

PURPOSE

To establish permitted uses of limited data sets and the method for creating them.

REVISION HISTORY

Issued: 04/14/2003
Revised: 01/01/2016
Reviewed: 01/01/2017
Next Review: 01/01/2018

POLICY

A limited data set is protected health information that does not directly identify the individual, but which contains certain potentially identifying information.

After review and approval by the Compliance Office or the department's IRB, a MDHHS covered agency may use and disclose a limited data set without an individual's authorization only for the purposes of research, public health or health care operations if the department enters into a data use agreement with the intended recipient of the limited data set. A MDHHS covered agency may use protected health information to create a limited data set, or disclose protected health information to a business associate to create a limited data set on behalf of the MDHHS covered agency.

If a covered agency knows of a pattern of activity or practice of the limited data set recipient that constitutes a material breach, the department must take action to resolve the issue. If the issue cannot be resolved, then the data use agreement will be terminated and the department will report the problem to the Secretary of the Department of Health and Human Services.

REFERENCES

45 CFR 164.515, §164.514(e)

CONTACT

For additional information concerning this policy, contact the MDHHS Compliance Office.