HMO may determine. When contracting for services, the county board must comply with sections 383B.141 to 383B.151 and other applicable law, except that the board may contract with a private or public cooperative purchasing organization if it can be established that the purchasing organization's services that are purchased have been awarded through a competitive or request for proposal process.

(f) This subdivision applies to the medical center, HMO, ambulatory health centers, or other clinics authorized under section 383B.219, as well as any other organization, association, partnership, or corporation authorized by Hennepin county under section 144.581.

Presented to the governor May 23, 2003

Signed by the governor May 25, 2003, 9:45 p.m.

CHAPTER 99—S.F.No. 1019

An act relating to health; establishing a reporting system for adverse health care events; amending Minnesota Statutes 2002, section 145.64, subdivision 1; proposing coding for new law in Minnesota Statutes, chapter 144.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. **[144.706] CITATION.**

Sections 144.706 to 144.7069 may be cited as the Minnesota Adverse Health Care Events Reporting Act of 2003.

Sec. 2. **[144.7063] DEFINITIONS.**

Subdivision 1. **SCOPE.** Unless the context clearly indicates otherwise, for the purposes of sections 144.706 to 144.7069, the terms defined in this section have the meanings given them.

Subd. 2. **COMMISSIONER.** "Commissioner" means the commissioner of health.

Subd. 3. **FACILITY.** "Facility" means a hospital licensed under sections 144.50 to 144.58.

Subd. 4. **SERIOUS DISABILITY.** "Serious disability" means (1) a physical or mental impairment that substantially limits one or more of the major life activities of an individual, (2) a loss of bodily function, if the impairment or loss lasts more than seven days or is still present at the time of discharge from an inpatient health care facility, or (3) loss of a body part.

Subd. 5. **SURGERY.** "Surgery" means the treatment of disease, injury, or deformity by manual or operative methods. Surgery includes endoscopies and other invasive procedures.

Sec. 3. **[144.7065] FACILITY REQUIREMENTS TO REPORT, ANALYZE, AND CORRECT.**

Subdivision 1. **REPORTS OF ADVERSE HEALTH CARE EVENTS REQUIRED.** Each facility shall report to the commissioner the occurrence of any of the adverse health care events described in subdivisions 2 to 7 as soon as is reasonably and practically possible, but no later than 15 working days after discovery of the event. The report shall be filed in a format specified by the commissioner and shall identify the facility but shall not include any identifying information for any of the health care professionals, facility employees, or patients involved. The commissioner may consult with experts and organizations familiar with patient safety when developing the format for reporting and in further defining events in order to be consistent with industry standards.

Subd. 2. **SURGICAL EVENTS.** Events reportable under this subdivision are:

(1) surgery performed on a wrong body part that is not consistent with the documented informed consent for that patient. Reportable events under this clause do not include situations requiring prompt action that occur in the course of surgery or situations whose urgency precludes obtaining informed consent;

(2) surgery performed on the wrong patient;

(3) the wrong surgical procedure performed on a patient that is not consistent with the documented informed consent for that patient. Reportable events under this clause do not include situations requiring prompt action that occur in the course of surgery or situations whose urgency precludes obtaining informed consent;

(4) retention of a foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained; and

(5) death during or immediately after surgery of a normal, healthy patient who has no organic, physiologic, biochemical, or psychiatric disturbance and for whom the pathologic processes for which the operation is to be performed are localized and do not entail a systemic disturbance.

Subd. 3. **PRODUCT OR DEVICE EVENTS.** Events reportable under this subdivision are:

(1) patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the facility when the contamination is the result of generally detectable contaminants in drugs, devices, or biologics regardless of the source of the contamination or the product;

(2) patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. Device includes, but is not limited to, catheters, drains, and other specialized tubes, infusion pumps, and ventilators; and

(3) patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a facility, excluding deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

Subd. 4. **PATIENT PROTECTION EVENTS.** Events reportable under this subdivision are:

(1) an infant discharged to the wrong person;

(2) patient death or serious disability associated with patient disappearance for more than four hours, excluding events involving adults who have decision-making capacity; and

(3) patient suicide or attempted suicide resulting in serious disability while being cared for in a facility due to patient actions after admission to the facility, excluding deaths resulting from self-inflicted injuries that were the reason for admission to the facility.

Subd. 5. **CARE MANAGEMENT EVENTS.** Events reportable under this subdivision are:

(1) patient death or serious disability associated with a medication error, including, but not limited to, errors involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration, excluding reasonable differences in clinical judgment on drug selection and dose;

(2) patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products;

(3) maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a facility, including events that occur within 42 days postdelivery and excluding deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy;

(4) patient death or serious disability directly related to hypoglycemia, the onset of which occurs while the patient is being cared for in a facility;

(5) death or serious disability, including kernicterus, associated with failure to identify and treat hyperbilirubinemia in neonates during the first 28 days of life. "Hyperbilirubinemia" means bilirubin levels greater than 30 milligrams per deciliter;

(6) stage 3 or 4 ulcers acquired after admission to a facility, excluding progression from stage 2 to stage 3 if stage 2 was recognized upon admission; and

(7) patient death or serious disability due to spinal manipulative therapy.

Subd. 6. **ENVIRONMENTAL EVENTS.** Events reportable under this subdivision are:

(1) patient death or serious disability associated with an electric shock while being cared for in a facility, excluding events involving planned treatments such as electric countershock;

(2) any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances;

(3) patient death or serious disability associated with a burn incurred from any source while being cared for in a facility;

(4) patient death associated with a fall while being cared for in a facility; and

(5) patient death or serious disability associated with the use of restraints or bedrails while being cared for in a facility.

Subd. 7. **CRIMINAL EVENTS.** Events reportable under this subdivision are:

(1) any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider;

(2) abduction of a patient of any age;

(3) sexual assault on a patient within or on the grounds of a facility; and

(4) death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of a facility.

Subd. 8. **ROOT CAUSE ANALYSIS; CORRECTIVE ACTION PLAN.** Following the occurrence of an adverse health care event, the facility must conduct a root cause analysis of the event. Following the analysis, the facility must: (1) implement a corrective action plan to implement the findings of the analysis or (2) report to the commissioner any reasons for not taking corrective action. If the root cause analysis and the implementation of a corrective action plan are complete at the time an event must be reported, the findings of the analysis and the corrective action plan must be included in the report of the event. The findings of the root cause analysis and a copy of the corrective action plan must otherwise be filed with the commissioner within 60 days of the event.

Subd. 9. **ELECTRONIC REPORTING.** The commissioner must design the reporting system so that a facility may file by electronic means the reports required under this section. The commissioner shall encourage a facility to use the electronic filing option when that option is feasible for the facility.

Subd. 10. **RELATION TO OTHER LAW.** (a) Adverse health events described in subdivisions 2 to 6 do not constitute "maltreatment" or "a physical injury that is not reasonably explained" under section 626.557 and are excluded from the reporting requirements of section 626.557, provided the facility makes a determination within 24 hours of the discovery of the event that this section is applicable and the facility files the reports required under this section in a timely fashion.

(b) A facility that has determined that an event described in subdivisions 2 to 6 has occurred must inform persons who are mandated reporters under section 626.5572, subdivision 16, of that determination. A mandated reporter otherwise required to report under section 626.557, subdivision 3, paragraph (e), is relieved of the duty to report an event that the facility determines under paragraph (a) to be reportable under subdivisions 2 to 6.

(c) The protections and immunities applicable to voluntary reports under section 626.557 are not affected by this section.

(d) Notwithstanding section 626.557, a lead agency under section 626.5572, subdivision 13, is not required to conduct an investigation of an event described in subdivisions 2 to 6.

Sec. 4. **[144.7067] COMMISSIONER DUTIES AND RESPONSIBILITIES.**

Subdivision 1. **ESTABLISHMENT OF REPORTING SYSTEM.** (a) The commissioner shall establish an adverse health event reporting system designed to facilitate quality improvement in the health care system. The reporting system shall not be designed to punish errors by health care practitioners or health care facility employees.

(b) The reporting system shall consist of:

(1) mandatory reporting by facilities of 27 adverse health care events;

(2) mandatory completion of a root cause analysis and a corrective action plan by the facility and reporting of the findings of the analysis and the plan to the commissioner or reporting of reasons for not taking corrective action;

(3) analysis of reported information by the commissioner to determine patterns of systemic failure in the health care system and successful methods to correct these failures;

(4) sanctions against facilities for failure to comply with reporting system requirements; and

(5) communication from the commissioner to facilities, health care purchasers, and the public to maximize the use of the reporting system to improve health care quality.

(c) The commissioner is not authorized to select from or between competing alternate acceptable medical practices.

Subd. 2. **DUTY TO ANALYZE REPORTS; COMMUNICATE FINDINGS.** The commissioner shall:

(1) analyze adverse event reports, corrective action plans, and findings of the root cause analyses to determine patterns of systemic failure in the health care system and successful methods to correct these failures;

(2) communicate to individual facilities the commissioner's conclusions, if any, regarding an adverse event reported by the facility;

(3) communicate with relevant health care facilities any recommendations for corrective action resulting from the commissioner's analysis of submissions from facilities; and

(4) publish an annual report:

(i) describing, by institution, adverse events reported;

(ii) outlining, in aggregate, corrective action plans and the findings of root cause analyses; and

(iii) making recommendations for modifications of state health care operations.

Subd. 3. **SANCTIONS.** (a) The commissioner shall take steps necessary to determine if adverse event reports, the findings of the root cause analyses, and corrective action plans are filed in a timely manner. The commissioner may sanction a facility for:

(1) failure to file a timely adverse event report under section 144.7065, subdivision 1; or

(2) failure to conduct a root cause analysis, to implement a corrective action plan, or to provide the findings of a root cause analysis or corrective action plan in a timely fashion under section 144.7065, subdivision 8.

(b) If a facility fails to develop and implement a corrective action plan or report to the commissioner why corrective action is not needed, the commissioner may suspend, revoke, fail to renew, or place conditions on the license under which the facility operates.

Sec. 5. **[144.7069] INTERSTATE COORDINATION; REPORTS.**

The commissioner shall report the definitions and the list of reportable events adopted in this act to the National Quality Forum and, working in coordination with the National Quality Forum, to the other states. The commissioner shall monitor discussions by the National Quality Forum of amendments to the forum's list of reportable events and shall report to the legislature whenever the list is modified. The commissioner shall also monitor implementation efforts in other states to establish a list of reportable events and shall make recommendations to the legislature as necessary for modifications in the Minnesota list or in the other components of the Minnesota reporting system to keep the system as nearly uniform as possible with similar systems in other states.

Sec. 6. Minnesota Statutes 2002, section 145.64, subdivision 1, is amended to read:

Subdivision 1. **DATA AND INFORMATION.** (a) Except as provided in subdivision 4, data and information acquired by a review organization, in the exercise of its duties and functions, or by an individual or other entity acting at the direction of a review organization, shall be held in confidence, shall not be disclosed to anyone except to the extent necessary to carry out one or more of the purposes of the review organization, and shall not be subject to subpoena or discovery. No person described in section 145.63 shall disclose what transpired at a meeting of a review organization except to the extent necessary to carry out one or more of the purposes of a review organization. The proceedings and records of a review organization shall not be subject to discovery or introduction into evidence in any civil action against a professional arising out of the matter or matters which are the subject of consideration by the review organization. Information, documents or records otherwise available from original

sources shall not be immune from discovery or use in any civil action merely because they were presented during proceedings of a review organization, nor shall any person who testified before a review organization or who is a member of it be prevented from testifying as to matters within the person's knowledge, but a witness cannot be asked about the witness' testimony before a review organization or opinions formed by the witness as a result of its hearings. For purposes of this subdivision, records of a review organization include Internet-based data derived from data shared for the purposes of the standardized incident reporting system described in section 145.61, subdivision 5, clause (q), and reports submitted electronically in compliance with sections 144.706 to 144.7069.

(b) Notwithstanding paragraph (a), a review organization may release nonpatient-identified aggregate trend data on medical error and iatrogenic injury and a facility may file the reports, analyses, and plans required by sections 144.706 to 144.7069 without violating this section or being subjected to a penalty under section 145.66 and without compromising the protections provided under sections 145.61 to 145.67 to the reporter of such information; to the review organization, its sponsoring organizations, and members; and to the underlying data and reports.

(c) The confidentiality protection and protection from discovery or introduction into evidence provided in this subdivision shall also apply to the governing body of the review organization and shall not be waived as a result of referral of a matter from the review organization to the governing body or consideration by the governing body of decisions, recommendations, or documentation of the review organization.

(d) The governing body of a hospital, health maintenance organization, or community integrated service network, that is owned or operated by a governmental entity, may close a meeting to discuss decisions, recommendations, deliberations, or documentation of the review organization. A meeting may not be closed except by a majority vote of the governing body in a public meeting. The closed meeting must be tape recorded and the tape must be retained by the governing body for five years.

Sec. 7. **ADVERSE HEALTH CARE EVENTS REPORTING SYSTEM TRANSITION PERIOD.**

(a) Effective July 1, 2003, limited implementation of the Adverse Health Care Events Reporting Act shall begin, provided the commissioner of health has secured sufficient nonstate funds for this purpose. During this period, the commissioner must:

(1) solicit additional nonstate funds to support full implementation of the system;

(2) work with organizations and experts familiar with patient safety to review reporting categories in Minnesota Statutes, section 144.7065, make necessary clarifications, and develop educational materials; and

(3) monitor activities of the National Quality Forum and other patient safety organizations, other states, and the federal government in the area of patient safety.

(b) Effective July 1, 2003, facilities defined in Minnesota Statutes, section 144.7063, subdivision 3, shall report any adverse health care events, as defined in

Minnesota Statutes, section 144.7065, to the incident reporting system maintained by the Minnesota Hospital Association. The association shall provide a summary report to the commissioner that identifies the types of events by category. The association shall consult with the commissioner regarding the data to be reported to the commissioner, storage of data received by the association but not reported to the commissioner, and eventual retrieval by the commissioner of stored data.

(c) The commissioner shall report to the legislature by January 15 of 2004 and 2005, with a list of the number of reported events by type and recommendations, if any, for reporting system modifications, including additional categories of events that should be reported.

(d) From July 1, 2003, until full implementation of the reporting system, the commissioner of health shall not make a final disposition as defined in Minnesota Statutes, section 626.5572, subdivision 8, for investigations conducted in licensed hospitals under the provisions of Minnesota Statutes, section 626.557. The commissioner's findings in these cases shall identify noncompliance with federal certification or state licensure rules or laws.

(e) Effective July 1, 2004, the reporting system shall be fully implemented, provided (1) the commissioner has secured sufficient funds from nonstate sources to operate the system during fiscal year 2005, and (2) the commissioner has notified facilities by April 1, 2004, of their duty to report.

(f) Effective July 1, 2005, the reporting system shall be operated with state appropriations.

Presented to the governor May 23, 2003

Signed by the governor May 27, 2003, 6:06 p.m.

CHAPTER 100—S.F.No. 39

An act relating to health; allowing application for designation as an essential community provider; amending Minnesota Statutes 2002, section 62Q.19, subdivision 2.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. Minnesota Statutes 2002, section 62Q.19, subdivision 2, is amended to read:

Subd. 2. **APPLICATION.** (a) Any provider may apply to the commissioner for designation as an essential community provider by submitting an application form developed by the commissioner. Except as provided in ~~paragraph~~ paragraphs (d) and (e), applications must be accepted within two years after the effective date of the rules adopted by the commissioner to implement this section.