



Data Use Agreement
Between
the Montana Department of Public Health and Human Services
And
Centers for Disease Control and Prevention (“CDC”), National Healthcare Safety Network (“NHSN”)

The Montana Department of Public Health and Human Services and CDC/NHSN enter into this Data Use Agreement (the “Agreement”) effective ____/____/____ (“Effective Date”). CDC/NHSN and the *Montana Department of Public Health and Human Services* 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 Montana Department of Public Health and Human Services. 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 Montana 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

The Montana Department of Public Health and Human Services 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). The Montana Department of Public Health and Human Services 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 *the Montana Department of Public Health and Human Services* will have access to as a result of this Agreement.

The Montana Department of Public Health and Human Services 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 the Montana Department of Public Health and Human Services is Christine Mulgrew, Epidemiologist (cmulgrew@mt.gov) Helena, Montana

the Montana Department of Public Health and Human Services 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.

The Montana Department of Public Health and Human Services 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.

The Montana Department of Public Health and Human Services 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:

- The Montana Department of Public Health and Human Services Communicable Disease Control and Prevention Bureau Security and Confidentiality Policy (CDCPB S&C) October 15, 2014 (compliant with Centers for Disease Control and Prevention Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Diseases, and Tuberculosis Programs: *Standards to facilitate Sharing and use of Surveillance Data for Public Health Action*).

The Montana Department of Public Health and Human Services 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:

- Title 50, Chapter 15, Montana Code Annotated
- Article 2, Section 10, Montana Constitution
- Montana Department of Public Health and Human Services Health Insurance Portability and Accountability Act (HIPAA) Policies and employee level signed agreement upon hire



- Montana Department of Public Health and Human Services Office of Epidemiology and Scientific Support *Guidelines for the Release of Public Health Data Derived from Personal Health Information Policy and Procedure*

The Montana Department of Public Health and Human Services 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. The Montana Department of Public Health and Human Services acknowledges that CDC/NHSN may terminate the Agreement as a result of this information.

PROVISION AND MANAGEMENT OF THE DATA

The Montana Department of Public Health and Human Services 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.

The Montana Department of Public Health and Human Services 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.

The Montana Department of Public Health and Human Services 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 Montana Department of Public Health and Human Services and can opt out of providing COVERED DATA to NHSN.

The Montana Department of Public Health and Human Services agrees to notify CDC in the event that Montana Department of Public Health and Human Services 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 Montana Department of Public Health and Human Services OR 5 days after CDC/NHSN receives a notice submitted by the Montana Department of Public Health and Human Services.

In addition, upon CDC/NHSN's knowledge of a pattern or practice that constitutes a material breach of this Agreement by the Montana Department of Public Health and Human Services, CDC/NHSN may immediately and unilaterally terminate this Agreement.

CDC requires that in the absence of a conflict with State law the Montana Department of Public Health and Human Services 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:



Montana Department of Public Health and Human Services

CDC/NHSN

Todd Harwell MPH

Director, CDC Division of Healthcare

Quality Promotion

Director, Public Health and Safety Division

Date _____

Date _____

Appendix 1

Data Use Agreement between CDC National Healthcare Safety Network and Montana Department of Public Health and Human Services
Data File Specifications Template - Patient Safety Component

The template below can be used to describe which data from the NHSN Patient Safety Component will be shared with the state health department. Only data that is included in a facility's monthly reporting plan will be included in datasets shared with the state health department. "Time Period" of data shared with state health department will be completed on template after signing of DUA. Please complete the template and provide to CDC/NHSN for further discussion.

Specify level of aggregation and patient identifiers to receive:

<input type="checkbox"/>	Only requesting facility level aggregate data (no patient level data)
<input type="checkbox"/>	Pt level data with all patient identifiers
<input checked="" type="checkbox"/>	Pt level data with no patient identifiers
<input type="checkbox"/>	Pt level data with specific patient identifiers (please select below)
<input type="checkbox"/>	DOB
<input type="checkbox"/>	Gender
<input type="checkbox"/>	Ethnicity
<input type="checkbox"/>	Race

General and surveys:

<input checked="" type="checkbox"/>	Monthly reporting plans
<input checked="" type="checkbox"/>	Facility annual surveys

Device-Associated Module events and denominators:
 Select event types of interest below:

<input checked="" type="checkbox"/>	Central line-associated bloodstream infection (CLABSI)
<input checked="" type="checkbox"/>	Catheter-associated urinary tract infection (CAUTI)
<input checked="" type="checkbox"/>	Ventilator-associated events (VAE)
<input type="checkbox"/>	Central line insertion practices (CLIP) - please note that requesting CLIP events will result in inserter code being shared
<input type="checkbox"/>	Dialysis Event (DE)

For these events, please specify the facility types, locations, and time period that will be shared with state health department below. You will receive both event (numerator) and summary (denominator) data for the locations that you specify.

Plan	Time Period	Location Type (Ex - ICUs, Wards, etc)	Specific Facility Types and Locations (Ex - All ICUs, Medical ICUs, etc)
IN		All inpatient locations	All
IN		All inpatient locations	All
IN		All inpatient locations	All
IN		All inpatient locations	
IN		All inpatient locations	
IN		All inpatient locations	

Procedure-Associated Module events and denominators:
 Select event types of interest below:

<input checked="" type="checkbox"/>	Surgical Site Infection (SSI) - please note that requesting SSI events/denominators will result in surgeon code being shared
<input type="checkbox"/>	Post-procedure Pneumonia (PPP)

For these events, please specify the facility types, procedures, and time period that will be shared with the state health department in the table below. You will receive both event (numerator) and procedure (denominator) data for the locations that you specify.

Plan	Time Period	NHSN Procedure Category	Specific Facility Types and Settings (Inpatient, Outpatient, or Both)
IN		HPRO, KPRO, COLO, HYST	Both
IN			

MDRO Module events and denominators:

Select event types of interest below:

<input type="checkbox"/>	Infection Surveillance
<input checked="" type="checkbox"/>	LabID Event - all specimens
<input type="checkbox"/>	LabID Event - blood specimens only

Select organisms of interest below:

<input checked="" type="checkbox"/>	MRSA
<input type="checkbox"/>	MRSA and MSSA
<input checked="" type="checkbox"/>	C. difficile
<input type="checkbox"/>	VRE
<input type="checkbox"/>	Ceph-R Klebsiella
<input type="checkbox"/>	CRE Klebsiella
<input type="checkbox"/>	CRE E. coli
<input type="checkbox"/>	MDR Acinetobacter

For these events, please specify the facility types, locations, and time period that will be shared with state health department below. You will receive both event (numerator) and summary (denominator) data for the locations that you specify.

Plan	Time Period	Location Type (Ex - ICUs, FACWIDE, etc)	Specific Locations (Ex - All ICUs, FACWIDEIN, etc)
IN		FACWIDE	FACWIDEIN
IN		ICU	All ICUs
IN		Non-ICU	Med, Surgical, Ortho, Step down units,
IN		NICU	NICU Level 3 and 4
IN		Rehab	All Rehab units
IN		Oncology	SCA