

**ACT 52 OF 2007**  
**MEDICAL CARE AVAILABILITY AND REDUCTION OF ERROR (MCARE) ACT**  
**CHAPTER 4. HEALTH CARE-ASSOCIATED INFECTIONS**  
**40 P.S. § 1303.401 – 1303.411 (2007)**

**§ 1303.401. Scope of chapter**

This chapter relates to the reduction and prevention of health care-associated infections.

**§ 1303.402. Definitions**

The following words and phrases when used in this chapter shall have the meanings given to them in this section unless the context clearly indicates otherwise:

"AMBULATORY SURGICAL FACILITY." An entity defined as an ambulatory surgical facility under the act of July 19, 1979 (P.L. 130, No. 48), known as the Health Care Facilities Act.

"ANTIMICROBIAL AGENT." A general term for drugs, chemicals or other substances that kill or slow the growth of microbes, including, but not limited to, antibacterial drugs, antiviral agents, antifungal agents and antiparasitic drugs.

"AUTHORITY." The Patient Safety Authority established under this act.

"CENTERS FOR DISEASE CONTROL AND PREVENTION" or "CDC." The United States Department of Health and Human Services Centers for Disease Control and Prevention.

"COLONIZATION." The first stage of microbial infection or the presence of nonreplicating microorganisms usually present in host tissues that are in contact with the external environment.

"COUNCIL." The Pennsylvania Health Care Cost Containment Council established under the act of July 8, 1986 (P.L. 408, No. 89), known as the Health Care Cost Containment Act.

"DEPARTMENT." The Department of Health of the Commonwealth.

"FUND." The Patient Safety Trust Fund as defined in section 305

"HEALTH CARE-ASSOCIATED INFECTION." A localized or systemic condition that results from an adverse reaction to the presence of an infectious agent or its toxins that:

- (1) occurs in a patient in a health care setting;
- (2) was not present or incubating at the time of admission, unless the infection was related to a previous admission to the same setting; and

(3) if occurring in a hospital setting, meets the criteria for a specific infection site as defined by the Centers for Disease Control and Prevention and its National Healthcare Safety Network.

"HEALTHCARE FACILITIES ACT." The act of July 19, 1979 (P.L. 130, No. 48), known as the Health Care Facilities Act.

"HEALTH CARE FACILITY." A hospital or nursing home licensed or otherwise regulated to provide health care services under the laws of this Commonwealth.

"HEALTH PAYOR." An individual or entity providing a group health, sickness or accident policy, subscriber contract or program issued or provided by an entity, including any one of the following:

(1) The act of June 2, 1915 (P.L. 736, No. 338), known as The Workers' Compensation Act.

(2) The act of May 17, 1921 (P.L. 682, No. 284), known as The Insurance Company Law of 1921

(3) The act of December 29, 1972 (P.L. 1701, No. 364), known as The Health Maintenance Organization Act.

(4) The act of May 18, 1976 (P.L. 123, No. 54), known as The Individual Accident and Sickness Insurance Minimum Standards Act.

(5) 40 Pa.C.S. Ch. 61 (relating to hospital plan corporations).

(6) 40 Pa.C.S. Ch. 63 (relating to professional health services plan corporations).

"MEDICAL ASSISTANCE." The Commonwealth's medical assistance program established under the act of June 13, 1967 (P.L. 31, No. 21), known as The Public Welfare Code.

"METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS" or "MRSA." A strain of bacteria that is resistant to certain antibiotics and is difficult to treat medically.

"MULTIDRUG-RESISTANT ORGANISM" or "MDRO." Microorganisms, predominantly bacteria, that are resistant to more than one class of antimicrobial agents.

"NATIONAL HEALTHCARE SAFETY NETWORK" or "NHSN." A secure Internet-based data collection system managed by the Division of Healthcare Quality Promotion at the Centers for Disease Control and Prevention.

"NATIONALLY RECOGNIZED STANDARDS." Standards developed by the Department of Health and Human Services Centers for Disease Control and Prevention (CDC) and its National Healthcare Safety Network.

"NURSING HOME." An entity licensed as a long-term care nursing facility under the act of July 19, 1979 (P.L. 130, No. 48), known as The Health Care Facilities Act.

"SURVEILLANCE SYSTEM." An ongoing and comprehensive method of measuring health status, outcomes and related processes of care, analyzing data and providing information from data sources within a health care facility to assist in reducing health care-associated infections.

### **§ 1303.403. Infection control plan**

(a) DEVELOPMENT AND COMPLIANCE. – Within 120 days of the effective date of this section, a health care facility and an ambulatory surgical facility shall develop and implement an internal infection control plan that shall be established for the purpose of improving the health and safety of patients and health care workers and shall include:

(1) A multidisciplinary committee including representatives from each of the following if applicable to that specific health care facility:

(i) Medical staff that could include the chief medical officer or the nursing home medical director.

(ii) Administration representatives that could include the chief executive officer, the chief financial officer or the nursing home administrator.

(iii) Laboratory personnel.

(iv) Nursing staff that could include a director of nursing or a nursing supervisor.

(v) Pharmacy staff that could include the chief of pharmacy.

(vi) Physical plant personnel.

(vii) A patient safety officer.

(viii) Members from the infection control team, which could include an epidemiologist.

(ix) The community, except that these representatives may not be an agent, employee or contractor of the health care facility or ambulatory surgical facility.

(2) Effective measures for the detection, control and prevention of health care-associated infections.

(3) Culture surveillance processes and policies.

(4) A system to identify and designate patients known to be colonized or infected with MRSA or other MDRO that includes:

(i) The procedures necessary for requiring cultures and screenings for nursing home residents admitted to a hospital.

(ii) The procedures for identifying other high-risk patients admitted to the hospital who necessitate routine cultures and screening.

(5) The procedures and protocols for staff who may have had potential exposure to a patient or resident known to be colonized or infected with MRSA or MDRO, including cultures and screenings, prophylaxis and follow-up care.

(6) An outreach process for notifying a receiving health care facility or an ambulatory surgical facility of any patient known to be colonized prior to transfer within or between facilities.

(7) A required infection-control intervention protocol which includes:

- (i) Infection control precautions, based on nationally recognized standards, for general surveillance of infected or colonized patients.
- (ii) Intervention protocols based on evidence-based standards.
- (iii) Isolation procedures.
- (iv) Physical plant operations related to infection control.
- (v) Appropriate use of antimicrobial agents.
- (vi) Mandatory educational programs for personnel.
- (vii) Fiscal and human resource requirements.

(8) The procedure for distribution of advisories issued under section 405(b)(4) so as to ensure easy access in each health care facility for all administrative staff, medical personnel and health care workers.

(b) DEPARTMENT REVIEW. – No later than 14 days after implementation of its infection control plan, a health care facility and an ambulatory surgical facility shall submit the plan to the department. The department shall review each health care facility's and ambulatory surgical facility's infection control plan to ensure compliance under the Health Care Facilities Act and section 408(3) If, at any time, the department finds that an infection control plan does not meet the requirements of this chapter or any applicable laws, the health care facility or ambulatory surgical facility shall modify its plan to come into compliance.

(c) NOTIFICATION. – Upon submission to the department of its infection control plan, a health care facility and an ambulatory surgical facility shall notify all health care workers, physical plant personnel and medical staff of the facility of the infection control plan. Compliance with the infection control plan shall be enforced by the facility.

#### **§ 1303.404. Health care facility reporting**

(a) NURSING HOME REPORTING. – In addition to reporting pursuant to The Health Care Facilities Act, a nursing home shall also electronically report health care-associated infection data to the department and the authority using nationally recognized standards based on CDC definitions, provided that the data is reported on a patient-specific basis in the form, with the time for reporting and format as determined by the department and the authority.

(b) HOSPITAL REPORTING. – A hospital shall report health care-associated infection data to the CDC and its National Healthcare Safety Network no later than 180 days following the effective date of this section. A hospital shall:

(1) Report all components as defined in the NHSN Manual, Patient Safety Component Protocol and any successor edition, for all patients throughout the facility on a continuous basis.

(2) Report patient-specific data to include, at a minimum, patient identification number, gender and date of birth. The patient identification number must be compatible with the patient identifier on the uniform billing forms submitted to the council.

(3) Report data on a monthly basis in accordance with protocols defined in the NHSN Manual as updated by the CDC.

(4) Authorize the department, the authority and the council to have access to the NHSN for facility-specific reports of health care-associated infection data contained in the NHSN database for purposes of viewing and analyzing that data.

(c) STRATEGIC ASSESSMENTS. – Each hospital, other than those currently using a qualified electronic surveillance system, shall by December 31, 2007, conduct a strategic assessment of the utility and efficacy of implementing a qualified electronic surveillance system pursuant to subsections (d) and (e) for the purpose of improving infection control and prevention. The assessment shall also include an examination of financial and technological barriers to implementation of a qualified electronic surveillance system pursuant to subsections (d) and (e). The assessment shall be submitted to the department within 14 days of completion.

(d) QUALIFIED ELECTRONIC SURVEILLANCE SYSTEM. – A qualified electronic surveillance system shall include the following minimum elements:

(1) Extractions of existing electronic clinical data from health care facility systems on an ongoing, constant and consistent basis.

(2) Translation of nonstandardized laboratory, pharmacy and/or radiology data into uniform information that can be analyzed on a population-wide basis.

(3) Clinical support, educational tools and training to ensure that information provided under this subsection will assist the hospital in reducing the incidence of health care-associated infections in a manner that meets or exceeds benchmarks.

(4) Clinical improvement measurements designed to provide positive and negative feedback to health care facility infection control staff.

(5) Collection of data that is patient-specific for the entire facility.

(e) **ELECTRONIC SURVEILLANCE SYSTEM IMPLEMENTATION.** – Except as otherwise provided in this subsection, a hospital shall have a qualified electronic surveillance system in place by December 31, 2008. The following apply:

(1) If a determination has been made under subsection (c) that a qualified electronic surveillance system can be implemented, the hospital shall comply with subsection (f) until implementation.

(2) If a determination has been made under subsection (c) that a qualified electronic surveillance system cannot be implemented, by December 31, 2008, the hospital shall comply with subsection (f) until such time as a qualified electronic surveillance system is implemented.

(f) **SURVEILLANCE SYSTEM.** – Until a hospital implements a qualified electronic surveillance system, the facility shall use a surveillance system that includes:

(1) A written plan of the elements of the surveillance process to include, but not be limited to, definitions, collection of surveillance data and reporting of information.

(2) Identification of personnel resources that will be used in the surveillance process.

(3) Identification of information or technological support needed to implement the surveillance system.

(4) A process for periodic evaluation and validation to ensure accuracy of surveillance.

(g) **CONTINUED REPORTING.** – Until hospitals begin reporting to NHSN and have authorized access to the department, the authority and the council, hospitals shall continue to meet reporting requirements pursuant to Chapter 3 of this act and section 6 of the act of July 8, 1986 (P.L. 408, No. 89), known as The Health Care Cost Containment Act.

### **§ 1303.405. Patient Safety Authority jurisdiction.**

(a) **HEALTH CARE FACILITY REPORTS TO AUTHORITY.** – The occurrence of a health care-associated infection in a health care facility shall be deemed a serious event as defined in section 302. The report to the authority shall also be subject to all of the confidentiality protections set forth in section 311. The occurrence of a health care-associated infection shall only constitute a serious event for hospitals if it meets the criteria for reporting as defined by the current CDC and NHSN Manual, Patient Safety Component Protocol and any successor edition.

(b) **DUTIES.** – In addition to its existing responsibilities, the authority is responsible for all of the following:

(1) Establishing, based on CDC definitions, uniform definitions using nationally recognized standards for the identification and reporting of health care-associated infections by nursing homes.

(2) Publishing a notice in the Pennsylvania Bulletin stating the uniform reporting requirements established pursuant to this subsection and the effective date for the commencement of required reporting by hospitals consistent with this chapter, which, at a minimum, shall begin 120 days after publication of the notice.

(3) Publishing a notice in the Pennsylvania Bulletin stating the uniform reporting requirements established pursuant to this subsection and section 404(a) and the effective date for the commencement of required reporting by nursing homes consistent with this chapter, which, at a minimum, shall begin 120 days after publication of the notice.

(4) Issuing advisories to health care facilities in a manner similar to section 304(a)(7).

(5) Including a separate category for providing information about health care-associated infections in the annual report under section 304(c).

(6) Creating and conducting training programs for infection control teams, health care workers and physical plant personnel about the prevention and control of health care-associated infections. Nothing in this act shall preclude the authority from working with the department or any organization in conducting these programs.

(7) Appointing an advisory panel of health care-associated infection control experts, including at least one representative of a not-for-profit nursing home, at least one representative of a for-profit nursing home, at least one representative of a county nursing home and at least two representatives of a hospital, one of which must be from a rural hospital, to assist in carrying out the requirements of this chapter.

(c) PUBLIC COMMENT. – Prior to publishing a notice under subsection (b)(2) and (3), the authority shall solicit public comments for at least 30 days. The authority shall respond to the comments it receives during the 30-day public comment period.

#### **§ 1303.406. Payment for performing routine cultures and screenings.**

The cost of routine cultures and screenings performed on patients in compliance with a health care facility's and ambulatory surgical facility's infection control plan shall be considered a reimbursable cost to be paid by health payors and medical assistance upon Federal approval. These costs shall be subject to any copayment, coinsurance or deductible in amounts imposed in any applicable policy issued by a health payor and to any agreements between a health care facility, ambulatory surgical facility and payor.

#### **§ 1303.407. Quality improvement payment.**

(a) GENERAL RULE. – Commencing on January 1, 2009, the Department of Public Welfare in consultation with the department shall make a quality improvement payment to a health care facility that achieves at least a 10% reduction for that facility in the total number of reported health care-associated infections over the preceding year pursuant to section 408(7)(i) For calendar year 2010 and thereafter, the Department of Public Welfare shall consult with the department to establish appropriate percentage benchmarks for the reduction of health care-associated infections in each health care facility in order to be eligible for a payment pursuant to this section.

(b) ADDITIONAL QUALITY IMPROVEMENT PAYMENTS. – Nothing in this section shall prevent the Department of Public Welfare in consultation with the department from providing additional quality improvement payments to a health care facility that has implemented a qualified electronic surveillance system and has achieved or exceeded reductions in the total number of reported health care-associated infections for that facility over the preceding year as provided in subsection (a).

(c) ELIGIBILITY. – In addition to meeting the requirements contained in this section, to be eligible for a quality improvement payment, a health care facility must be in compliance with health care-associated reporting requirements contained in this act and the Health Care Facilities Act.

(d) DISTRIBUTION OF FUNDS. – Funds for the purpose of implementing this section shall be appropriated to the Department of Public Welfare and distributed to eligible health care facilities as set forth in this section. Quality improvement payments to health care facilities shall be limited to funds available for this purpose.

### **§ 1303.408. Duties of Department of Health.**

The department is responsible for the following:

(1) The development of a public health awareness campaign on health care-associated infections to be known as the Community Awareness Program. The program shall provide information to the public on causes and symptoms of health care-associated infections, diagnosis and treatment prevention methods and the proper use of antimicrobial agents.

(2) The consideration and determination of the feasibility of establishing an active surveillance program involving other entities, such as athletic teams or correctional facilities for the purpose of identifying those persons in the community that are colonized and at risk of susceptibility to and transmission of MRSA bacteria.

(3) The review of each health care facility's and ambulatory surgical facility's infection control plan. This review shall be performed pursuant to the department's authority under the Health Care Facilities Act and the regulations promulgated thereunder.

(4) The development of recommendations and best practices that implement and effectuate improved screenings and cultures and other means for the reduction and elimination of health care-associated infections.

(5) The development of recommendations regarding evidence-based screening protocols for an individual with MRSA and MDRO prior to admission to a hospital.

(6) The review of strategic assessments under section 404(c) and the provision of assistance to hospitals in implementing a qualified electronic surveillance system pursuant to the requirements of section 404(d) and (e).

(7) The development of a methodology, in consultation with the authority and the council, for determining and assessing the rate of health care-associated infections that occur in health care facilities in this Commonwealth. This methodology shall be used:

(i) to determine the rate of reduction in health care-associated infection rates within a health care facility during a reporting period;

(ii) to compare health care-associated infection rates among similar health care facilities within this Commonwealth; and

(iii) to compare health care-associated infection rates among similar health care facilities nationwide.

(8) The development, in consultation with the authority and the council, of reasonable benchmarks to measure the progress health care facilities make toward reducing health care-associated infections. Beginning in 2010, all health care facilities shall be measured against these benchmarks. A health care facility with a rate of health care-associated infections that does not meet the benchmark appropriate to that type of facility shall be required to submit a plan of correction to the department within 60 days of receiving notification that the rate does not meet the benchmark. After 180 days, a facility that has not shown progress in reducing its rate of infection shall consult with and obtain department approval for a new plan of correction that includes resources available to assist the health care facility. After an additional 180 days, a facility that fails to show progress in reducing its rate of infection may be subject to action under The Health Care Facilities Act.

(9) Publishing a notice in the Pennsylvania Bulletin of the specific benchmarks the department shall use to measure the progress of health care facilities in reducing health care-associated infections. Prior to publishing the notice, the department shall seek public comments for at least 30 days. The department shall respond to the comments it receives during the 30-day public comment period.

**§ 1303.409. Nursing home assessment to Patient Safety Authority.**

(a) ASSESSMENT. – Commencing July 1, 2008, each nursing home shall pay the department a surcharge on its licensing fee as necessary to provide sufficient revenues for the authority to perform its responsibilities under this chapter. The total annual assessment for all nursing homes shall not be more than an aggregate amount of \$ 1,000,000. The department shall transfer the total assessment amount to the fund within 30 days of receipt.

(b) BASE AMOUNT. – For each succeeding calendar year, the authority shall determine the appropriate assessment amount and the department shall assess each nursing home its proportionate share of the authority's budget for its responsibilities under this chapter. The total assessment amount shall not be more than \$ 1,000,000 in fiscal year 2008-2009 and shall be increased according to the Consumer Price Index in each succeeding fiscal year.

(c) EXPENDITURES. – Money appropriated to the fund under this chapter shall be expended by the authority to implement this chapter.

(d) DISSOLUTION. – In the event that the fund is discontinued or the authority is dissolved by operation of law, any balance paid by nursing homes remaining in the fund, after deducting administrative costs of liquidation, shall be returned to the nursing homes in proportion to their financial contributions to the fund in the preceding licensing period.

(e) FAILURE TO PAY SURCHARGE. – If, after 30 days' notice, a nursing home fails to pay a surcharge levied by the department under this chapter, the department may assess an administrative penalty of \$ 1,000 per day until the surcharge is paid.

(f) REIMBURSABLE COST. – Subject to Federal approval, the annual assessment amount paid by a nursing home shall be a reimbursable cost under the medical assistance program. The Department of Public Welfare shall pay each nursing home, as a separate, pass-through payment, an amount equal to the assessment paid by a nursing home multiplied by the facility's medical assistance occupancy rate as reported in its annual cost report.

#### **§ 1303.410. Scope of reporting.**

For purposes of reporting health care-associated infections to the Commonwealth, its agencies and independent agencies, this chapter sets forth the applicable criteria to be utilized by health care facilities in making such reports. Nothing in this act shall supersede the requirements set forth in the act of April 23, 1956 (1955 P.L. 1510, No. 500), known as the Disease Prevention and Control Law of 1955, and the regulations promulgated thereunder.

#### **§ 1303.411. Penalties.**

(a) VIOLATION OF HEALTH CARE FACILITIES ACT. – The failure of a health care facility to report health care-associated infections as required by sections 404 and 405 or the failure of a health care facility or ambulatory surgical facility to develop, implement and comply with its

infection control plan in accordance with the requirements of section 403 shall be a violation of the Health Care Facilities Act.

(b) ADMINISTRATIVE PENALTY. – In addition to any penalty that may be imposed under the Health Care Facilities Act, a health care facility which negligently fails to report a health care-associated infection as required under this chapter may be subject to an administrative penalty of \$ 1,000 per day imposed by the department.