

**HEALTHCARE-ASSOCIATED AND RESISTANT PATHOGENS  
SURVEILLANCE AND PREVENTION PROJECT**

**Master Data Use and Confidentiality Agreement  
& Authorization to Release NHSN Data to Outside Third Party(ies)**

**Agreement between  
The Michigan Department of Community Health  
And**

\_\_\_\_\_ **Healthcare Facility**

The Michigan Department of Community Health (“MDCH” or “Data Recipient”) and \_\_\_\_\_ (“Healthcare Facility”) enter into this Data Use and Confidentiality Agreement (the “Agreement”) effective \_\_\_\_/\_\_\_\_/\_\_\_\_ (“Effective Date”). The Healthcare Facility and the MDCH shall both be referred to individually as a “Party,” or collectively as the “Parties.”

**RECITALS**

***WHEREAS**, the MDCH is a Public Health Authority, as defined by the HIPAA Privacy Rule, which is authorized by the Public Health Code to collect or receive protected health information for the purpose of preventing or controlling disease, injury, or disability, and to conduct public health surveillance, public health investigations, and public health interventions. MCL 333.2221, 45 CFR 164.512(b)(1)(i).*

***WHEREAS**, the Healthcare Facility is a health care provider that participates in the National Healthcare Safety Network (NHSN) and has been invited by the MDCH to participate in the Michigan Healthcare-Associated and Resistant Pathogens Surveillance and Prevention Project (the “Project”).*

***WHEREAS**, as a Public Health Authority, the MDCH has developed the Michigan Healthcare-Associated and Resistant Pathogens Surveillance and Prevention Project, using modules within the National Healthcare Safety Network (the “Data System”), and following guidance within the Department of Health and Human Services (HHS) Action Plan to Prevent Healthcare-Associated Infections.*

***WHEREAS**, NHSN fulfills the Data System components of the cooperative agreement administered by the Centers for Disease Control and Prevention (CDC) and the HHS pursuant to the American Recovery and Reinvestment Act (ARRA) of 2009, Public Law 111-5.*

**WHEREAS**, pursuant to such cooperative agreements, CDC and HHS have provided funding to the State of Michigan to enhance surveillance and prevention of health-associated infections to further the objectives of improving patient safety and reducing healthcare costs.

**WHEREAS**, this Agreement sets forth the terms and conditions pursuant to which the Data Recipient will access and use Healthcare Facility Data covered by this Agreement, and by which Data Recipient may disclose or transmit a Limited Data Set to specified outside third parties.

**WHEREAS**, the Michigan Health and Hospital Association (MHA) Keystone Center for Patient Safety and Quality, the Michigan Vermont Oxford Network (VON) Neonatal Intensive Care Unit (NICU) Quality Collaborative, and any other entities named in Section V.D. of this document shall be considered individually as an “Outside Third Party”, or collectively as “Outside Third Parties”.

**WHEREAS**, the parties shall abide by all applicable federal and state laws, rules and regulations, including without limitation all patient confidentiality and medical records requirements, and any applicable Institutional Review Board (“IRB”) requirements.

**NOW, THEREFORE**, in consideration of the foregoing recitals and other good and valuable considerations, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

**I. PURPOSE**

- A. This Agreement sets forth the terms and conditions pursuant to which the Data Recipient will access and use Healthcare Facility Data covered by this Agreement, and by which Data Recipient may disclose or transmit Limited Data Sets belonging to the Healthcare Facility to Outside Third Party(ies) as outlined below.
- B. Data Recipient represents and warrants that Healthcare Facility Data will be used for the purposes as stated below.
  - 1. To permit valid estimation of the magnitude of adverse events (i.e. healthcare-associated infections) among Michigan patients;
  - 2. To permit recognition of trends in adverse event rates, antimicrobial use and resistance, and pathogens associated with healthcare-associated infections;
  - 3. To utilize this data to prepare aggregate reports to show the occurrence of these infections and organisms in the state;
  - 4. To provide facilities with risk-adjusted adverse event data that can be used for comparison purposes;

5. To assist facilities in developing surveillance and analysis methods that permit timely recognition of patient problems and prompt intervention with appropriate measures;
6. To use aggregate, de-identified data to educate healthcare providers and the general public on healthcare-associated infection prevention and the importance of using antibiotics appropriately;
7. To disclose specified Limited Data Set(s) belonging to the Healthcare Facility to Outside Third Party(ies) identified in this Agreement and as outlined below.

## II. DEFINITIONS

- A. “*HIPAA Privacy Rule*” means regulations adopted by the United States Department of Health and Human Services pursuant to the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, which establishes national standards for the use and disclosure of health information. The HIPAA Privacy Rule is set out at 45 CFR Parts 160 and 164.
- B. “*Healthcare Facility Data*” is (1) protected health information including patient symptoms; lab or diagnostic testing results; hospital location; gender, age, and ethnicity of patients; types of infections; and dates directly related to the patient including birth dates, date of death, admission dates, discharge dates, visit dates and diagnosis dates and (2) includes the NHSN data element(s) that the Healthcare Facility elects to make available to the Data Recipient.
- C. “*Confidential Information*” shall consist of (1) all the Healthcare Facility Data made available to MDCH under this Agreement, as necessary for the performance of the Project, and (2) all other written or orally disclosed information or electronically exchanged information of any Party provided to any other Party, directly or indirectly, pursuant to the Project which is clearly designated in writing as “Confidential”, or in the case of oral disclosure, is identified in writing as “Confidential” within ten days, with the exception of any information that:
  - a. was in the recipient Party’s lawful possession prior to disclosure by the owner Party; or
  - b. is lawfully received by a Party without restriction regarding use or confidentiality from an independent third party who, to the recipient Party’s best knowledge, is in lawful possession of said information; or
  - c. is now or hereafter becomes generally available to the public through no action, inaction, or fault of any Party hereto.
- D. “*Use*” means the sharing, employment, application, utilization, examination or analysis of individually identifiable health information (as defined by the HIPAA Privacy Rule) within the entity that maintains such information.

- E. “*Disclosure*” means the release, transfer, provision of access to, or divulging in any manner, of information outside the entity holding the information.
- F. “*Limited Data Set*” means protected health information that does not contain any direct individual identifiers, as defined by the HIPAA Privacy Rule.
- G. “*Patient De-identified*” means the exclusion of patient-level protected health information (PHI), as defined by the HIPAA Privacy Rule.

### III. ASSURANCES OF CONFIDENTIALITY

- A. Use or disclosure of the Healthcare Facility Data provided to Data Recipient through the NHSN, pursuant to this Agreement, will be in strict conformance with the provisions of this Agreement. Any other Confidential Information to be disclosed pursuant to the Project will be held in strict confidence, as provided by this Agreement.
- B. The Confidential Information and Healthcare Facility Data will be used only for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, and/or the institution in accordance with this Agreement and Sections 304, 306 and 308(d) of the Public Health Service Act (42 USC 242b, 242k, and 242m(d)).
- C. No party shall release any Confidential Information of any other party without the express written consent of the other Parties, or without notice to the other Parties, where release is required by law or by court order.
- D. Each Party shall strictly limit access to the relevant portions of the Confidential Information of the other Parties to such of its employees, or to designated Outside Third Parties as delineated herein, who have a need to know such portions of the Confidential Information regarding the Project.
- E. The Healthcare Facility, as a “covered entity” under HIPAA Privacy Rule, is authorized to release the Healthcare Facility Data to the MDCH, without individual patients’ authorization, for research or public health purposes, subject to assurances of confidentiality, as provided by the Privacy Rule. 45 CFR 164.514(e)(3)(i), 164.514(e)(4), 164.512(b)(1)(i).
- F. Consistent with this Agreement, the MDCH shall exercise its discretion to exempt from public disclosure the Healthcare Facility Data, which is provided voluntarily by the Healthcare Facility pursuant to this Agreement, as permitted under Section 13(1) under the Michigan Freedom of Information Act (FOIA) MCL 15.231 et seq.

G. Pursuant to Part 26 of the Public Health Code, MCL 333.2601 et seq., this Project has been designated by MDCH's Chief Medical Executive as a designated medical research project, and thus, information voluntarily provided by the Healthcare Facility pursuant to this Agreement is confidential pursuant to MCL 333.2631 and 333.2632.

#### IV. PENALTIES FOR NON-COMPLIANCE

A. The unauthorized use or disclosure of Confidential Information may be punishable by imprisonment or fine, or both, under Michigan and federal laws specific to the type of information released.

#### V. OBLIGATIONS OF HEALTHCARE FACILITY

A. The Healthcare Facility agrees to voluntarily participate in the MDCH Surveillance of Healthcare-Associated & Resistant Pathogens (SHARP) Unit User Group of the National Healthcare Safety Network (NHSN) Surveillance System. By participating, the Healthcare Facility agrees to confer rights to the Data Recipient to view and use the Healthcare Facility Data from one or more of the following modules from NHSN:

##### 1. Patient Safety Component

##### a) Multidrug-Resistant Organisms / *Clostridium difficile* Infection (MDRO/CDI) Module

##### i. Multidrug-Resistant Organisms (MDRO) Measures

a. MDRO Infection Surveillance

b. Laboratory Identified Event

##### ii. Prevention Process Measures

a. Hand Hygiene

b. Gown & Glove Use

c. Active Surveillance Testing

d. Active Surveillance Testing Outcome Measures

##### iii. *Clostridium difficile* Infection (CDI) Measures

a. CDI Infection Event

b. Laboratory-Identified CDI Event

##### b) Device-Associated Module

i. CLABSI – Central Line-Associated Bloodstream Infection

ii. CLIP – Central Line Insertion Practices Adherence

iii. VAP/VAE– Ventilator-Associated Pneumonia / Ventilator-Associated Event

iv. CAUTI – Catheter-Associated Urinary Tract Infection

v. Dialysis Event

##### c) Procedure-Associated Module

i. SSI—Surgical Site Infection

##### d) Antimicrobial Use & Resistance Module

i. Antimicrobial Use Option

ii. Antibiotic Resistance Option

##### e) Vaccination Module

- 2. Healthcare Personnel Safety Component
  - a) Healthcare Personnel Exposure Module
  - b) Healthcare Personnel Vaccination Module

- B. The Healthcare Facility Data that is collected and submitted to NHSN and accessed by the MDCH will not contain the patient name. The data will include only a patient ID number that is not derived from, or related to, information about the individual and is not otherwise capable of being translated so as to identify the individual, as allowed by 45 CFR 164.514(c).
- C. The Facility agrees that the following Outside Third Party(ies) may receive a Limited Data Set from the MDCH but that the data shall be patient de-identified and shall contain no PHI as defined by the HIPAA Privacy Rule. Outside Third Party(ies) may monthly, or more frequently as needed, receive a Limited Data Set containing facility-identified counts of the following NHSN healthcare-associated infection event(s) and corresponding denominator/summary data by unit/ward from the Data Recipient as outlined below. **(Facility must check all boxes below that apply):**

My facility's NHSN data, as indicated below, may be released to:

- Michigan Health and Hospital Association (MHA) Keystone Center for Patient Safety and Quality
  - Central Line-Associated Bloodstream Infection (CLABSI)\*
  - Catheter-Associated Urinary Tract Infection (CAUTI)\*
  - Surgical Site Infection (SSI)\*
  - Ventilator-Associated Pneumonia (VAP)\*
  - Ventilator-Associated Events (VAE)<sup>†</sup>

\*Note: This data, when available, will be released to MHA retroactive to March 1, 2012

<sup>†</sup>Note: This data, when available, will be released to MHA retroactive to January 1, 2013

- Michigan Vermont Oxford Network (VON) Neonatal Intensive Care Unit (NICU) Quality Collaborative
  - NICU CLABSI\*

\*Note: This data, when available, will be released to VON retroactive to January 1, 2012.

Other Outside Third Parties and NHSN data to release to: (specify)

Outside Third Party #1: \_\_\_\_\_

Central Line-Associated Bloodstream Infection (CLABSI)

Catheter-Associated Urinary Tract Infection (CAUTI)

Surgical Site Infection (SSI)

Ventilator-Associated Pneumonia (VAP)

Ventilator-Associated Events (VAE)

MDRO/CDI LabID Events

Antimicrobial Use & Resistance Data

Healthcare Personnel Flu Vaccination Data

Effective release date: \_\_\_\_\_

Outside Third Party #2: \_\_\_\_\_

Central Line-Associated Bloodstream Infection (CLABSI)

Catheter-Associated Urinary Tract Infection (CAUTI)

Surgical Site Infection (SSI)

Ventilator-Associated Pneumonia (VAP)

Ventilator-Associated Events (VAE)

MDRO/CDI LabID Events

Antimicrobial Use & Resistance Data

Healthcare Personnel Flu Vaccination Data

Effective release date: \_\_\_\_\_

D. Protected health information which will **NOT** be transmitted to designated Outside Third Parties includes the following:

1. Patient names
2. All geographic subdivisions smaller than a State
3. All elements of dates (except year) for dates directly related to an individual including birth date, admission date, discharge date, date of death
4. Telephone numbers
5. Fax numbers
6. Account numbers
7. Certificate/License numbers
8. Vehicle identifiers and serial numbers, including license plate numbers

9. Device identifiers and serial numbers
10. Web Universal Resource Locators (URLs)
11. Internet Protocol (IP) address numbers
12. Biometric identifiers, including finger and voice prints
13. Full face photographic images and any comparable images
14. Any other unique identifying number, characteristic, code, or combination that allows identification of an individual.

E. The Healthcare Facility will consider offers of support from the MDCH to assist with data validation activities.

VI. OBLIGATIONS AND ACTIVITIES OF DATA RECIPIENT (MDCH)

**With regarding to data provided under this agreement, the MDCH agrees to:**

- A. Use appropriate safeguards to prevent use or disclosure of Healthcare Facility Data other than as provided for by this Agreement, or otherwise as required by applicable state or federal law;
- B. Limit access to Healthcare Facility Data within MDCH only to the following:
  1. The Michigan Department of Community Health (MDCH), Division of Communicable Diseases, Surveillance of Healthcare-Associated and Resistant Pathogens (SHARP) Unit;
  2. The Michigan Department of Community Health (MDCH), Bureau of Laboratories, Infectious Disease Division, Microbiology Section.
- C. Release the Facility Identified, Patient De-identified Limited Data Set monthly, or more frequently as needed, to an Outside Third Party(ies), as directed by the Facility in this Addendum;
- D. Ensure that any Outside Third Parties, agent(s), or subcontractor(s) who access the Limited Data Set, agree to the same restrictions and conditions that apply to the Data Recipient;
- E. Make reasonable efforts to limit the use or disclosure of Healthcare Facility Data to the minimum amount necessary to accomplish the intended purposes of the use or disclosure of the Data;
- F. Provide written notice to Healthcare Facility of any use or disclosure of Healthcare Facility Data not provided for by this Agreement;
- G. Make no attempt to contact or identify any individuals or entities whose health or provider information may be represented in the Healthcare Facility Data;
- H. Return or destroy all originals and copies of any potentially identifiable information upon completion of project, or upon request, unless otherwise approved in this Agreement;

- I. Not use the data provided to engage in any method, act, or practice which constitutes a commercial solicitation or advertisement of goods or services to consumers; and
  - J. Not use the data provided as a basis for legal, administrative or other actions which may affect particular individuals or establishments as a result of their specific identification in this project.
- VII. PROVISION AND MANAGEMENT OF HEALTHCARE FACILITY DATA
- A. The Healthcare Facility shall provide Healthcare Facility Data access to the MDCH for use in connection with surveillance of healthcare-associated infections. The Healthcare Facility shall transmit the data to the MDCH electronically through the National Healthcare Safety Network (NHSN).
  - B. Some of the Healthcare Facility Data may be extracted and stored in a computer maintained by the MDCH, and/or the Michigan Department of Technology, Management and Budget (DTMB), serving as the MDCH's agent.
  - C. The MDCH and its agent, the Michigan Department of Technology, Management and Budget (DTMB), shall use all reasonable administrative, physical and technical safeguards (based on industry best practices) to secure, protect and manage the Healthcare Facility Data in compliance with the terms of this Agreement.
  - D. The MDCH SHARP Unit shall monthly, or more frequently as needed, transmit Limited Data Sets to Outside Third Party (ies) via an encrypted email, or otherwise in an equally secure and confidential manner.
  - E. Outside Third Party(ies) shall be responsible for using all reasonable administrative, physical, and technical safeguards (based on industry best practices) to secure, protect and manage the Limited Data Sets while in their possession.
  - F. Throughout the term of this Agreement, the MDCH shall make the Healthcare Facility and all aggregated data provided by other participants in the Project, including data summaries and analysis produced by the Project, available to designated personnel of the MDCH and local health departments, as required in order to carry out the public health surveillance functions of the Project.
  - G. Participants in the Project will receive regular updates on the status of the Surveillance and Prevention Project. Further, an Advisory Group will determine the most appropriate presentation of data for participants.
  - H. All the Healthcare Facility Data shall, at all times, remain the property of the Healthcare Facility and shall be returned to the Healthcare Facility in its original form, and any aggregated or derivative form, immediately upon request.

## VIII. GOVERNANCE

- A. This Project will be directed by a board comprised of representatives of the state of Michigan, medical professionals, the state hospital association, hospital quality assurance and safety agencies, and consumer representatives (the “HAI Prevention Advisory Group”).
- B. The Advisory Group shall be responsible for oversight of this Project.

## IX. INSTITUTIONAL REVIEW BOARD (IRB) APPROVALS

- A. As relevant and appropriate, the Parties shall abide by all applicable IRB requirements and/or requirements of the Health Facility Information Security Committee (“ISC”). Where IRB and ISC oversight is required, the Parties shall provide such documentation of compliance to each other.

## X. MISCELLANEOUS

- A. The terms and conditions of this Agreement supersede all previous oral or written representations, understandings or agreements not incorporated into this Agreement.
- B. This Agreement shall not be amended or modified, unless approved in writing by the Parties.
- C. If any provision of this Agreement shall be held illegal or unenforceable by a court having jurisdiction, such provision shall be modified to the extent necessary to render it enforceable by a court having jurisdiction. Such provision shall be modified to the extent necessary to render it enforceable without losing its intent, or severed from this Agreement if no such modification is possible, and other provisions of this Agreement shall remain in full force and effect.
- D. The relationship between the MDCH and the Health Facility is that of independent contractors and neither Party, nor its agents including the Outside Third Party(ies), shall have any authority to bind the other Party in any way.
- E. Nothing express or implied in this Agreement is intended to confer, nor shall anything in this Agreement confer upon any person, other than the MDCH and the Health Facility, and their respective successors or assigns, any rights, remedies, obligations or liabilities whatsoever.

## XI. TERM AND TERMINATION OF AGREEMENT

- A. This Agreement shall be effective as of the Agreement Effective Date, and shall continue until the Agreement is terminated in writing by either Party, or by the Outside Third Party(ies).

- B. Termination Without Cause. Health Facility may terminate this Agreement without cause upon thirty (30) days written notice to Data Recipient.
- C. Termination With Cause. Upon Health Facility's knowledge of a pattern or practice that constitutes a material breach of this Agreement by Data Recipient or by the Third Party(ies), the, Health Facility will take, and Data Recipient and/or Third Party(ies) will cooperate in taking, reasonable steps to cure the breach and mitigate any reasonably anticipated consequences of such breach. If such steps are unsuccessful, Health Facility may, in addition to any other rights Health Facility may have under this Agreement or by operation of law, immediately terminate this Agreement; discontinue authorization for disclosure of Health Facility Data to Data Recipient and to Third Party(ies); and report the problem to the Secretary of the U.S. Department of Health and Human Services.

*[Signatures to follow]*

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

**DATA RECIPIENT:**

*Michigan Department of Community Health (MDCH)*  
*Bureau of Disease Control, Prevention & Epidemiology*  
*Division of Communicable Diseases*  
*Surveillance and Infectious Disease Epidemiology (SIDE) Section*  
*Surveillance of Healthcare-Associated & Resistant Pathogens (SHARP) Unit*  
201 Townsend  
Capitol View Bldg, 5<sup>th</sup> Floor  
Lansing, MI 48913  
Phone: 517-335-8165  
Fax: 517-335-8263

\_\_\_\_\_  
Corinne Miller  
Director  
Bureau of Disease Control,  
Prevention & Epidemiology  
MDCH  
Date: \_\_\_\_\_

\_\_\_\_\_  
James Collins  
Director  
Communicable Disease Division  
  
MDCH  
Date: \_\_\_\_\_

**HEALTHCARE FACILITY:**

Hospital Name: \_\_\_\_\_

Signature: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_  
Address: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
Phone: \_\_\_\_\_  
Fax: \_\_\_\_\_  
E-Mail: \_\_\_\_\_

**AUTHORIZATION OF PROMISE OF CONFIDENTIALITY**

I authorize the promise of confidentiality that is made to the Healthcare Facility, as set out in this agreement, pursuant to the Michigan Freedom of Information Act, MCL 15.243(1)(f).

\_\_\_\_\_  
James K. Haveman  
Director  
Michigan Department of Community Health

Date: \_\_\_\_\_