Document: Proposed Rule, **Register Page Number:** 29 IR 1742
Source: February 1, 2006, Indiana Register, Volume 29, Number 5
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TITLE 410 INDIANA STATE DEPARTMENT OF HEALTH

Proposed Rule
LSA Document #05-193

DIGEST

Amends 410 IAC 15-1.1 by adding new definitions. Adds 410 IAC 15-1.4-2.2 to include serious adverse event reporting in the requirements for a hospital's quality assessment and improvement program. Effective 30 days after filing with the Secretary of State.

IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses

Description of Rule:

The Indiana State Department of Health (ISDH) has responsibility for the licensure and regulation of hospitals pursuant to IC 16-21. In January 2005, Governor Daniels issued Executive Order 05-10 requiring the ISDH to develop and implement a medical errors reporting system (MERS). In response to the Executive Order, the Hospital Council recommended and the ISDH Executive Board preliminarily adopted rules requiring the reporting of medical errors resulting in death or serious disability.

The proposed rule is based on the National Quality Forum's 27 serious reportable events or 'never' events as they are frequently called. The proposed rule requires hospitals to have a serious adverse event reporting system in place by January 1, 2006, and requires reports of serious adverse events to be submitted to the ISDH not later than 15 days after the serious adverse event occurs. Data submission will occur on-line in real-time utilizing the existing ISDH electronic portal. Hospitals must review the serious adverse events through their quality assessment and improvement program. The ISDH is required to analyze and publish the data no less than annually.

Fiscal Impact

Indiana Code 4-22-2-28(c) requires an agency to submit to the Office of Management and Budget any proposed rule with an estimated economic impact of greater than $500,000 on all persons regulated by the rule. After the preliminary adoption of such a rule, the Office of Management and Budget must prepare a fiscal impact statement concerning the effect that compliance with the proposed rule will have on the state and all persons regulated by the proposed rule.

The department has reviewed the proposed rule to determine whether the total economic impact of the rule on regulated persons will exceed $500,000. The department has determined, based on the information available at the time of the rule promulgation, that the proposed rule does not have an estimated economic impact of greater than $500,000 on the persons regulated by the rule. The ISDH therefore did not submit the proposed rule to the Office of Management and Budget prior to the rule being adopted.

Economic Impact on Small Businesses

1. Estimate of the number of small businesses, classified by industry sector, that will be subject to the proposed rule.

IC 4-22-2.1-4 defines a small business as any person, firm, corporation, limited liability company, partnership, or association that:

(1) is actively engaged in business in Indiana and maintains its principal place of business in Indiana;
(2) is independently owned and operated;
(3) employs one hundred (100) or fewer full-time employees; and
(4) has gross annual receipts of five million dollars ($5,000,000) or less.

The ISDH licenses 140 hospitals. The North American Industry Classification System classifies these institutions as General Medical and Surgical Hospitals (NAICS 622110). The ISDH reviewed data reported by the licensed hospitals. After review of the most recent data submitted by Indiana hospitals, the ISDH has determined that no Indiana hospitals regulated by the proposed rule meet the definition of a small business. All Indiana hospitals reported gross annual receipts in excess of $5,000,000. Nineteen hospitals reported fewer than 100 full-time employees but most, if not all of these hospitals, are not independently owned and operated. These are primarily long-term care hospitals classified as hospitals within hospitals.

Conclusion

Because no Indiana hospitals licensed under this rule are a small business, there is no economic impact of the proposed rule on small businesses.

410 IAC 15-1.1-1 **410 IAC 15-1.1-13.5**
410 IAC 15-1.1-2.5 **410 IAC 15-1.1-13.6**
410 IAC 15-1.1-3.3 **410 IAC 15-1.1-14.2**
410 IAC 15-1.1-3.7 **410 IAC 15-1.1-15.5**
410 IAC 15-1.1-8.5 **410 IAC 15-1.1-20**
410 IAC 15-1.1-13.1 **410 IAC 15-1.1-21**
410 IAC 15-1.1-13.2 **410 IAC 15-1.1-22**
410 IAC 15-1.1-13.3 **410 IAC 15-1.1-23**
410 IAC 15-1.1-13.4 **410 IAC 15-1.4-2.2**

SECTION 1. 410 IAC 15-1.1-1 IS AMENDED TO READ AS FOLLOWS:

410 IAC 15-1.1-1 Applicability
Authority: IC 16-21-1-7; IC 16-21-1-8; IC 16-21-1-9
Affected: IC 16-19-3; IC 16-21-1

Sec. 1. The definitions in this rule apply throughout this article **except as otherwise indicated.** *(Indiana State Department of Health; 410 IAC 15-1.1-1; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1261; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

SECTION 2. 410 IAC 15-1.1-2.5 IS ADDED TO READ AS FOLLOWS:

410 IAC 15-1.1-2.5 "ASA Class I patient" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 2.5. "ASA Class I patient" means a normal, healthy patient. *(Indiana State Department of Health; 410 IAC 15-1.1-2.5)*

SECTION 3. 410 IAC 15-1.1-3.3 IS ADDED TO READ AS FOLLOWS:

410 IAC 15-1.1-3.3 "Biologics" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 3.3. "Biologics" means a biological product, such as:
(1) a globulin;
(2) a serum;
(3) a vaccine;
(4) an antitoxin;
(5) blood; or
(6) an antigen;
used in the prevention or treatment of disease. *(Indiana State Department of Health; 410 IAC 15-1.1-3.3)*

SECTION 4. 410 IAC 15-1.1-3.7 IS ADDED TO READ AS FOLLOWS:

410 IAC 15-1.1-3.7 "Burn" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 3.7. "Burn" means any injury or damage to the tissues of the body caused by exposure to any of the following:
(1) Fire.
(2) Heat.
(3) Chemicals.
(4) Electricity.
(5) Radiation.
(6) Gases.

(Indiana State Department of Health; 410 IAC 15-1.1-3.7)

SECTION 5. 410 IAC 15-1.1-8.5 IS ADDED TO READ AS FOLLOWS:

410 IAC 15-1.1-8.5 "Elopement" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 8.5. "Elopement" means any situation in which a registered or admitted patient, excluding adults with decision making capacity, leaves the hospital without staff being aware that the patient has done so. *(Indiana State Department of Health; 410 IAC 15-1.1-8.5)*

SECTION 6. 410 IAC 15-1.1-13.1 IS ADDED TO READ AS FOLLOWS:

410 IAC 15-1.1-13.1 "Hyperbilirubinemia" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 13.1. "Hyperbilirubinemia" means total serum bilirubin levels greater than twenty-five (25) mg/dl in a neonate. *(Indiana State Department of Health; 410 IAC 15-1.1-13.1)*

SECTION 7. 410 IAC 15-1.1-13.2 IS ADDED TO READ AS FOLLOWS:

410 IAC 15-1.1-13.2 "Hypoglycemia" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 13.2. "Hypoglycemia" means a physiologic state in which:
(1) the blood sugar falls below sixty (60) mg/dl (forty (40) mg/dl in neonates); and
(2) physiological or neurological, or both, dysfunction begins.
(Indiana State Department of Health; 410 IAC 15-1.1-13.2)

SECTION 8. 410 IAC 15-1.1-13.3 IS ADDED TO READ AS FOLLOWS:

410 IAC 15-1.1-13.3 "Immediately postoperative" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 13.3. "Immediately postoperative" means within twenty-four (24) hours after either of the following:
(1) Induction of anesthesia (if surgery or other invasive procedure is not completed).
(2) Completion of surgery or other invasive procedure.
(Indiana State Department of Health; 410 IAC 15-1.1-13.3)

SECTION 9. 410 IAC 15-1.1-13.4 IS ADDED TO READ AS FOLLOWS:

410 IAC 15-1.1-13.4 "Informed consent" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 13.4. "Informed consent" means a patient's authorization or agreement to undergo surgery or other invasive procedure that is based upon communication between a patient and his or her physician regarding the surgery or other invasive procedure. *(Indiana State Department of Health; 410 IAC 15-1.1-13.4)*

SECTION 10. 410 IAC 15-1.1-13.5 IS ADDED TO READ AS FOLLOWS:

410 IAC 15-1.1-13.5 "Intended use" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 13.5. "Intended use" means the use of a device as described on the label and associated materials provided by the device's manufacturer. *(Indiana State Department of Health; 410 IAC 15-1.1-13.5)*

SECTION 11. 410 IAC 15-1.1-13.6 IS ADDED TO READ AS FOLLOWS:

410 IAC 15-1.1-13.6 "Kernicterus" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 13.6. "Kernicterus" means the medical condition in which elevated levels of bilirubin cause brain damage. *(Indiana State Department of Health; 410 IAC 15-1.1-13.6)*

SECTION 12. 410 IAC 15-1.1-14.2 IS ADDED TO READ AS FOLLOWS:

410 IAC 15-1.1-14.2 "Low-risk pregnancy" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 14.2. "Low-risk pregnancy" means a woman sixteen (16) to thirty-nine years of age with no previous diagnosis of any of the following:
(1) Essential hypertension.
(2) Renal disease.
(3) Collagen-vascular disease.
(4) Liver disease.
(5) Preeclampsia.
(6) Cardiovascular disease.
(7) Placenta previa.
(8) Multiple gestation.
(9) Intrauterine growth retardation.
(10) Smoking.
(11) Pregnancy-induced hypertension.
(12) Premature rupture of membranes.
(13) Other previously documented condition that poses a high risk of pregnancy-related mortality.
(Indiana State Department of Health; 410 IAC 15-1.1-14.2)

SECTION 13. 410 IAC 15-1.1-15.5 IS ADDED TO READ AS FOLLOWS:

410 IAC 15-1.1-15.5 "Neonates" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 15.5. "Neonates" means infants in the first twenty-eight (28) days of life. *(Indiana State Department of Health; 410 IAC 15-1.1-15.5)*

SECTION 14. 410 IAC 15-1.1-20 IS ADDED TO READ AS FOLLOWS:

410 IAC 15-1.1-20 "Serious disability" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 20. "Serious disability" means either of the following:

(1) Significant loss of function including sensory, motor, physiologic, or intellectual impairment:
(A) not present on admission and requiring continued treatment; or
(B) for which there is a high probability of long term or permanent lifestyle change at discharge.
(2) Unintended loss of a body part.
(Indiana State Department of Health; 410 IAC 15-1.1-20)

SECTION 15. 410 IAC 15-1.1-21 IS ADDED TO READ AS FOLLOWS:

410 IAC 15-1.1-21 "Spinal manipulative therapy" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 21. "Spinal manipulative therapy" means all types of manual techniques, including spinal:
(1) mobilization (movement of a joint within its physiologic range of motion); and
(2) manipulation (movement of a joint beyond its normal voluntary physiologic range of motion);
regardless of their precise anatomic and physiologic focus or their discipline of origin. *(Indiana State Department of Health; 410 IAC 15-1.1-21)*

SECTION 16. 410 IAC 15-1.1-22 IS ADDED TO READ AS FOLLOWS:

410 IAC 15-1.1-22 "Surgery or other invasive procedure" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 22. For purposes of this rule, 410 IAC 15-1.4-2.2, and 410 IAC 15-2.4-2.2, "surgery or other invasive procedure" means surgical or other invasive procedures that involve a skin incision or puncture including, but not limited to, the following:
(1) Open or percutaneous surgical procedures.
(2) Percutaneous aspiration.
(3) Selected injections.
(4) Biopsy.
(5) Percutaneous cardiac and vascular diagnostic or interventional procedures.
(6) Laparoscopies.
(7) Endoscopies.
(8) Colonoscopies.
The term excludes intravenous therapy, venipuncture for phlebotomy, or diagnostic tests without intravenous contrast agents.
(Indiana State Department of Health; 410 IAC 15-1.1-22)

SECTION 17. 410 IAC 15-1.1-23 IS ADDED TO READ AS FOLLOWS:

410 IAC 15-1.1-23 "Toxic substance" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 23. "Toxic substance" means chemicals that are present in sufficient concentration to pose a hazard to human health.
(Indiana State Department of Health; 410 IAC 15-1.1-23)

SECTION 18. 410 IAC 15-1.4-2.2 IS ADDED TO READ AS FOLLOWS:

410 IAC 15-1.4-2.2 Reporting serious adverse events
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1; IC 25

Sec. 2.2. (a) The hospital's quality assessment and improvement program under section 2 of this rule shall include the following:
(1) A process for determining the occurrence of the following serious adverse events within the hospital:

(A) The following surgical events:

(i) Surgery performed on the wrong body part, defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excluded are emergent situations:

(AA) that occur in the course of surgery; or

(BB) whose exigency precludes obtaining informed consent;

or both.

(ii) Surgery performed on the wrong patient, defined as any surgery on a patient that is not consistent with the documented informed consent for that patient.

(iii) Wrong surgical procedure performed on a patient, defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. Excluded are emergent situations:

(AA) that occur in the course of surgery; or

(BB) whose exigency precludes obtaining informed consent;

or both.

(iv) Retention of a foreign object in a patient after surgery or other invasive procedure. The following are excluded:

(AA) Objects intentionally implanted as part of a planned intervention.

(BB) Objects present before surgery that were intentionally retained.

(v) Intraoperative or immediately postoperative death in an ASA Class I patient. Included are all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out.

(B) The following product or device events:

(i) Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the hospital. Included are generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination or product.

(ii) 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. Included are, but not limited to, the following:

(AA) Catheters.

(BB) Drains and other specialized tubes.

(CC) Infusion pumps.

(DD) Ventilators.

(iii) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in the hospital. Excluded are deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

(C) The following patient protection events:

(i) Infant discharged to the wrong person.

(ii) Patient death or serious disability associated with patient elopement (disappearance) for more than four (4) hours. Excluded are events involving adults with decision making capacity.

(iii) Patient suicide or attempted suicide resulting in serious disability, while being cared for in the hospital, defined as events that result from patient actions after admission to the hospital. Excluded are deaths resulting from self-inflicted injuries that were the reason for admission to the hospital.

(D) The following care management events:

(i) Patient death or serious disability associated with a medication error, for example, errors involving the wrong:

(AA) drug;

(BB) dose;

(CC) patient;

(DD) time;

(EE) rate;

(FF) preparation; or

(GG) route of administration.

Excluded are reasonable differences in clinical judgment on drug selection and dose.

(ii) Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.

(iii) Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in the hospital. Included are events that occur within forty-two (42) days postdelivery. Excluded are deaths from any of the following:

(AA) Pulmonary or amniotic fluid embolism.

(BB) Acute fatty liver of pregnancy.

(CC) Cardiomyopathy.

(iv) Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in the hospital.

(v) Death or serious disability (kernicterus) associated with hyperbilirubinemia in neonates.

(vi) Stage 3 or 4 pressure ulcers acquired after admission to the hospital. Excluded is progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission.

(vii) Patient death or serious disability due to spinal manipulation therapy performed in the hospital.

(E) The following environmental events:

(i) Patient death or serious disability associated with an electric shock while being cared for in the hospital. Excluded are events involving planned treatment, such as electrical countershock.

(ii) Any incident in which a line designated for oxygen or other gas to be delivered to a patient:

(AA) contains the wrong gas; or

(BB) is contaminated by toxic substances.

(iii) Patient death or serious disability associated with a burn incurred from any source while being cared for in the hospital.

(iv) Patient death associated with a fall while being cared for in the hospital.

(v) Patient death or serious disability associated with the use of restraints or bedrails while being cared for in the hospital.

(F) The following criminal events:

(i) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider.

(ii) Abduction of a patient of any age.

(iii) Sexual assault on a patient within or on the grounds of the hospital.

(iv) Death or significant injury of a patient or staff member resulting from a physical assault, that is, battery, that occurs within or on the grounds of the hospital.

(2) A process for reporting to the department each serious adverse event listed in subdivision (1) that is determined by the hospital's quality assessment and improvement program to have occurred within the hospital.

(b) Subject to subsection (e), the process for determining the occurrence of the serious adverse events listed in subsection (a)(1) by the hospital's quality assessment and improvement program shall be designed by the hospital to accurately determine the occurrence of any of the serious adverse events listed in subsection (a)(1) within the hospital in a timely manner.

(c) Subject to subsection (e), the process for reporting the occurrence of a serious adverse event listed in subsection (a)(1) shall comply with the following:

(1) The report shall:

(A) be made to the department;

(B) be submitted not later than fifteen (15) working days after the serious adverse event is determined to have occurred by the hospital's quality assessment and improvement program; and

(C) identify the serious adverse event and the hospital, but shall not include any identifying information for any:

(i) patient;

(ii) individual licensed under IC 25; or

(iii) hospital employee involved;

or any other information.

(2) The report, and any documents permitted under this section to accompany the report, shall be submitted in an electronic format, including a format for electronically affixed signatures.

(d) The hospital's report of a serious adverse event listed in subsection (a)(1) shall be used by the department for purposes of publicly reporting the type and number of such serious adverse events occurring within each hospital. The department's public report will be issued not less frequently than annually.

(e) Any serious adverse event listed in subsection (a)(1), that:

(1) is determined to have occurred within the hospital between:

(A) January 1, 2006; and

(B) the effective date of this rule; and

(2) has not been previously reported;

must be reported within five (5) days of the effective date of this rule. *(Indiana State Department of Health; 410 IAC 15-1.4-2.2)*

Notice of Public Hearing

Under IC 4-22-2-24, notice is hereby given that on February 23, 2006 at 10:00 a.m., at the Indiana State Department of Health, 2 North Meridian Street, Rice Auditorium, Indianapolis, Indiana the Indiana State Department of Health will hold a public hearing on a proposed rule to add 410 IAC 15-1.4-2.2 to include serious adverse event reporting to the requirements for a hospital's quality assessment and improvement program and to add various definitions to 410 IAC 15-1.1.

These rules are added to meet the Governor's Executive Order 05-10 requiring the Indiana State Department of Health to develop and implement a medical errors reporting system. Requirements for reporting are based on the National Quality Forum's 27 serious reportable events.

Copies of these rules are now on file at the Health Care Regulatory Commission at the Indiana State Department of Health, 2 North Meridian Street and Legislative Services Agency, One North Capitol, Suite 325, Indianapolis, Indiana and are open for public inspection.

Sue Uhl
Deputy State Health Commissioner
Indiana State Department of Health