

What is a Limited Data Set (“LDS”)?

A limited data set is a set of patient identifiable information with certain types of information removed, as described under the Health Insurance Portability and Accountability Act’s (“HIPAA”) Privacy Rule. The limited data set excludes specific patient identifiers of the individual or the individual’s relatives, employers, or household members. The Privacy Rule allows covered entities and researchers to use and disclose a limited data set to the researcher with a data use agreement for research, public health, or health care operations purposes.¹ The Final Omnibus HIPAA Rule also added a provision that allows a covered entity to use or disclose a limited data set based on its existing data use agreement (including for research purposes) until it is renewed, modified, or one year from the compliance date (September 23, 2013) of the rule, whichever is earlier.²

A limited data set may include the following elements:

- City, state, and a zip code
- Elements of date
- Other numbers, characteristics, or codes not listed as direct identifiers

The following identifiers must be removed for health information to qualify as a limited data set:

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|---|---|
| • Names | • Account numbers |
| • Address information other than city, state, or zip code | • Certificate/license numbers |
| • Telephone or fax numbers | • Vehicle identification or license plate numbers |
| • E-mail addresses | • Device identifiers and serial numbers |
| • Social security numbers | • URLs or IP addresses |
| • Medical record numbers | • Biometric identifiers |
| • Health plan beneficiary numbers | • Full-face photograph |

The data use agreement must:

- Establish the permitted uses and disclosures of the limited data set by the recipient, and may not include any use or disclosure contrary to the Privacy Rule;
- Limit who can use or receive the data; and
- Require the recipient of the data to:
 - Not to use or disclose the limited data set other than as specified in the data use agreement or as required by law;
 - Use appropriate safeguards to prevent use or disclosure of the limited data set not outlined in the data use agreement;
 - Report any use or disclosure of the limited data set not included in the data use agreement that the covered entity becomes aware of;
 - Ensure that any agent or subcontractor to whom the recipient provides the limited data set abides by the data use agreement; and
 - Not identify the information or contact the individual.

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¹ 45 CFR § 164.514(e).

² 78 Fed. Reg. at 5608; 45 C.F.R. § 164.532(f).