and is not otherwise capable of being translated so as to identify the patient; and
 - ii. The covered entity 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.

Note: 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. Minimum Necessary Applies:

- a. 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 provider 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 provider can rely on a requested disclosure as the minimum necessary. *See* Policy No. 7 entitled, “Minimum Necessary Uses, Disclosures and Requests of Protected Health Information.”

5. 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. Equinox, Inc. must obtain satisfactory assurance, in the form of a Data Use Agreement that meets the requirements of the HIPAA Privacy Rule, setting forth that the recipient will only use or disclose the Protected Health Information for the limited purpose.
 - b. The Data Use Agreement between Equinox, Inc. and the recipient of the limited data set must:
 - i. Establish the permitted uses and disclosures of such information by the limited data set recipient, as stated above;
 - ii. Not authorize the limited data set recipient to use or further disclose information in a manner that would violate the HIPAA Privacy Rule;
 - iii. Establish who is permitted to use or receive the limited data set;
 - iv. 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 Equinox, Inc.’s 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 to whom it 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; and
 - (E) Not identify the information or contact any of the patients, or the patient’s family members, employers, or household members, whose Protected Health Information is included in the limited data set.
6. Data Use Agreement Form: The Limited Data Set Request and Data Use Agreement Form must be reviewed, approved or denied by the Privacy Officer.
7. Fee Schedule:
- a. The requestor of a limited data set may be asked to compensate Equinox, Inc. for resource expenditures related to the request. Before establishing a fee schedule for a limited data

set, Equinox, Inc. shall consult with counsel and the determination to establish the fee schedule must be documented.

Consideration of fee structures must address certain requirements for research studies that are federally funded, if applicable, and appropriate estimates as to the potential fees (*see* below).

- b. Equinox, Inc. may establish a fee schedule to compensate for the use of personnel, time, software, hardware, and supplies for:
 - i. Reviewing requests for limited data sets (Application Fee);
 - ii. Generating the limited data set; and
 - iii. Other specified activities related to the production and delivery of the limited data set.
- c. Equinox, Inc. 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.

8. Improper Use or Disclosure of Limited Data Sets:

- a. Equinox, Inc. is not in compliance with this Policy and 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 Equinox, Inc. takes reasonable steps to cure the breach or end the violation, and if such steps are unsuccessful:
 - i. Discontinues disclosure of Protected Health Information to the recipient; and
 - ii. Reports the problems to the Secretary of the United States Department of Health and Human Services (DHHS).
- b. Equinox, Inc. is not in compliance with this Policy and the HIPAA Privacy Rule if Equinox, Inc. receives a limited data set and violates the Data Use Agreement.

REFERENCES

Health Insurance Portability and Accountability Act of 1996; 45 CFR §§164.514(e); 65 FR 82462, Dec. 28, 2000, as amended at 67 FR 53182, Aug. 14, 2002; 78 FR 5566, Jan. 25, 2013.