Title: HIPAA - De-identification, Re-identification, and the Creation of Limited Data Sets of Protected Health Information (PHI)

Policy Statement: Saint Alphonsus will take steps to ensure that it De-identifies, Re-identifies or creates a Limited Data Set (LDS) of PHI, in accordance with the Privacy Standards of the Health Insurance Portability and Accountability Act of 1996, and its implementing regulations, 45 CFR Parts 160 and 164, as they are amended from time to time (collectively “HIPAA”). Saint Alphonsus will evaluate situations to determine when it is possible and appropriate to De-identify PHI, or to create an LDS and enter into a Data Use Agreement. All requests for data that involves the use of PHI and is to be shared external to Saint Alphonsus are handled by the Data Team.

Procedure:

I. KEY DEFINITIONS of terms used in this policy may be found in the "HIPAA Definitions" (H-7) document in the Administrative Policy Manual.

II. De-Identification
   A. The Data Team will be responsible for all requests to De-identify PHI and all requests to Re-identify all previously De-identified PHI.
   B. The Data Team will be responsible for implementing the process of De-identifying of PHI.
   C. The Data Team will be responsible for making final decisions on designating PHI as De-identified. This De-identification Determination will be made by one of the following methods:
      1. The Data Team will retain or designate an expert ("identity expert") who will be responsible for determining if PHI is De-identified. The identity expert must be someone who has appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods related to De-identification. The identity expert will determine if submitted PHI is De-identified using generally accepted statistical and scientific principles and methods and, if the identity expert determines that the PHI is De-identified, will submit a memorandum to the Data Team and Performance Improvement certifying that the submitted PHI has been De-identified.
a) The memorandum submitted to the Data Team and Performance Improvement by the identity expert must contain the following information:
   1) A description of how the generally accepted statistical and scientific principles and methods were applied in De-identifying the submitted PHI;
   2) A statement whether any code or other means of record identification may exist that would allow the De-identified information to be Re-identified;
   3) A statement that in his or her professional opinion, the identity expert believes that the De-identified information, used alone or in combination with other information, could not be Used to identify the Individual who is the subject of the information or that the risk of identification is small; and
   4) The signature of the identity expert.

b) If the Data Team does not have actual knowledge that the PHI could not be used alone or in combination with other information to identify an Individual who is subject of the information, then they may De-identify the information by removing the following identifiers of the Individual or relatives, employees or household members of the Individual:
   1) Names;
   2) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:
      a. The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
      b. The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people are changed to 000.
   3) All elements of dates (except year) for dates directly related to an Individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
   4) Telephone numbers;
   5) Fax numbers;
   6) Electronic mail addresses;
   7) Social security numbers;
   8) Medical record numbers;
9) Health plan beneficiary numbers;
10) Account numbers;
11) Certificate/license numbers;
12) Vehicle identifiers and serial numbers, including license plate numbers;
13) Device identifiers and serial numbers;
14) Web Universal Resource Locators (URLs);
15) Internet Protocol (IP) address numbers;
16) Biometrics identifiers, including finger and voice prints;
17) Full face photographic images and any comparable images; and
18) Any other unique identifying number, characteristic, or code.

c) The Data Team, as part of the De-identification process, will be responsible for creating a method for Re-identifying PHI that has been De-identified. Such method must be approved by the Privacy Official and must comply with the following:
   1) The code or other means of recording is not derived from or related to information about the Individual, and cannot otherwise be used to identify the Individual; and
   2) Saint Alphonsus does not disclose the code or other means of record identification for any other purpose except that for which the mechanism for Re-identification was approved, and does disclose the mechanism for Re-identification.

III. Re-Identification
   A. The Data Team will be responsible for handling all requests for Re-identifying PHI.
   B. In the event that the Data Team receives a request, or otherwise determines that it is necessary for De-identified PHI to be Re-identified, the Data Team will consult with the Privacy Official. The Privacy Official will be responsible for making the final decision as to Re-identification under this Section.
   C. Requests to Re-identify previously De-identified PHI must be approved in writing by the Privacy Official.

IV. Limited Data Set (LDS)
   A. The Data Team and Privacy Official will be responsible for reviewing and approving requests for a LDS in cooperation with the IRB.
   B. An LDS is PHI that excludes the following direct identifiers of the Individual or of relatives, employers, or household members of the Individual:
      1. Names;
      2. Postal address information, other than town or city, state and zip code;
3. Telephone numbers;
4. Fax numbers;
5. Electronic mail addresses;
6. Social Security numbers;
7. Medical record numbers;
8. Health plan beneficiary numbers;
9. Account numbers;
10. Certificate/license numbers;
11. Vehicle identifiers and serial numbers, including license plate numbers;
12. Device identifiers and serial numbers;
13. Web Universal Resource Locators (URLs);
14. Internet Protocol (IP) address numbers;
15. Biometric identifiers, including finger and voice prints; and
16. Full face photographic images and any comparable images.

C. The LDS, unlike a De-identified data set, is permitted to contain all elements of dates and the geographic elements of town, city, and full zip code. In addition, the LDS, unlike a De-identified data set, is not required to exclude any other unique identifying number, characteristic or code.

D. An Individual, whose data is included in an LDS, is not entitled to receive an accounting of this Use or Disclosure of his/her PHI.

E. Saint Alphonsus will apply the Minimum Necessary standard to the determination of which PHI data elements will be included in an LDS.

F. Saint Alphonsus may use PHI to create an LDS or it may disclose PHI to a Business Associate to create an LDS on Saint Alphonsus’ behalf.

G. Saint Alphonsus will Use or Disclose an LDS only for the purposes of Research, public health, or Health Care Operations.

H. Saint Alphonsus will only Use or Disclose an LDS if it has obtained a satisfactory assurance, in the form of a Data Use Agreement, that the recipient will only Use or Disclose the PHI for limited and permitted purposes.

I. Saint Alphonsus will ensure that a Data Use Agreement includes the following:
   1. The permitted Uses and Disclosures of such information by the LDS recipient;
   2. The requirement that the LDS recipient may not Use or further Disclose the PHI in a manner that would violate HIPAA requirements if done by Saint Alphonsus;
   3. The identity of those permitted to Use or receive the LDS; and
   4. The requirement that the recipient will:
      a) Not Use or further Disclose the information in the LDS except as permitted by the Data Use Agreement or as required by law;
      b) Use appropriate safeguards to prevent Use or Disclosure in any way other than what is permitted in the Data Use Agreement.
c) Report to Saint Alphonsus any Use or Disclosure of information in the LDS that is not permitted by the Data Use Agreement;
d) Ensure that any agents, including subcontractors, to whom the recipient provides the LDS, agrees to the same restrictions and conditions that apply to the LDS recipient; and
e) Not identify the information in the LDS or contact the Individuals whose PHI is contained in the LDS.

J. Saint Alphonsus will take reasonable steps to cure a material breach or violation of the Data Use Agreement if it becomes aware of an inappropriate pattern of activity or practice by the LDS recipient.

K. In the event that Saint Alphonsus’ efforts are not successful in curing the breach or ending the violation, it will:
   1. Discontinue Disclosure of PHI in the LDS to the recipient; or
   2. Report the problem to the Secretary of DHHS.

V. Documentation Retention
   A. All documents required under this procedure will be retained, at a minimum, for six (6) years from the date of its creation or the date when it was last effective, whichever is the latest date.
   B. No documents will be destroyed before consultation with the Privacy Official and/or legal counsel.

VI. Contact for Questions
   A. If a Workforce Member has any questions or is uncertain about the requirements of this policy, such Workforce Member should contact the Data Team Manager or Privacy Official.

Related Forms:
Data Use Agreement
De-Identification Memorandum
Request to Re-identify PHI
Request for a Limited Data Set

Related Policies:
Admin: H-7: HIPAA Definitions
Admin: H-8: Minimum Necessary Use and Disclosure of Protected Health Information
Admin: H-14: Use and Disclosure of Protected Health Information