



Data Use Agreement

Between

State of North Dakota, acting through its Department of Health, Division of Disease Control
And
Centers for Disease Control and Prevention (“CDC”), National Healthcare Safety Network
 (“NHSN”)

The State of North Dakota, acting through its Department of Health, (“State”) and CDC/NHSN enter into this Data Use Agreement (the “Agreement”) effective 2 / 8 / 16 (“Effective Date”). CDC/NHSN and the State shall be referred to individually as a “Party,” or collectively as the “Parties.”

This Agreement establishes a formal data access and data use relationship between CDC/NHSN and the State. This Agreement covers individual- and institution-identifiable data, received by the CDC/NHSN subject to the Federal Privacy Act, 5 USC §§552 and 552a, from the NHSN Patient Safety Component and Healthcare Personnel Safety Component as listed in the attached document that have been voluntarily submitted to NHSN by healthcare institutions in North Dakota and for which there is **no** State mandate for reporting of such individual- or institution-identifiable data (“COVERED DATA”). However, COVERED DATA shall NOT include data pertaining to federal or tribal healthcare institutions.

The Parties shall abide by all applicable Federal and State laws, rules, and regulations including, without limitation, all patient confidentiality and medical record requirements and any applicable Institutional Review Board (“IRB”) requirements.

STATE’S USES OF COVERED DATA

State agrees to use the COVERED DATA for surveillance and/or prevention purposes only (e.g., evaluating the impact of a targeted program to reduce central line-associated bloodstream infections). State specifically agrees not to use the COVERED DATA obtained under this data use agreement for purpose of public reporting of institution-specific data or any regulatory or punitive actions against healthcare institutions, such as a fine or licensure action. The Parties acknowledge that COVERED DATA is limited to those data specified in the attached document, which identifies the complete set of data items, e.g., facility survey data, central line associated bloodstream infection numerator data, that State will have access to as a result of this Agreement.

State agrees to designate an NHSN Group Administrator and CDC/NHSN agrees to grant the State’s designated NHSN Group Administrator access to the State’s COVERED DATA. In the event that the NHSN Group Administrator leaves that role prior to assigning a replacement via the NHSN application, CDC/NHSN requires notification in writing on official letterhead from the signatory or the signatory’s successor to assure continuity.

- The designated NHSN Group Administrator for ND is Faye Salzer, HAI Activities Coordinator, fsalzer@nd.gov, Bismarck.

State agrees that access to individual- and institution-identifiable data provided under the terms of the Agreement will be limited solely to department staff or contractors who are explicitly authorized to use those data for surveillance and/or prevention purposes only.



DATA PROTECTIONS

CDC's legal authorities to obtain COVERED DATA from healthcare institutions are 42 U.S.C. section 241(a) (Public Health Service Act section 301(a)), pertaining to CDC's broad public health authority to conduct research and investigations, and 42 U.S.C. section 242k (Public Health Service Act section 306), pertaining to the collection of statistical data. CDC's authority to keep the COVERED DATA confidential (i.e., protected from an unauthorized release) is 42 U.S.C. section 242m (Public Health Service Act section 308(d)) and the Federal Privacy Act, 5 USC §§552 and 552a.

State acknowledges that Federal statutes, including 18 U.S.C. section 1001 (providing penalties for making false statements to the Government of the United States), may be implicated if the State does not protect the COVERED DATA from release pursuant to this Agreement.

State acknowledges that it will be the custodian of COVERED DATA stored in its data files and, as such, will be responsible for establishing and maintaining appropriate administrative, technical, and physical safeguards to prevent unauthorized access to or use of these files, for example, security awareness training and signed rules of behavior for all persons who have access to COVERED DATA, strong passwords and auditing for all access to COVERED DATA, approved encryption of COVERED DATA stored digitally.

The State will use the following safeguards to protect COVERED DATA stored in its data files:

Limited NDDoH personnel will have direct access to NHSN data and include the following positions in the Division of Disease Control (DC): Healthcare Associated Infections Coordinator, ELC Program Manager, and Infection Control Assessment Coordinator.

Any electronic files containing highly confidential data and information will be encrypted using a program that meets AES-256bit standards. Any analysis datasets must be protected by protective software to control storage, removal, and uses of the data. All computer files containing highly confidential personal health information (PHI) must be guarded by a minimum of two levels of security—the computer must be maintained in a locked office and must be password protected. All passwords to computer files containing confidential information must be changed quarterly to maintain the highest level of security. Once a password has been compromised, that password must be changed immediately. All COVERED DATA electronic files will be saved on state servers under state firewall protections. Electronic COVERED DATA line lists will be deleted once summarized or no longer in use.

All PHI, including COVERED DATA, in electronic or paper form, must be maintained in a secure, locked area with limited access. A secure area is an area in which it is protected by at least one level of physical security. Rooms where PHI and COVERED DATA is stored or viewed should not have windows. If the room does have a window, it cannot be placed in an area in which it can be seen through the window. Keys or key cards cannot be loaned or shared at any time. All visitors must be signed into the building by a NDDoH, DC staff member and wear a visitor's badge. All visitors must be escorted by an NDDoH, DC staff member while they travel through the building. Visitors are any persons who otherwise do not have access to the workspace. Exemptions include employees from other areas of the NDDoH who have key card access to the building. Persons with authorized access to the NDDoH, DC must be able to identify when a visitor is present and must adjust behaviors accordingly. Secured doors must remain closed unless prior approval from the Division Director is obtained to have them opened or disabled.



State specifically agrees that, to the extent permitted by State and federal law, it will not release COVERED DATA requested under a State's open records laws; to media; for litigation purposes; that is proprietary and if disclosed could cause competitive harm; or to anyone other than department staff or contractors who are explicitly authorized to use those data for surveillance and/or prevention purposes only.

The following State statutes, regulations, or policies provide additional safeguards that protect against the release of COVERED DATA:

- N.D.C.C. 44-04-18
- N.D.A.C. 33-06-03-04
- N.D.C.C. 23-01-15
- N.D.C.C. 23-01.3-02

State agrees to inform CDC/NHSN in advance of any forthcoming changes to State law(s) that will reduce legal safeguards that protect against release of COVERED DATA. State acknowledges that CDC/NHSN may terminate the Agreement as a result of this information.

PROVISION AND MANAGEMENT OF THE DATA

State acknowledges that its access to COVERED DATA will be for adverse healthcare events and/or processes of care that occur subsequent to signing this agreement, specifically occurring on or after the first day of the fourth month following the signing date. COVERED DATA reported to NHSN for prior events or processes will not be accessible.

State acknowledges that CDC/NHSN will provide a time-limited opportunity for healthcare institutions participating in NHSN in their jurisdiction to opt out of reporting COVERED DATA to NHSN.

State acknowledges that CDC/NHSN will notify newly enrolling institutions of the provisions of this Data Use Agreement so that enrolling institutions will have full knowledge of how their COVERED DATA will be used by the State and can opt out of providing COVERED DATA to NHSN.

State agrees to notify CDC in the event that the State is obligated or chooses to release COVERED DATA for a purpose other than surveillance and prevention.

TERM AND TERMINATION OF AGREEMENT

This Agreement shall be effective for a period of 5 years beginning on the Agreement Effective Date. The Agreement may be terminated before the 5-year period upon submission by either Party of written notice by Signatory or Signatory successor, in which case the Agreement shall cease 5 days after the date that CDC/NHSN submits the notice to the State OR 5 days after CDC/NHSN receives a notice submitted by the State.

In addition, upon CDC/NHSN's knowledge of a pattern or practice that constitutes a material breach of this Agreement by State, CDC/NHSN may immediately and unilaterally terminate this Agreement.



CDC requires that in the absence of a conflict with State law the State must delete or otherwise destroy COVERED DATA stored in its files within one year of the conclusion of this Agreement or a successor Agreement. CDC will retain all COVERED DATA in its files.

NOW, THEREFORE, by signing below, the Parties agree that they have read, understand, and agree to the conditions set forth above:

N.D. DEPARTMENT OF HEALTH

CDC/NHSN

State Health Officer

Director, CDC Division of Healthcare

Terry Dwelle, M.D., M.P.H.T.M.
State Health Officer

Quality Promotion

Denise M. Cardo, MD

Date 2-8-16

Date 2/9/16