House Amendment 8335

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Amend the amendment, H=8309, to House File 2716, as follows:

#1. Page 1, by inserting after line 1 the following:

<#___. Page 1, by inserting before line 1 the following:

<Section 1. NEW SECTION. 135N.1 TITLE.

This chapter shall be known and may be cited as the "Patient Safety and Quality Assurance Act".

Sec. 2. NEW SECTION. 135N.2 DEFINITIONS.

As used in this chapter:

1. "Action plan" means a written plan prepared after a root cause analysis that identifies strategies that a health care provider intends to implement to reduce the risk and reoccurrence of actual and potential risks to patient safety. The plan shall address health care provider responsibility for implementation, oversight, pilot testing as appropriate, timelines, and strategies for measuring the effectiveness of the actions.

2. "Health care provider" means a physician or surgeon, osteopath, osteopathic physician or surgeon, dentist, podiatric physician, optometrist, pharmacist, chiropractor, or nurse licensed in this state, a hospital licensed pursuant to chapter 135B, or a health care facility licensed pursuant to chapter 135C.

3. "Health care provider leaders" means a health care provider, executive, physician as defined in section 135C.1, registered or licensed practical nurse or nurse practitioner, or health care provider administrator.

4. "Quality assessment and assurance activities" means the procedure by which a quality assessment and assurance committee monitors, evaluates, recommends, and implements actions to improve and assure the delivery and quality of services and patient safety through identification, correction, and prevention of sentinel events.

5. "Quality assessment and assurance committee" means a committee of a health care provider consisting of individuals responsible for the identification of sentinel events that may adversely impact the health and safety of patients, and for the development of root cause analyses, action plans, and other plans to correct identified quality of care issues. The quality assessment and assurance committee shall include health care provider leaders, including but not limited to the health care provider administrator and the director of nursing.

6. "Quality assessment and assurance committee records" means complaint files, investigation files, reports, and other investigative information relating to licensee discipline or professional competence in the possession of a quality assessment and assurance committee or an employee of the committee.

7. "Risk of death or serious injury" means any variation in a process related to quality of care or patient safety which may result in a serious adverse outcome.

8. "Root cause analysis" means the process for identifying causal factors that relate to any variation in the delivery and quality of services and patient safety, including the occurrence or possible occurrence of a sentinel event. A root cause analysis focuses primarily on systems and processes, and not on individual performances.

9. "Sentinel event" means an unexpected occurrence resulting in the death or serious physical or psychological injury of a patient of a health care provider, or a risk of death or serious physical or psychological injury to a patient of a health care provider.

10. "Unanticipated outcome" means a result that

differs significantly from what was anticipated to be the result of a treatment or procedure, including an outcome caused by an error of an employee of a health care provider or an independent practitioner who provides medical services at a health care provider's facility.

Sec. 3. NEW SECTION. 135N.3 ACCOUNTABILITY OF HEALTH CARE PROVIDER LEADERS.

The health care provider leaders, including the health care provider administrator and director of nursing, and the quality assessment and assurance committee, are responsible for all of the following:

1. Assuring the implementation of an integrated patient safety program throughout the health care provider facility. The patient safety program shall include, at a minimum, all of the following:

a. A designation of one or more qualified individuals or an interdisciplinary group to manage the health care provider safety program.

b. A definition of the scope of the program activities, including the types of occurrences to be addressed.

c. A procedure for immediate response to medical or health care errors or patient abuse, including care of an affected patient, containment of risk to others, and the preservation of factual information for subsequent analysis.

d. A system for internal and external reporting of information relating to medical and health care errors or patient abuse.

e. A defined mechanism for support of staff involved in a sentinel event.

f. An annual report to the department of inspections and appeals concerning medical or health care errors and patient neglect or abuse, and actions taken to improve patient safety, both proactively and in response to actual occurrences.

2. Defining and implementing processes for identifying and managing sentinel events, including establishing processes for the identification, reporting, analysis, and prevention of sentinel events and assuring the consistent and effective implementation of a mechanism to accomplish those activities.

3. Establishing a continuous proactive program for identifying risks to patient safety and reducing medical and health care errors and patient neglect or abuse.

4. Allocating adequate resources for measuring, assessing, and improving patient safety.

5. Assigning personnel to participate in activities to improve patient safety and providing adequate time for personnel to participate in such activities.

6. Providing staff training on the improvement of patient safety.

7. Allocating physical and financial resources to support safety improvement.

8. Analyzing undesirable patterns or trends in staff performance and sentinel events.

9. Assuring the health care provider identifies changes for improved patient safety.

Sec. 4. NEW SECTION. 135N.4 PATIENT RIGHTS AND DUTY OF DISCLOSURE.

1. Patients and their immediate families have a right to know about the quality of care outcomes involved in patient care, including unanticipated outcomes and sentinel events.

2. The health care provider leaders shall fully disclose all of the facts and circumstances relating to a sentinel event or an unanticipated outcome.

Sec. 5. NEW SECTION. 135N.5 SENTINEL EVENT REPORTING.

1. A health care provider involved in a sentinel event shall submit a root cause analysis and an action plan that describes the health care provider's risk reduction strategy and a strategy for evaluating the effectiveness of the risk reduction strategy to the department of inspections and appeals.

2. A root cause analysis shall contain an analysis focusing primarily on systems and processes involved

in quality of care and patient safety which includes changes that may be made to such systems and processes, and shall be thorough, credible, and acceptable as defined by industry standards.

Sec. 6. NEW SECTION. 135N.6 CONFIDENTIALITY OF RECORDS.

1. Quality assessment and assurance committee records shall be confidential and privileged and shall not be subject to discovery or subpoena.

2. Information or documents discoverable from sources other than a quality assessment and assurance committee, a health care provider, or the department of inspections and appeals do not become nondiscoverable from the other sources because they are subject to a claim of confidentiality under this section.>>

#2. By renumbering as necessary.

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