Fiscal Note for addition to rule for North Carolina Division of Public Health
Requires OSBM Review

Agency: Department of Health and Human Services, Division of Public Health, Epidemiology Section, Communicable Disease Branch

Contact: Zack Moore, MD, MPH Public Health Physician II (zack.moore@dhhs.nc.gov, 919-715-4698)

Rule Citations: 10A NCAC 41A .0106

Purpose of Addition: Establish rules necessary to implement the statewide surveillance and reporting system for healthcare-associated infections established pursuant to NCGS 130A-150

Relevant Statute: NCGS 130A-150

State Impact: Yes
Local Impact: No
Substantial economic impact: No
Significant Rule Change: Yes

Additional Funds Necessary to Cover State Costs?
No additional state funds are required for the additional state costs

Summary of Rule Change
This rule change specifies which healthcare-associated infections must be reported by hospitals to the Department and establishes timeframes for reporting.

Purpose of Rule Change
The purpose of this rule change is to address the requirements set forth in NCGS 130A-150. These requirements were initially addressed by a temporary rule adopted November 30, 2011.

Healthcare-associated infections are a growing public health concern. National estimates from 2002 suggest that 1.7 million infections and 99,000 deaths resulted from healthcare-associated infections that year.[1] A recent study in North Carolina indicated that 5 common healthcare-associated infections cost acute care hospitals alone $281–$779 million dollars per year.[2]

On June 27, 2011, Governor Perdue signed into law House Bill 809 (NCGS 130A-150) which requires the Department of Health and Human Services to implement a mandatory statewide surveillance system for healthcare-associated infections by December 31, 2011. The statute also requires that the Public Health Commission adopt rules for the implementation of this system. In order to meet the requirements of NCAC 130A-150 within the timeframe established, a temporary rule requiring the reporting of healthcare-associated infections by hospitals was approved by the Commission for Public Health on October 21, 2011 and adopted by the Rules Review Commission on November 17, 2011 (appendix 1). The rule became effective on November 30, 2011, and will remain in effect until August 26, 2012. The language of the permanent rule proposed here is similar to that passed in the temporary rule (appendix 2).

The establishment of a mandatory system for reporting of healthcare-associated infections from hospitals to the Department is intended to increase transparency and allow healthcare consumers access to information needed to make healthcare decisions. The state Healthcare-Associated Infections Advisory Group will work with the Communicable Disease Branch to develop appropriate methodologies and reporting standards to ensure that data are presented appropriately for public consumption and facility comparison. Information gathered through this system will be posted on the Communicable Disease Branch website on a quarterly basis.

Timely and accurate reporting of HAI data will also provide healthcare providers, hospital epidemiologists and other public health professionals' access to data which may be used to evaluate prevention and control efforts and identify areas of need.

Description of Fiscal Impact

This note is required to specify the fiscal impacts of a statewide surveillance and reporting system for healthcare-associated infections established pursuant to NCGS 130A-150 and further described in the proposed rule.

The addition of these reporting requirements would require staff at the Communicable Disease Branch to monitor statewide healthcare-associated infection surveillance data and generate necessary reports (presented below in Item 1). Since April 2010, the North Carolina Healthcare-Associated Infection Prevention Program has operated a voluntary reporting and surveillance program for healthcare-associated infections using the National Healthcare Safety Network (NHSN), a free online surveillance system managed by the Centers for Disease Control and Prevention (CDC). The mandatory reporting of healthcare-associated infections from all North Carolina hospitals, as required under NCGS 130A-150 (Session Law 2011-386), will require the Department to work with hospitals to ensure completeness of reporting, validate reported data to ensure accuracy, monitor and analyze the reported data, generate reports on a quarterly basis, and provide support to hospital staff for surveillance activities.

The adoption of this rule will result in minimal compliance burden to the one hundred and two (102) healthcare facilities in North Carolina that will be impacted by the Mandatory Report Statute, as the healthcare-associated infections specified for reporting are those for which reporting to the Centers for Medicare and Medicaid Services (CMS) is already required under the CMS Inpatient Prospective Payment System (IPPS) Rules (CMS-1498),[3] which are incorporated by reference in 10A NCAC 41A .0106. The 102 healthcare facilities include the three State Psychiatric Facilities and 99 facilities listed in the February 2012 listing of Hospitals Licensed by the State of North Carolina, Department of Health and Human Services – Divisions of Health Service Regulation, and meet the definition of "hospital" in NCGS 131E-76(3) that is required to report. Hospitals will report the same data elements that are required by CMS using the same reporting platform (NHSN). They must initially confer rights for NC DHHS to access to their data in NHSN. After that step is complete, no additional actions are necessary to comply with this rule. Medical facilities not defined as hospitals per NCGS 131E-76(3) are not subject to this rule and will therefore incur no additional compliance burden.

Of note, the three state operated psychiatric hospitals (Broughton Hospital, Central Regional Hospital, and Cherry Hospital) are defined as hospitals per NCGS 131E-76(3) but do not participate in the CMS IPPS and do not report healthcare-associated infection data to CMS. According to the CMS-IPPS reporting schedule incorporated by reference in the proposed rule, these facilities will be required to report laboratory-identified methicillin-resistant *Staphylococcus aureus* bacteremias and *Clostridium difficile* infections beginning in January 2013. Management at the Division of State-Operated Facilities indicates that the burden on staff would be minimal and can be performed by current staff. These facilities experience a very number low number of reportable events. For example, during 2011, there were a total of 4 laboratory-confirmed *Clostridium difficile* infections and 0 methicillin-resistant *Staphylococcus aureus* bacteremias identified among these facilities. Estimated staff costs that would be associated with reporting these events are presented below (Item 2).

The adoption of this rule will result in no additional burdens to local health departments, since hospitals will report healthcare-associated infections directly to CDC (and thereby to the Communicable Disease Branch) through NHSN, and analysis will be performed at the state level.

Disclosure of healthcare-associated infection data will have little or no direct impact or opportunity cost for facilities submitting data. There are, however, potential significant second-order (i.e. indirect) impacts on hospitals and the general public associated with public disclosure of HAI data. Disclosure of HAI data to the public and to hospitals has the potential to incentivize improvements in patient safety, thereby reducing infections and the associated costs. However, any potential second-order benefits of HAI surveillance and reporting can only be realized if the data are appropriately validated and analyzed, including risk-adjustment based on characteristics of the facility and patient population. In general, any health benefits, cost savings, and costs associated with public disclosure of healthcare-associated infections are highly uncertain based on currently available research. Since research has not yet validated the potential impacts of HAI disclosure, these potential impacts are not included in this fiscal note.

Annual estimates of expenditure due to rule passage

Item 1	**Count**	**Cost**
Division of Public Health (DPH)		
Annual midpoint salary for an Epidemiologist 1 position[4]	N/A	$56,667
Annual work hour expectation for a state employee[4]	2080	N/A
Hourly salary for an Epidemiologist 1 position	1	$27.24
Hours spent doing monthly data generation, management and analysis	480	$13,077.00
Hours spent developing monthly internal reports	140	$3,814.13
Hours spent developing quarterly reports for public disclosure	160	$4,359.00
Hours spent developing the annual report for the general assembly	140	$3,814.13
Hours spent working on internal data validation	320	$8,718.00
Hours spent working on external data validation working with hospitals	620	$16,891.13
DPH Opportunity Cost of Staff Time	1860	$50,673.38
DPH Opportunity Cost, including .34% Total Compensation Adjustment		**$67,902.32**
Item 2		
Division of State Operated Healthcare Facilities (DSOHF)		
Annual midpoint salary for a Medical Laboratory Technologist II[4]	N/A	$49,903
Annual work hour expectation for a state employee	2080	N/A
Hourly salary for a Medical Laboratory Technologist II	1	$23.99
Hours spent identifying events and communicating required elements to Hospital Infection Preventionist (1 hours per year x 3 hospitals)	3	$71.98
Annual midpoint salary for Hospital Infection Preventionist (Infection Control Nurse)[4]	N/A	$54,271
Annual work hour expectation for a state employee	2080	N/A
Hourly salary for a Hospital Infection Preventionist	1	$26.09
Hours spent completing one-time training on surveillance requirements and reporting through NHSN (24 hours x 3 hospitals – non-recurring)	72	$1,878.61
Hours spent reporting data into NHSN (3 hours per year x 3 hospitals)	9	$234.83
DSOHF Opportunity Cost of Staff Time	84	$2,185.41
DSOF Opportunity Cost including .34% Total Compensation Adjustment		**$2,928.45**
Total Recurring Costs (per year) incl. compensation factor	**1872**	**$68,313.44**
Total Non-Recurring Costs (one time) incl. compensation factor	**72**	**$2,517.34**
Total Costs incl. compensation factor		**$70,830.78**

References:

1. Klevens RM, Edwards JR, Richards CL, et al. Estimating healthcare-associated infections in US hospitals, 2002. Public Health Rep. Mar 2007; 122(2):160-6.

2. Estimates for Cost of Healthcare-Associated Infections (HAIs) in North Carolina Acute Care Hospitals – Report from the Economic Impact Subgroup of the North Carolina Department of Public Health HAI Advisory Group. Submitted: 12 January 2011.

3. Centers for Medicare and Medicaid Services Inpatient Prospective Payment System Rules (CMS – 1498), Centers for Medicare and Medicaid Services.

4. 2008 State of North Carolina Salary Plan, Office of State Personnel. Available at http://www.osp.state.nc.us/CompWebSite/salaryplanbook.pdf

Appendix 1: Temporary Rule

10A NCAC 41A .0106 REPORTING OF HEALTH-CARE- ASSOCIATED INFECTIONS

(a) The following definitions apply throughout this Rule:

(1) "Hospital" means any facility designated as such in G.S. 131E-76(3).

(2) "National Healthcare Safety Network" is an internet-based surveillance system managed by the Centers for Disease Control and Prevention. This system is designed to be used for the direct, standardized reporting of healthcare quality information, including health care-associated infections, by health care facilities to public health entities.

(3) "Health care-associated infection" means a localized or systemic condition resulting from an adverse reaction to the presence of an infectious agent(s) or its toxin(s) with no evidence that the infection was present or incubating at the time of admission to the health care setting.

(4) "Electronic surveillance system" means an electronic platform which has the ability to collect, manipulate, store, analyze or transmit electronic health data which may be used for surveillance of health care-associated infections.

(5) "Denominator or summary data" refers to referent or baseline data required to generate meaningful statistics for communicating health care-associated infection rates.

(6) "The Centers for Medicare and Medicaid Services - Inpatient Prospective Payment System (CMS – IPPS) rules" are regulations promulgated for the disbursement of operating costs by the Centers for Medicare and Medicaid Services for acute care hospital stays under Medicare Part A based on prospectively set rates for care.

(b) Hospitals shall electronically report all health care-associated infections required by Paragraph (c) of this Rule through the National Healthcare Safety Network and shall make the data available to the Department. Hospitals also shall:

(1) Report all specified health care-associated infections within 30 days following the end of every calendar month during which the infection occurred;

(2) Report all required health care-associated infection denominator or summary data for healthcare-associated infections within 30 days following the end of every calendar month; and

(3) Comply with all reporting requirements for general participation in the National Healthcare Safety Network.

(c) Except as provided in rules of this Section, hospitals shall report the healthcare-associated infections required by the Centers for Medicare and Medicaid Services listed in the CMS-IPPS rules beginning on the dates specified therein. The CMS-IPPS rules are hereby incorporated by reference including subsequent amendments and editions. A current copy of the CMS-IPPS rules may be obtained through the CMS-IPPS website at http://www.cms.gov/AcuteInpatientPPS/. A copy of the current CMS-IPPS rules, applicable to this section, is available for inspection in the Division of Public Health, 225 N. McDowell Street, Raleigh NC 27601.

(d) Beginning October 1, 2012 and quarterly thereafter, the Department shall release reports to the public on health care-associated infection(s) in North Carolina.

History Note: *Authority G.S. 130A-150;*
Temporary Adoption Eff. November 30, 2011

:

Appendix 2: Proposed Rule

10A NCAC 41A .0106 REPORTING OF HEALTH-CARE- ASSOCIATED INFECTIONS

(a) The following definitions apply throughout this Rule:

(1) "Hospital" means any facility designated as such in G.S. 131E-76(3).

(2) "National Healthcare Safety Network" is an internet-based surveillance system managed by the Centers for Disease Control and Prevention. This system is designed to be used for the direct, standardized reporting of healthcare quality information, including health care-associated infections, by health care facilities to public health entities.

(3) "Health care-associated infection" means a localized or systemic condition resulting from an adverse reaction to the presence of an infectious agent(s) or its toxin(s) with no evidence that the infection was present or incubating at the time of admission to the health care setting.

(4) "Denominator or summary data" refers to referent or baseline data required to generate meaningful statistics for communicating health care-associated infection rates.

(5) "The Centers for Medicare and Medicaid Services - Inpatient Prospective Payment System (CMS – IPPS) rules" are regulations promulgated for the disbursement of operating costs by the Centers for Medicare and Medicaid Services for acute care hospital stays under Medicare Part A based on prospectively set rates for care.

(b) Hospitals shall electronically report all health care-associated infections required by Paragraph (c) of this Rule through the National Healthcare Safety Network and shall make the data available to the Department. Hospitals also shall:

(1) Report all specified health care-associated infections within 30 days following the end of every calendar month during which the infection occurred;

(2) Report all required health care-associated infection denominator or summary data for healthcare-associated infections within 30 days following the end of every calendar month; and

(3) Comply with all reporting requirements for general participation in the National Healthcare Safety Network.

(c) Except as provided in rules of this Section, hospitals shall report the healthcare-associated infections required by the Centers for Medicare and Medicaid Services listed in the CMS-IPPS rules beginning on the dates specified therein. The CMS-IPPS rules are hereby incorporated by reference including subsequent amendments and editions. A summary of the HAI reporting requirements from current copy of the CMS-IPPS rules may be obtained through the CMS QualityNet site at http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228760487021 The CMS IPPS rules themselves can be obtained from the CMS IPPS website at http://www.cms.gov/AcuteInpatientPPS/IPPS2011/list.asp#TopOfPage and http://www.cms.gov/AcuteInpatientPPS/FR2012/list.asp#TopOfPage. A copy of the current CMS-IPPS rules, applicable to this section, is available for inspection in the Division of Public Health, 225 N. McDowell Street, Raleigh NC 27601.

(d) Beginning October 1, 2012 and quarterly thereafter, the Department shall release reports to the public on health care-associated infection(s) in North Carolina.

History Note: Authority G.S. 130A-150