

House Amendment 8343

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1 1 Amend House File 2716 as follows:
1 2 #1. Page 1, by inserting before line 1 the
1 3 following:
1 4 <Section 1. NEW SECTION. 135N.1 TITLE.
1 5 This chapter shall be known and may be cited as the
1 6 "Patient Safety and Quality Assurance Act".
1 7 Sec. 2. NEW SECTION. 135N.2 DEFINITIONS.
1 8 As used in this chapter:
1 9 1. "Action plan" means a written plan prepared
1 10 after a root cause analysis that identifies strategies
1 11 that a health care provider intends to implement to
1 12 reduce the risk and reoccurrence of actual and
1 13 potential risks to patient safety. The plan shall
1 14 address health care provider responsibility for
1 15 implementation, oversight, pilot testing as
1 16 appropriate, timelines, and strategies for measuring
1 17 the effectiveness of the actions.
1 18 2. "Health care provider" means a physician or
1 19 surgeon, osteopath, osteopathic physician or surgeon,
1 20 dentist, podiatric physician, optometrist, pharmacist,
1 21 chiropractor, or nurse licensed in this state, a
1 22 hospital licensed pursuant to chapter 135B, or a
1 23 health care facility licensed pursuant to chapter
1 24 135C.
1 25 3. "Health care provider leaders" means a health
1 26 care provider, executive, physician as defined in
1 27 section 135C.1, registered or licensed practical nurse
1 28 or nurse practitioner, or health care provider
1 29 administrator.
1 30 4. "Quality assessment and assurance activities"
1 31 means the procedure by which a quality assessment and
1 32 assurance committee monitors, evaluates, recommends,
1 33 and implements actions to improve and assure the
1 34 delivery and quality of services and patient safety
1 35 through identification, correction, and prevention of
1 36 sentinel events.
1 37 5. "Quality assessment and assurance committee"
1 38 means a committee of a health care provider consisting
1 39 of individuals responsible for the identification of
1 40 sentinel events that may adversely impact the health
1 41 and safety of patients, and for the development of
1 42 root cause analyses, action plans, and other plans to
1 43 correct identified quality of care issues. The
1 44 quality assessment and assurance committee shall
1 45 include health care provider leaders, including but
1 46 not limited to the health care provider administrator
1 47 and the director of nursing.
1 48 6. "Quality assessment and assurance committee
1 49 records" means complaint files, investigation files,
1 50 reports, and other investigative information relating
2 1 to licensee discipline or professional competence in
2 2 the possession of a quality assessment and assurance
2 3 committee or an employee of the committee.
2 4 7. "Risk of death or serious injury" means any
2 5 variation in a process related to quality of care or
2 6 patient safety which may result in a serious adverse
2 7 outcome.
2 8 8. "Root cause analysis" means the process for
2 9 identifying causal factors that relate to any
2 10 variation in the delivery and quality of services and
2 11 patient safety, including the occurrence or possible
2 12 occurrence of a sentinel event. A root cause analysis
2 13 focuses primarily on systems and processes, and not on
2 14 individual performances.
2 15 9. "Sentinel event" means an unexpected occurrence
2 16 resulting in the death or serious physical or
2 17 psychological injury of a patient of a health care
2 18 provider, or a risk of death or serious physical or
2 19 psychological injury to a patient of a health care
2 20 provider.
2 21 10. "Unanticipated outcome" means a result that
2 22 differs significantly from what was anticipated to be
2 23 the result of a treatment or procedure, including an
2 24 outcome caused by an error of an employee of a health

2 25 care provider or an independent practitioner who
2 26 provides medical services at a health care provider's
2 27 facility.

2 28 Sec. 3. NEW SECTION. 135N.3 ACCOUNTABILITY OF
2 29 HEALTH CARE PROVIDER LEADERS.

2 30 The health care provider leaders, including the
2 31 health care provider administrator and director of
2 32 nursing, and the quality assessment and assurance
2 33 committee, are responsible for all of the following:

2 34 1. Assuring the implementation of an integrated
2 35 patient safety program throughout the health care
2 36 provider facility. The patient safety program shall
2 37 include, at a minimum, all of the following:

2 38 a. A designation of one or more qualified
2 39 individuals or an interdisciplinary group to manage
2 40 the health care provider safety program.

2 41 b. A definition of the scope of the program
2 42 activities, including the types of occurrences to be
2 43 addressed.

2 44 c. A procedure for immediate response to medical
2 45 or health care errors or patient abuse, including care
2 46 of an affected patient, containment of risk to others,
2 47 and the preservation of factual information for
2 48 subsequent analysis.

2 49 d. A system for internal and external reporting of
2 50 information relating to medical and health care errors
3 1 or patient abuse.

3 2 e. A defined mechanism for support of staff
3 3 involved in a sentinel event.

3 4 f. An annual report to the department of
3 5 inspections and appeals concerning medical or health
3 6 care errors and patient neglect or abuse, and actions
3 7 taken to improve patient safety, both proactively and
3 8 in response to actual occurrences.

3 9 2. Defining and implementing processes for
3 10 identifying and managing sentinel events, including
3 11 establishing processes for the identification,
3 12 reporting, analysis, and prevention of sentinel events
3 13 and assuring the consistent and effective
3 14 implementation of a mechanism to accomplish those
3 15 activities.

3 16 3. Establishing a continuous proactive program for
3 17 identifying risks to patient safety and reducing
3 18 medical and health care errors and patient neglect or
3 19 abuse.

3 20 4. Allocating adequate resources for measuring,
3 21 assessing, and improving patient safety.

3 22 5. Assigning personnel to participate in
3 23 activities to improve patient safety and providing
3 24 adequate time for personnel to participate in such
3 25 activities.

3 26 6. Providing staff training on the improvement of
3 27 patient safety.

3 28 7. Allocating physical and financial resources to
3 29 support safety improvement.

3 30 8. Analyzing undesirable patterns or trends in
3 31 staff performance and sentinel events.

3 32 9. Assuring the health care provider identifies
3 33 changes for improved patient safety.

3 34 Sec. 4. NEW SECTION. 135N.4 PATIENT RIGHTS AND
3 35 DUTY OF DISCLOSURE.

3 36 1. Patients and their immediate families have a
3 37 right to know about the quality of care outcomes
3 38 involved in patient care, including unanticipated
3 39 outcomes and sentinel events.

3 40 2. The health care provider leaders shall fully
3 41 disclose all of the facts and circumstances relating
3 42 to a sentinel event or an unanticipated outcome.

3 43 Sec. 5. NEW SECTION. 135N.5 SENTINEL EVENT
3 44 REPORTING.

3 45 1. A health care provider involved in a sentinel
3 46 event shall submit a root cause analysis and an action
3 47 plan that describes the health care provider's risk
3 48 reduction strategy and a strategy for evaluating the
3 49 effectiveness of the risk reduction strategy to the
3 50 department of inspections and appeals.

4 1 2. A root cause analysis shall contain an analysis
4 2 focusing primarily on systems and processes involved
4 3 in quality of care and patient safety which includes
4 4 changes that may be made to such systems and
4 5 processes, and shall be thorough, credible, and

4 6 acceptable as defined by industry standards.
4 7 Sec. 6. NEW SECTION. 135N.6 CONFIDENTIALITY OF
4 8 RECORDS.
4 9 1. Quality assessment and assurance committee
4 10 records shall be confidential and privileged and shall
4 11 not be subject to discovery or subpoena.
4 12 2. Information or documents discoverable from
4 13 sources other than a quality assessment and assurance
4 14 committee, a health care provider, or the department
4 15 of inspections and appeals do not become
4 16 nondiscoverable from the other sources because they
4 17 are subject to a claim of confidentiality under this
4 18 section.>
4 19 #2. Page 4, by inserting after line 13 the
4 20 following:
4 21 <Sec. _____. Section 515F.5, Code 2005, is amended
4 22 by adding the following new subsection:
4 23 NEW SUBSECTION. 1A. The commissioner shall
4 24 provide written notice to the public, as provided in
4 25 rules adopted under chapter 17A, that an insurer has
4 26 made a rate filing pursuant to this section, including
4 27 the proposed effective date of the filing, and the
4 28 character and extent of the coverage contemplated.>
4 29 #3. Page 5, by inserting after line 4 the
4 30 following:
4 31 <Sec. _____. Section 622.10, subsection 3, paragraph
4 32 d, Code 2005, is amended to read as follows:
4 33 d. Any physician or surgeon, physician assistant,
4 34 advanced registered nurse practitioner, or mental
4 35 health professional who provides records or consults
4 36 with the counsel for the adverse party shall be
4 37 entitled to charge a reasonable fee for production of
4 38 the records, diagnostic imaging, and consultation.
4 39 Any party seeking consultation shall be responsible
4 40 for payment of all charges. ~~The fee for copies of any~~
~~4 41 records shall be based upon actual cost of production.~~
4 42 Upon written request from a party or a party's
4 43 representative accompanied by a legally sufficient
4 44 patient's waiver, copies of the requested records or
4 45 diagnostic images shall be provided to the party or
4 46 the party's representative within thirty days of
4 47 receipt of the written request. A fee shall be
4 48 charged for the cost of producing such copies but the
4 49 fee shall not exceed the following:
4 50 (1) For printed or photocopied records, twelve
5 1 cents per single-sided page or seventeen cents per
5 2 double-sided page based upon a page measuring eight
5 3 and one-half inches by eleven inches or less.
5 4 (2) For X rays, diagnostic images, photographs, or
5 5 other graphic image records, the actual cost of
5 6 materials and supplies used to produce the copies of
5 7 such images or ten dollars per item, whichever is
5 8 less.
5 9 (3) For electronically scanned or produced
5 10 records, the actual cost of the materials and supplies
5 11 incurred in producing the records, or five dollars,
5 12 whichever is less.
5 13 (4) If applicable, reasonable and actual costs of
5 14 postage or delivery charges.
5 15 Fees charged pursuant to this subsection are not
5 16 subject to a sales or use tax. A physician or
5 17 surgeon, physician assistant, advanced registered
5 18 nurse practitioner, or mental health professional may
5 19 require payment in advance if the copies are requested
5 20 in writing and fees are itemized.>
5 21 #4. Page 5, line 5, by striking the words <REGRET
5 22 OR> and inserting the following: <REGRET.>
5 23 #5. Page 5, by striking line 6.
5 24 #6. Page 5, line 13, by inserting after the word
5 25 <occupation,> the following: <that portion of>.
5 26 #7. Page 5, line 14, by striking the word
5 27 <apology,>.
5 28 #8. By striking page 5, line 22, through page 6,
5 29 line 6, and inserting the following:
5 30 <Sec. _____. CLOSED=CLAIM REPORT. An insurer
5 31 providing medical malpractice insurance coverage to a
5 32 health care provider or a health care provider who
5 33 maintains professional liability insurance coverage
5 34 through a self-insurance plan shall file annually with
5 35 the commissioner of insurance on or before March 15 a
5 36 report of all medical malpractice insurance closed

5 37 claims during the preceding calendar year. In
5 38 addition, any insurer who provided medical malpractice
5 39 insurance coverage to a health care provider or a
5 40 health care provider who maintained professional
5 41 liability coverage through a self-insurance plan
5 42 between January 1, 1991, and December 31, 2005, shall
5 43 file a report with the commissioner of all medical
5 44 malpractice closed claims during the period. The
5 45 commissioner shall prepare a comprehensive analysis of
5 46 the closed claim data for that period for submission
5 47 to the general assembly on or before January 15,
5 48 2007.>

5 49 [#9.](#) By renumbering as necessary.

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6 3 JOCHUM of Dubuque

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6 7 R. OLSON of Polk

6 8 HF 2716.202 81

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