GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2011

H **D**

HOUSE DRH11158-MGf-46A (02/24)

Short Title:	Model Healthcare-Associated Infections Law.	(Public)
Sponsors:	Representative Burr.	
Referred to:		

A BILL TO BE ENTITLED

AN ACT TO REQUIRE THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIVISION OF PUBLIC HEALTH, TO ESTABLISH A HEALTHCARE-ASSOCIATED INFECTION SURVEILLANCE, PREVENTION, AND CONTROL PROGRAM, TO ESTABLISH A REGULATORY FEE FOR THE PROGRAM, AND TO AUTHORIZE THE DEPARTMENT TO ASSESS AN ADMINISTRATIVE PENALTY AGAINST HEALTH CARE FACILITIES THAT FAIL TO COMPLY WITH PROGRAM REQUIREMENTS.

The General Assembly of North Carolina enacts:

SECTION 1. Article 6 of Chapter 130A of the General Statutes is amended by adding a new Part to read:

"Part 1A.

"Healthcare-Associated Infection Surveillance, Prevention, and Control Program.

"**§ 130A-150. Legislative findings and purpose.**

(a) The legislature finds and declares all of the following:

(1) The protection of patients in health care facilities is of paramount importance to the citizens of this State.

(2) During the past two decades, healthcare-associated infections (HAIs), especially those that are resistant to commonly used antibiotics, have increased dramatically. The federal Centers for Disease Control and Prevention (CDC) estimates that there are over two million cases of HAIs per year in the United States, resulting in 100,000 preventable deaths.

(3) There is currently no system within the Department of Health and Human Services (Department) to determine the incidence or prevalence of HAIs or to determine if current infection prevention and control measures are effective in reducing HAIs.

(4) A significant percentage of HAIs can be prevented with intense programs for surveillance and the development, implementation, and constant evaluation and monitoring of prevention strategies.

(5) There is currently inadequate regulatory oversight by the State of HAI surveillance, prevention, and control programs in health care facilities.

(6) The Department will only be able to protect patients from HAIs through the development of a comprehensive, robust, and efficient system to monitor and report the incidence of antibiotic-resistant and other organisms causing infection that are acquired by patients in health care facilities.

(b) In recognition of the need to reduce the incidence of HAIs among health care facilities in this State, the General Assembly directs the Secretary of the Department of Health and Human Services to establish and maintain a comprehensive HAI surveillance, prevention and control program designed to ensure that health care facilities in this State comply with State laws and regulations designed to reduce the incidence and spread of HAIs.

"**§ 130A-150.1. Definitions.**

The following definitions apply in this Article:

(1) "Colonized" or "colonization" means a pathogen is present on a patient's body but is not causing any signs or symptoms of an infection.

(2) "Committee" means the Healthcare Associated Infection Advisory Committee established pursuant to G.S. 130A-150.2.

(3) "Department" means the North Carolina Department of Health and Human Services.

(4) "Health care facility" means a hospital licensed under G.S. 131E-77, a nursing home licensed under G.S. 131E-102, and an ambulatory surgical facility licensed under G.S. 131E-147.

(5) "Health payer" includes any self-insured plan, group health plan (as defined in section 607(1) of the Employee Retirement Income Security Act of 1974, [29 U.S.C. § 1167(1)]), service benefit plan, managed care organization, or other party that is, by statute, contract, or agreement, legally responsible for payment of a claim for a health care item or service as a condition of doing business in the State; the State Medical Assistance Program established under G.S. 108A-54; and The Health Insurance Program for Children established under G.S. 108A-70.20.

(6) "Healthcare-associated infection" or "HAI" means a Clostridium difficile infection, methicillin-resistant Staphylococcus aureus (MRSA) infection, or any one of the following four most prevalent categories of infection that a patient acquires while receiving treatment for a medical or surgical condition, as determined by the United States Department of Health and Human Services Action Plan to Prevent Healthcare-Associated Infections:

a. Surgical site infection.

b. Catheter-associated urinary tract infection.

c. Central line-associated bloodstream infection.

d. Ventilator-associated pneumonia.

(7) "Infection prevention professional" means a registered nurse, medical technologist, or other salaried employee or consultant who, within two years of appointment as an infection prevention professional, meets the education and experience requirements for certification in infection prevention and control and applied epidemiology by the national Certification Board for Infection Control and Epidemiology (CBIC). The term does not include a physician who is appointed or receives a stipend as an infection prevention and control committee chairperson or hospital epidemiologist.

(8) "MRSA" means methicillin-resistant Staphylococcus aureus.

(9) "NHSN" means the Centers for Disease Control and Prevention's National Healthcare Safety Network.

(10) "Program" means the HAI Surveillance, Prevention, and Control Program established under this Part.

"**§ 130A-150.2. Healthcare-Associated Infections Advisory Committee; purpose; composition.**

(a) The HAI Advisory Committee is established within the Department.

(b) The Committee shall have up to 13 members, including the Secretary of the Department or the Secretary's designee. The Speaker of the House of Representatives and the President Pro Tempore of the Senate shall each appoint six members, each of whom shall have expertise in the surveillance, prevention, and control of healthcare-associated infections. The membership shall be representative of the Department, local health departments, healthcare infection control professionals, hospital administrators, healthcare providers, healthcare consumers, physicians with expertise in infectious disease and hospital epidemiology, not-for-profit nursing homes, for-profit nursing homes, and integrated healthcare systems. The members of the Committee shall elect a chair and vice-chair from among the Committee membership. The Committee shall meet at the call of the chair at least once every quarter.

(c) Members shall serve without compensation but, within available funds, shall be allowed travel and subsistence expenses in accordance with G.S. 138-5 or G.S. 138-6, as appropriate.

(d) The Committee has the following duties and responsibilities:

(1) Make recommendations on the preferred method by which health care facilities will report HAIs to the Department pursuant to this Part.

(2) Make recommendations on the adoption of national guidelines for preventing the spread of HAIs.

(3) Make recommendations on the public reporting of process measures for preventing the spread of HAIs.

(4) Review and evaluate federal and State laws, regulations, and accreditation standards pertaining to infection control and prevention and communicate to the Department how existing infection control and prevention programs will be impacted by implementation of this Part.

(5) Recommend a method for determining the number of infection prevention professionals in each health care facility.

(6) Recommend training and education requirements for State employees charged with inspecting health care facilities for compliance with the Program established under this Part.

(7) Recommend a method for auditing the validity and reliability of data submitted by health care facilities to the NHSN and Department.

(8) Recommend a standardized method for identifying HAIs that occur after a patient is discharged from a health care facility.

(9) Recommend a method by which risk-adjusted HAI data will be reported to the Governor, the General Assembly, and the public.

(10) Recommend methods by which health care facilities may, whenever possible, use epidemiological data to comply with the HAI reporting requirements established under this Part.

(11) Recommend a standardized method for evaluating health care facilities' compliance with this Part and for evaluating health care workers' compliance with infection prevention procedures, including hand hygiene and environmental sanitation procedures.

(12) Recommend training requirements for hospital infection prevention professionals on how to use the NHSN HAI surveillance reporting system.

(13) Consider and determine the feasibility of establishing active surveillance programs involving other entities, including athletic teams, correctional facilities, and other persons in the community that are colonized and at risk of susceptibility to and transmission of MRSA.

"**§ 130A-150.3. Healthcare-Associated Infections Surveillance, Prevention, and Control Program; Department duties.**

(a) By January 1, 2012, the Department shall establish a comprehensive HAI Program under which all of the following are accomplished:

(1) Federal funds allocated to the Program will be used to assess the Department's HAI resource needs, educate health care facility evaluator nurses in HAI, educate Department staff on methods for implementing recommendations for HAI prevention, and monitor emerging science and best practices in HAI prevention whenever possible.

(2) Each health care facility shall be required to meet current CDC guidelines and standards for HAI prevention.

(3) Each health care facility shall be required to develop a process for evaluating the judicious use of antibiotics, the results of which shall be monitored jointly by appropriate health care facility representatives and committees involved in quality improvement activities.

(4) The Department shall provide education and training to Department staff responsible for, and consultants hired to assist Department staff with, evaluating health care facilities for compliance with Program requirements.

(5) The Department shall provide current information to the public on HAI prevention and control, including information on causes and symptoms, diagnosis and treatment, prevention methods, and the proper use of antimicrobial agents and antibiotics, through the Department's Internet Web site.

(b) Beginning January 1, 2013, and annually thereafter, the Department shall provide to the Governor, the Senate Appropriations Committee on Health and Human Services, and the House of Representatives Appropriations Committee on Health and Human Services a report summarizing the HAI information reported by health care facilities to the NHSN and the Department pursuant to this Part. The Department shall make this annual report available to the public on its Internet Web site.

(c) Beginning January 1, 2013, the Division of Health Service Regulation shall post on its Internet Web site information regarding the incidence rate of HAIs in each health care facility subject to this Part, as reported to the NHSN and the Department using the data and components as defined in the NHSN Manual, Patient Safety Component Protocol, and any successor edition.

(d) Any information reported publicly as required under this section shall follow a risk adjustment process that is consistent with NHSN and use the NHSN's risk adjustment definitions, unless the Commission adopts rules under G.S. 130A-150.8 to establish a fair and equitable risk adjustment process that is consistent with the recommendations of the HAI Advisory Committee.

(e) The Secretary of the Department shall designate a HAI Coordinator to coordinate the HAI Program.

"**§ 130A-150.4. Health care facility infection control requirements.**

(a) Each health care facility subject to this Part shall do all of the following:

(1) Implement an infection control policy consistent with the rules adopted by the Commission pursuant to G.S. 130A-150.8.

(2) Designate an infection control officer responsible for directing the facility's infection control activities and ensuring the facility's compliance with the testing and reporting requirements established under this Part. The name of the infection control officer shall be made publicly available, upon request.

(3) Conduct an infection control risk assessment at least once every 12 months, using industry best practices and guidelines. The results of the risk assessment shall be made publicly available, upon request.

(4) Train its environmental services staff in health care facility sanitation measures at the start of employment, and annually thereafter, or whenever the hospital adopts new prevention measures and monitor staff compliance with sanitation measures by randomly sampling cultures of the environment.

(5) Require each physician designated as a health care facility's epidemiologist or infection control officer to complete a continuing medical education (CME) training program in infection surveillance, prevention, and control offered by the CDC and the Society for Healthcare Epidemiology of America, or other recognized professional organization. The health care facility shall retain documentation of the physician's successful completion of the CME training program in the physician's credentialing file.

(6) Require all health care facility staff and contract physicians and all other licensed independent contractors, including nurse practitioners and physician assistants, to be trained in methods to prevent transmission of HAI, including MRSA and Clostridium difficile infection.

(7) Require all permanent and temporary health care facility employees and contractual staff, including students, to participate in training in health care facility-specific infection prevention and control policies, including hand hygiene, isolation procedures, patient hygiene, and environmental sanitation procedures. The health care facility shall make this training available to employees and contractual staff annually and when new policies have been adopted by the hospital's infection surveillance, prevention, and control committee.

"**§ 130A-150.5. Health care facility active surveillance requirements.**

(a) Each health care facility shall test patients for MRSA up to 10 days prior to an elective admission or within 24 hours of admission in the following cases:

(1) The patient is scheduled for inpatient surgery and has a documented medical condition that makes the patient susceptible to infection, based either upon CDC findings or the Committee's recommendations.

(2) The patient has been previously discharged from a general acute care hospital within 30 days prior to the current hospital admission.

(3) The patient has previously had MRSA or has previously cared for a patient with MRSA.

(4) The patient will be admitted to an intensive care unit or burn unit of the hospital.

(5) The patient receives inpatient dialysis treatment.

(6) The patient is being transferred from a skilled nursing facility.

(7) The patient has any open wound or lesion that appears to be infectious.

(8) The patient has been transferred from a prison or jail.

(9) The patient suffers from a condition that compromises the immune system, including HIV/AIDS or cancer.

(10) The patient is homeless.

(11) The patient has taken drugs intravenously.

(12) The patient has had antibiotic therapy repeatedly or within the recent past.

(b) If a patient tests positive for MRSA, the attending physician shall inform the patient or the patient's representative immediately or as soon as practically possible.

(c) A health care facility shall retest a patient for MRSA at least once per week upon transfer to a different critical care setting and immediately prior to discharge from the facility if the patient shows evidence of increased risk of invasive MRSA after being tested in accordance with subsection (a) of this section. This section does not apply to a patient who has tested positive for MRSA or colonization upon entering the facility.

(d) A health care facility shall provide each patient who tests positive for MRSA oral and written instruction regarding available decolonization protocols, aftercare, and precautions to prevent the spread of infection to others. The health care facility shall provide this information to the patient at the time the positive results are communicated to the patient.

"**§ 130A-150.6. Health care facility reporting requirements.**

(a) Beginning January 1, 2013, and quarterly thereafter, each health care facility shall report to the Department and NHSN all healthcare-associated infection data and components as defined in the NHSN Manual, the United States Department of Health and Human Services Action Plan to Prevent Healthcare-Associated Infections, Patient Safety Component Protocol, or any successor edition, for all patients throughout the health care facility.

(b) Each health care facility shall report patient-specific data including, at a minimum, patient identification number, gender, and date of birth. In reporting the patient identification number, the health care facility shall ensure compatibility with the patient identifier on the uniform billing forms submitted to the Department.

(c) Each health care facility shall report data on a monthly basis in accordance with protocols defined by the NHSN Manual, as updated by the CDC.

(d) Each health care facility shall give the Department and the Committee access to its reports of healthcare-associated infection data contained in the NHSN database for the purposes of allowing the Department and the Committee to view and analyze the data.

"**§ 130A-150.7. Financial incentives for health care facility compliance.**

(a) Health payers shall provide coverage for routine cultures and screenings performed on patients in compliance with a health care facility's infection control plan. The Department shall seek federal approval, as necessary, to provide coverage for these services under the State Medical Assistance Program and The Health Insurance Program for Children. These costs shall be subject to any co-payment or deductible in effect at the time service is rendered.

(b) Beginning January 1, 2013, the Department shall, within available appropriations, make a quality improvement payment to each health care facility that achieves the metrics identified in the United States Department of Health and Human Services Action Plan to Prevent Healthcare-Associated Infections for that health care facility in the total number of reported HAIs over the preceding year. For calendar year 2013, and annually thereafter, the Department shall consult with the HAI Advisory Committee to establish appropriate percentage benchmarks for the reduction of healthcare-associated infections in each health care facility in order to be eligible for a payment pursuant to this subsection.

(c) A health care facility that is not in compliance with the HAI infection reporting requirements of G.S. 130A-150.6 is not eligible for a quality improvement payment under this section.

(d) A health care facility shall not charge or otherwise seek to obtain payment from a patient for costs associated with a hospital acquired condition subject to the hospital acquired condition payment provisions of the Medicare program, as established by regulation of the federal Centers for Medicare and Medicaid Services. Each health care facility shall notify its patients, in writing, of the provisions of this subsection on a form or in a manner prescribed by the Department.

(e) The attending physician responsible for causing a condition for which a health care facility is prohibited from charging or seeking payment from a patient pursuant to subsection (d) of this section shall not charge or otherwise seek to obtain payment from a patient for costs associated with the condition. Each health care facility shall notify its patients, in writing, of the provisions of this subsection on a form or in a manner prescribed by the Department.

"**§ 130A-150.8. Rules.**

The Commission shall adopt rules, as necessary, to implement the provisions of this Part. The rules shall incorporate current CDC guidelines and standards for HAI prevention. The rules

shall also require each health care facility subject to this Part to adopt a written infection control policy that includes at least all of the following:

(1) Procedures to reduce HAIs.

(2) Procedures for regular disinfection of all restrooms, countertops, furniture, televisions, telephones, bedding, office equipment, and surfaces in patient rooms, nursing stations, and storage units.

(3) Procedures for regular removal of accumulations of bodily fluids and intravenous substances, and cleaning and disinfection of all movable medical equipment, including point-of-care testing devices such as glucometers and transportable medical devices.

(4) Procedures for regular cleaning and disinfection of all surfaces in common areas in the facility such as elevators, meeting rooms, and lounges.

(5) A facility-wide hand hygiene program.

"**§ 130A-150.9. Fees.**

(a) Each health care facility shall pay the Department a surcharge on its licensing fee in an amount determined by the Department to be necessary to provide sufficient revenues for the Department and the HAI Advisory Committee to perform their responsibilities under this Part. The total aggregate annual assessment for all health care facilities shall not exceed five thousand dollars ($5,000).

"**§ 130A-150.10. Administrative penalty.**

(a) The Department may impose an administrative penalty in the amount of one thousand dollars ($1,000) per incident on any health care facility that negligently fails to report a HAI as required under this Part. Each day of a continuing violation shall constitute a separate violation. In determining the amount of the penalty, the Department shall consider the degree and extent of the harm caused by the violation. Any facility assessed a penalty shall be notified of the assessment by registered or certified mail, and the notice shall specify the reasons for the assessment.

(b) Any facility wishing to contest a penalty or order issued under this section shall be entitled to an administrative hearing and judicial review in accordance with the procedures outlined in Articles 3, 3A, and 4 of Chapter 150B of the General Statutes.

SECTION 2. This act becomes effective January 1, 2012.