

## MEMORANDUM

Dear Healthcare Facility Administrator;

In December 2009 the North Carolina Division of Public Health, Communicable Disease Branch began a healthcare-associated infections (HAI) prevention program to coordinate HAI activities with prevention partners, healthcare facilities and government organizations throughout the state.

The NC-HAI prevention program has begun collecting data on central line-associated bloodstream infections (CLABSI) as an initial phase of public health surveillance of HAI. The National Healthcare Safety Network (NHSN) has been selected as the chosen reporting platform and participation in this network by your facility has already been confirmed. We would like to respectfully request that you allow your facility's data to be collected by DPH by allowing DPH to access your facility's data through NHSN. This data use agreement outlines the aims, processes and terms of the surveillance piece of the HAI prevention program, which we ask that you review at your leisure.

Upon agreeing to the terms outlined in this document we will work with your staff to make the appropriate arrangements. This process is very brief and will only require a minimal time investment. Thank you for your time and attention and please feel free to contact me at your leisure if you have any questions or comments.

Respectfully yours,



**Levi Njord, MSc.**

HAI Epidemiologist  
North Carolina Department of Health and Human Services  
Division of Public Health  
Epidemiology Section  
Communicable Disease Branch  
Medical Consultation Unit  
HAI Prevention Program  
Email: [levi.njord@dhhs.nc.gov](mailto:levi.njord@dhhs.nc.gov)  
Phone: 919-410-2196

# North Carolina Healthcare-Associated Infections Prevention Program

## Data Use and Confidentiality Agreement Between

The North Carolina Department of Health and Human Services, Division of Public Health,  
Epidemiology Section, Communicable Disease Branch  
And

---

The North Carolina Department of Health and Human Services, Division of Public Health, Epidemiology Section, Communicable Disease Branch (NC-DPH or "Data Recipient") and \_\_\_\_\_ ("Health System") enter into this Data Use and Confidentiality Agreement (the "Agreement") effective \_\_\_\_ / \_\_\_\_ / \_\_\_\_ ("Effective Date"). The Health System and the NC-DPH shall be referred to individually as a "Party", or collectively as the "Parties".

### BACKGROUND

1. The NC-DPH is a Public Health Authority, as defined by the HIPAA Privacy Rule, which is authorized by the HIPAA Privacy Rule (45 CFR 164.512(b)(1)(i)) to collect or receive protected health information for the purpose preventing or controlling disease, injury, or disability, and conduct public health surveillance, public health investigations, and public health interventions.
2. The Health System is a healthcare provider that participates in the National Healthcare Safety Network (NHSN) and has been invited by NC-DPH to participate in the North Carolina Healthcare-Associated Infections Prevention Program (the "Program"). The Health System is permitted under the HIPAA Privacy Rule to provide protected health information to a Public Health Authority for the purposes defined in 1 above.
3. As a Public Health Authority, NC-DPH has developed a surveillance system for the North Carolina Healthcare-Associated Infections Prevention Program, using modules within the National Healthcare Safety Network (the "Data System") and following guidance within the United States Department of Health and Human Services (HHS) *Action Plan to Prevent Healthcare-Associated Infections*.
4. Pursuant to long-term dedicated funding provided by CDC, NC-DPH under NC legislative authority NC S.L 2007-480 and with American Recovery and Reinvestment Act of 2009 (ARRA) funding seeks to enhance surveillance and prevention of healthcare-associated infections to further the objectives of improving patient safety and reducing healthcare costs.
5. The Centers for Medicaid and Medicare Services (CMS) recently revised the 2011 fiscal year Inpatient Prospective Payment System (IPPS) reimbursement ruling to require healthcare facilities to report central line-associated bloodstream infections (beginning 1 Jan 2011) and surgical site infections (beginning 1 Jan 2012) via the National Healthcare Safety Network (NHSN) in order to receive their annual IPPS reimbursement.

#### I. PURPOSE

- A. This agreement sets forth the terms and conditions pursuant to which the Data Recipient will access and use the Health System Data covered by this agreement.
- B. Data Recipient agrees that Health System Data will be used for the purposes as stated below:
  - i. To permit valid estimation of the magnitude of selected healthcare-associated infections (HAI) among North Carolina patients;
    1. The following HAI(s) are included;
      - a. Central line-associated bloodstream infections (CLABSI)

- ii. To permit recognition of trends in rates of indicators associated with HAI;
- iii. To utilize this data to prepare aggregate reports to show the occurrence of HAI in the state which are free from specific facility identifiers;

## 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. "Health System Data" is (1) protected health information that has all direct individual identifiers removed so that it meets the criteria of a "limited data set", as set out in the HIPAA Privacy Rule, 45 CFR 164.514(e)(2), and (2) includes NHSN data element(s) that the Health System elects to make available to the Data Recipient as part of the Program.
- C. "Confidential Information" shall consist of (1) the Health System data contained in a limited data set made available to NC-DPH under this agreement, as necessary for the performance of the Program.
- D. "Use" means the sharing, application, utilization, examination or analysis of health information (as defined by the HIPAA Privacy Rule) within the entity that maintains such information.
- E. "Disclosure" means the releases, 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.

## III. ASSURANCES OF CONFIDENTIALITY

- A. The parties shall abide by all applicable federal and state laws, rules and regulations, including without limitation all patient confidentiality and medical records requirements.
- B. The Health System data provided to the Data Recipient through the NHSN pursuant to this agreement will constitute a limited data set and use or disclosure of this data will be in strict confidence with the provision of this agreement.
- C. Confidential Health System data will be used only for the purposes stated, and will not otherwise be disclosed or released without receiving permission from the institution in accordance with this Agreement.
- D. The Health System, as a "covered entity" under HIPAA Privacy Rule, is permitted to release a limited data set to the NC-DPH, without individual patients' authorization, for research or public health purposes, subject to assurances of confidentiality, as provided by 10A NCAC 41A .0104.

## IV. ACTIVITIES AND RESPONSIBILITIES OF THE HEALTH SYSTEM

- A. The Health System agrees to participate voluntarily in the North Carolina Healthcare-Associated Infections Prevention Program User Group of the National Healthcare Safety Network (NHSN) Surveillance System ("NC Division of Public Health" user group). By participating, the Health System agrees to confer rights to the Data Recipient to view the Health System's data in the limited data set and to utilize this data from the following module from NHSN:
  - 1. Patient Safety Component
    - a. Device-Associated Module
      - i. CLABSI – Central line-associated bloodstream infections

- B. The Health System Data collected and submitted to NHSN and accessed by NC-DPH will not contain the patient name or any other directly individual identifier (as defined by the HIPAA Privacy Rule). The data will include only a patient identification 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. If the Health System data set submitted to NHSN contains any individual identifiers, NC DPH will remove said identifiers as the initial step of data management activities before analysis to ensure that the data conforms to the limited data requirements

#### V. ACTIVITIES AND RESPONSIBILITIES OF THE DATA RECIPIENT (NC-DPH)

With regard to data the Health System's limited data set provided under this agreement, NC-DPH agrees to:

- A. Use and disclose Health System Data only for public health purposes as stated herein, except as otherwise required by applicable state or federal law;
- B. Limit access to Health System raw data only to the following:
  - i. The North Carolina Department of Health and Human Services, Division of Public Health (NC-DPH), North Carolina Healthcare-Associated Infections Prevention Program.
- C. Use appropriate safeguards as required by S.L 2007-480, the NHSN, and NC DPH privacy and security policies to prevent use or disclosure of Health System data other than as provided for by this Agreement;
- D. Provide written notice to and receive written permission from the Health System prior to any use or disclosure of Health System data not covered in this Agreement.

#### VI. PROVISION AND MANAGEMENT OF HEALTH SYSTEM DATA

- A. The Health System shall provide Health System data access to NC-DPH for use in connection with surveillance of indicated HAI. The Health System shall transmit the data electronically through the National Healthcare Safety Network (NHSN) where it will be housed.
- B. All of the Health System data transmitted to the NHSN shall, at all times, remain the property of the Health System and remain housed at the National Healthcare Safety Network (NHSN). The Health System data shall only be extracted for local use by NC-DPH in its original submitted format for the purposes of data management, validation and analysis.
- C. All NC DPH activities for data management, validation and analysis will occur on physically secure and password protected computers operated by NC-DPH. Data stored locally will be encrypted to appropriate federal and North Carolina security standards.
- D. NC-DPH shall be allowed to make available, in a manner that does not identify source Health Systems, aggregate reports resulting from analysis of the Health System data and data from other Program participants, to personnel of NC-DPH, local health departments, and the public in general as required in order to carry out the public health surveillance functions of the Program as stated herein.

#### VII. MISCELLANEOUS

- A. This Agreement shall not be amended or modified, unless approved in writing by the Parties.
- B. The relationship between NC-DPH and the Health System is that of independent contractors and neither Party, nor its agents, shall have any authority to bind the other Party in any way.

## VIII. 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.
- B. Termination Without Cause. The Health System may terminate this Agreement without cause upon thirty (30) days written notice to the Data Recipient.
- C. Termination With Cause. Upon Health System's knowledge of a pattern or practice that constitutes a material breach of this Agreement by Data Recipient, Health System will take, and Data Recipient 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 System may, in addition to any other rights Health System may have under this Agreement or by operation of law, immediately terminate this Agreement; discontinue authorization for disclosure of Health System Data to Data Recipient.
- D. Termination With Statewide Mandatory Reporting. This Agreement will also terminate if and at such time that Health Systems throughout the state of North Carolina are required to report healthcare-associated infections through legislative mandate. Notification of, and instruction surrounding, any said legislative mandate(s) will be communicated by the Data Recipient to the Health System at least thirty (30) days before effective date of said legislation.

[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**


North Carolina Healthcare-Associated Infections Prevention Program, Communicable Disease Branch, Epidemiology Section, Division of Public Health, NC Department of Health and Human Services  
1902 Mail Service Center, Raleigh, NC 27699-1902

Physical address: 225 N. McDowell Street, Copper Building, 3<sup>rd</sup> Floor, Raleigh, NC 27603

Phone: 919-733-3419; Fax: 919-733-0490

  
Levi Njord, MSc  
Epidemiologist for Healthcare-Associated Infections  
NC-DPH

Date: 10/NOV/2010

  
Evelyn Foust, MPH  
Head, Communicable Disease Branch  
NC-DPH

Date: 10/NOV/2010

**HEALTH SYSTEM**

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

Signature: \_\_\_\_\_

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

Title: \_\_\_\_\_

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

Address: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

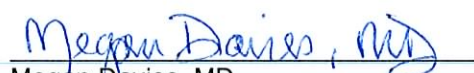
Phone: \_\_\_\_\_

Fax: \_\_\_\_\_

E-Mail: \_\_\_\_\_

**Authorization of Promise of Confidentiality**

I authorize the promise of confidentiality that is made to the Health System, as outlined in this agreement.

  
Megan Davies, MD  
State Epidemiologist – Epidemiology Section Chief  
NC-DPH

Date: 11/12/2010