

68-11-211. Health data reporting.

(a) This section shall be known as the "Health Data Reporting Act of 2002."

(b) The general assembly desires to ensure the delivery of the best medical care for the citizens of Tennessee. The collection and assimilation of relevant health data, particularly aggregate health data, can facilitate the development and implementation of best standards practices among health care providers. The early detection of medical errors, and unexpected events, and the identification of measures to improve the delivery of health care and to prevent the re-occurrence of such errors, will also enhance the quality of health care services delivered to Tennesseans. The purpose of this section is to assist health care providers and the department of health to work together to collect meaningful health care data so as to minimize the frequency and severity of unexpected events and improve the delivery of health care services.

(c) The following definitions shall apply to this section:

(1) "Board" means the board for licensing health care facilities;

(2) "Commissioner" is the commissioner of the department of health;

(3) "Department" is the department of health;

(4) "Facility" is any facility licensed under this part;

(5) "Patient" means a person receiving health care services from a facility, and includes a resident at a nursing home facility;

(6) "Patient abuse" includes patient neglect, and means the intentional infliction of pain, injury, or mental anguish, or the deprivation of services by a caretaker which are necessary to maintain the health and welfare of a patient or resident. Nothing in this section shall be construed as authorizing or requiring the provision of medical care to any terminally ill person if such person has executed an unrevoked living will in accordance with the Tennessee Right to Natural Death Law, compiled in title 32, chapter 11, or other applicable state law, if the provision of such medical care would conflict with the terms of such living will; and

(7) "Unusual event" is an unexpected occurrence or accident resulting in death or life-threatening or serious injury to a patient that is not related to a natural course of the patient's illness or underlying condition. An unusual event also includes an incident resulting in the abuse of a patient.

(d) (1) Every facility shall report unusual events, and certain other defined incidents, to the department. Any such unusual event or other defined incident shall be reported to the department by the facility within seven (7) business days from the facility's identification of the event or incident. If a facility incorrectly reports an event or incident, the facility shall file a notice of correction with the department. An unusual event report form shall be developed by the department, in a format similar to the format utilized by the joint commission on accreditation of healthcare organizations (JCAHO), and shall be utilized for reporting the event or incident. The event report and the corrective action report reviewed or obtained by the department pursuant to this section and amendments thereto, shall be confidential and not subject to discovery, subpoena or legal compulsion for release to any person or entity, nor shall the report be admissible in any civil or administrative proceeding other than a disciplinary proceeding by the department or the appropriate regulatory board. The report is not discoverable or admissible in any civil or administrative action except that information in any such report may be transmitted to an appropriate regulatory agency having jurisdiction for disciplinary or license sanctions against the impacted facility. However, the department must reveal upon request its awareness that a specific event or incident has been reported. The affected patient and the patient's family, as may be appropriate, shall also be notified of the event or incident by the facility. The provisions of this subsection (d) and of § 68-11-804(c)(23) shall not affect any of the provisions of § 63-6-219, or the protections provided by § 63-6-219.

(2) The following represent circumstances that could result in an unusual event that is an unexpected occurrence or accident resulting in death or life-threatening or serious injury to a patient, not related to a natural course of the patient's illness or underlying condition. The circumstances that could result in an unusual event include, but are not limited to:

(A) Medication errors;

(B) Aspiration in a non-intubated patient related to conscious/moderate sedation;

(C) Intravascular catheter related events including necrosis or infection requiring repair, or intravascular catheter related pneumothorax;

(D) Volume overload leading to pulmonary edema;

(E) Blood transfusion reactions, use of wrong type of blood and/or delivery of blood to the wrong patient;

(F) Perioperative or periprocedural related complications that occur within forty-eight (48) hours of the operation or the procedure, including:

(i) Procedure which results in any new central neurological deficit; or

(ii) New peripheral neurological deficit with motor weakness;

(G) Burns of a second or third degree;

(H) Falls resulting in radiologically proven fractures, subdural or epidural hematoma, cerebral contusion, traumatic subarachnoid hemorrhage, and/or internal trauma, but does not include fractures resulting from pathological conditions; and

(I) Procedure related incidents, regardless of setting and within thirty (30) days of the procedure and includes readmissions, which include:

(i) Procedure related injury requiring repair or removal of an organ;

(ii) Hemorrhage;

(iii) Displacement, migration or breakage of an implant, device, graft or drain;

(iv) Post operative wound infection following clean or clean/contaminated case;

(v) Any unexpected operation or reoperation related to the primary procedure;

(vi) Hysterectomy in a pregnant woman;

(vii) Ruptured uterus;

(viii) Circumcision;

(ix) Incorrect procedure or incorrect treatment that is invasive;

(x) Wrong patient/wrong site surgical procedure;

(xi) Unintentionally retained foreign body;

(xii) Loss of limb, impairment of limb, and the impairment is present at discharge or for at least two (2) weeks after occurrence;

(xiii) Criminal acts;

(xiv) Suicide or attempted suicide;

(xv) Elopement from the facility;

(xvi) Infant abduction, or infant discharged to the wrong family;

(xvii) Adult abduction;

(xviii) Rape;

(xix) Patient altercation;

(xx) Patient abuse or misappropriation of funds;

(xxi) Restraint related incidents; or

(xxii) Poisoning occurring within the facility.

(3) Specific incidents that might result in a disruption of the delivery of health care services at the facility shall also be reported by the facility to the department, on the unusual event form, within seven (7) days after the facility learns of the incident. These specific incidents include the following:

(A) Strike by the staff at the facility;

(B) External disaster impacting the facility;

(C) Disruption of any service vital to the continued safe operation of the facility or to the health and safety of its patients and personnel; and

(D) Fires at the facility which disrupt the provision of patient care services or cause harm to patients or staff, or which are reported by the facility to any entity, including but not limited to a fire department, charged with preventing fires.

(4) If health services are delivered in a home setting, only those unusual events actually witnessed or known by the person delivering health care services are required to be reported.

(5) Within forty (40) days of the identification of the event, the facility shall file with the department a corrective action report for the unusual event or incident reported to the department. The corrective action report shall either:

(A) Explain why a corrective action plan is not necessary; or

(B) Detail the actions taken to correct any error identified that contributed to the unusual event or incident, the date the corrections were implemented, how the facility will prevent the error from recurring in the future and who will monitor the implementation of the corrective action plan.

(6) The department shall approve in writing the corrective action report if the department is satisfied that the corrective action plan appropriately addresses errors that contributed to the unusual event and takes the necessary steps to prevent the recurrence of the errors. If the department fails to approve the corrective action report, then the department shall provide the facility with a list of actions that the department believes are necessary to address the errors. The facility shall be offered an informal

meeting with the commissioner or the commissioner's representative to attempt to resolve any disagreement over the corrective action report. If the department and the facility fail to agree on an appropriate corrective action plan, then the final determination on the adequacy of the corrective action plan shall be made by the board after a contested case hearing.

(7) The department shall have access to facility records as allowed in part 3 of this chapter. The department may copy any portion of a facility medical record relating to the reported event unless otherwise prohibited by rule or statute. This section and the provisions of § 68-11-804(c)(23) do not change or affect the privilege and confidentiality provided by § 63-6-219.

(8) The department, in developing the unusual event report form, shall establish an event occurrence code that categorizes events or specific incidents by the examples set forth in subdivisions (d)(1) and (2). If an event or specific incident fails to come within these examples, it shall be classified as "other" with the facility explaining the facts related to the event or incident.

(9) This section does not preclude the department from using information obtained under this section in a disciplinary action commenced against a facility, or from taking disciplinary action against a facility. Nor does this section preclude the department from sharing such information with any appropriate governmental agency charged by federal or state law with regulatory oversight of the facility. However, all such information must at all times be maintained as confidential and not available to the public. Failure to report an unusual incident, submit a corrective action report, or comply with a plan of correction as required herein may be grounds for disciplinary action pursuant to § 68-11-207.

(10) Nothing in this section precludes the department from using the information obtained to develop "best practices" and other criteria to assist facilities in improving the delivery of health care services.

(e) The department shall provide educational information designed to assist facilities in complying with this section and to assist facilities in implementing procedures designed to prevent medical errors.

(f) During the second quarter of each year, the department shall provide the board an aggregate report summarizing by type the number of unusual events and other reportable specific incidents reported by facilities to the department for the preceding calendar year.

(g) The department shall work with representatives of facilities subject to this section, and other interested parties, to develop recommendations to improve the collection and assimilation of specific aggregate health care data that, if known, would track health care trends over time and identify system-wide problems for broader quality improvement. The goal of such recommendations should be to better coordinate the

collection of such data, to analyze the data, to identify potential problems and to work with facilities to develop best practices to remedy identified problems. The department shall prepare and issue a report regarding such recommendations by July 1, 2003.

(h) Nothing in this section shall be construed to eliminate or alter in any manner the required reporting of abuse, neglect, or exploitation of children or adults, or any other provisions of title 37, chapter 1, parts 4 and 6, and title 71, chapter 6, part 1.

[Acts 2002, ch. 508, § 1.]