PH-16 – Limited Data Set: Permitted Purposes for Use/Disclosure

Key Points

- UH may use1 or disclose2 protected health information3 to create a limited data set4 for research5, public health or health care operations purposes only. The limited data set may be disclosed to a third party only after the recipient has signed a data use agreement in a form acceptable to UH.

- UH may disclose protected health information to a business associate to create a limited data set, provided that the business associate has signed a data use agreement in a form acceptable to UH.

Policy & Procedure

1. Creation of a Limited Data Set (LDS)

   1.1 UH may use or disclose protected health information (PHI) to create a LDS for research, public health or health care operations purposes only.

   1.2 A LDS may be disclosed to a third party only after the recipient has signed a data use agreement (DUA) in a form acceptable to UH. The UH Law Department must approve, in writing, any DUA prior to its execution.

   1.2.1 UH may disclose protected health information to a business associate, to create a LDS, when there is a written contract or agreement in compliance with UH Policy and Procedure PH-11, Business Associate Disclosures of PHI. A business associate that creates a LDS may also be the LDS recipient.

   1.2.2 An individual entering into a DUA that is not approved in advance and in writing by the UH Law Department is in violation of this policy, and the Law Department may deem such DUA unenforceable.

   1.3 A DUA must include all of the following requirements:

   1.3.1 Establish the permitted uses and disclosures of the LDS set by the recipient, consistent with the purposes of the disclosure, and which may not include any use or disclosure that would violate the Health Insurance Portability and Accountability Act of 1996 (as amended by Health Information Technology for Economic and Clinical Health Act of 2009 and all implementing regulations thereunder) if done by the UH entity; and

   1.3.2 Limit who can use or receive the data; and
1.3.3 Require the LDS recipient to agree to all of the following provisions:
   1.3.3.1 Not to use or disclose the information other than as permitted by the DUA or as otherwise required by law; and
   1.3.3.2 Use appropriate safeguards to prevent the use or disclosure of the information other than as provided for in the DUA; and
   1.3.3.3 Report in writing to the UH entity any use, disclosure or breach of the information not provided for by HIPAA or the DUA of which the recipient knew or should have known; and
   1.3.3.4 Ensure that any agents, including a subcontractor, to whom the recipient provides the LDS agree to the same restrictions and conditions that apply to the recipient with respect to the LDS; and
   1.3.3.5 Not to re-identify the information or contact the patients who are the subjects of the LDS.

1.4. If UH knows of or is aware of a material breach or violation of a DUA by the creator or recipient of a LDS, UH must take reasonable steps to cure the breach or end the violation. If these efforts are unsuccessful, UH must take both of the following steps:
   1.4.1 Discontinue disclosure of the LDS to the recipient; and
   1.4.2 Consult with the UH Law Department or the Compliance & Ethics Department to report the problem to the Secretary of the Department of Health and Human Services.

1.5 The DUA is to be kept on file by UH for a period of at least six (6) years from the date of creation or the date it was last in effect, whichever is later.

See Also

45 CFR § 164.514(e)(1) - Standard: limited data set.
1 Use means the sharing, employment, application, utilization, examination or analysis of protected health information (PHI) in any form or manner.

2 Disclose means the release, transfer, provision of access to, or divulgence of PHI in any form or manner.

3 Protected health information (PHI) means information created or received by a UH entity relating to (a) the past, present or future physical or mental health or condition of a patient; or (b) payment for the provision of healthcare to a patient that is transmitted or maintained in any form or medium. PHI contains identifiers that can identify a patient or for which there is a reasonable basis to believe the information can be used to identify a patient, such as demographic or insurance information, medical record number, physician, admission date or photographic images.

4 A limited data set (LDS) is PHI that has all of the following 16 direct identifiers of the patient or of relatives, household members or employers removed:
   A. Names
   B. Post 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/prescription 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

5 Research means systematic investigation, including research development, testing and evaluation, designed to develop or contribute to general knowledge. See UH Policy & Procedure, R-3 - Uses & Disclosures of PHI for Research.