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TITLE 410 INDIANA STATE DEPARTMENT OF HEALTH

Proposed Rule
LSA Document #05-321

DIGEST

Adds 410 IAC 15-2.4-3, amends 410 IAC 26-1-1, amends 410 IAC 26-1 by adding new definitions, adds 410 IAC 26-6-2, amends 410 IAC 27-1-1, amends 410 IAC 27-1 by adding new definitions, and adds 410 IAC 27-6-2 to require ambulatory outpatient surgical centers, abortion clinics, and birthing centers to implement a medical errors reporting system and report medical errors reporting data to the department. 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 ambulatory surgery centers, abortion clinics, and birthing centers 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 ISDH Hospital Council recommended and the ISDH Executive Board preliminarily adopted rules requiring the reporting of medical errors.

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 ambulatory surgery centers, abortion clinics, and birthing centers to have a serious adverse event reporting system in place and requires reports of serious adverse events that occur on or after January 1, 2006, to be reported to the ISDH. The rule requires the facility's quality assessment and improvement program to review incidents and determine whether a serious adverse event occurred. If a serious adverse event occurs, the facility must report the event to the ISDH not later than 15 working days after the facility's quality assessment and improvement program determines that a serious adverse event occurred. Data submission will occur utilizing the ISDH Web-based portal system. 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 reviewed the proposed rule to determine whether the total economic impact of the rule on regulated persons will exceed $500,000. The department 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 123 ambulatory surgery centers. The ISDH does not have data on the gross annual receipts of ambulatory surgery centers. Based on factors such as the number and type of procedures performed at the center, the ISDH estimates that fewer than 25 percent of centers would meet the definition of a small business. The ISDH therefore estimates there to be no more than 30 ambulatory surgery centers that are small businesses. The North American Industry Classification System classifies these institutions as ambulatory surgery centers (NAICS 621493).

In 2005, a public law was passed by the Indiana General Assembly requiring the licensing of abortion clinics beginning July 1, 2006. The ISDH has not yet begun the licensing of abortion clinics so does not have a definitive number of these clinics. The ISDH

estimates the number of abortion clinics to be nine. The North American Industry Classification System classifies these institutions as abortion clinics (NAICS 621410).

In 2005, a public law was passed by the Indiana General Assembly requiring the licensing of birthing centers. Rules allowing to the licensing of birthing centers became effective on March 5, 2006. The ISDH has not yet begun the licensing of birthing centers so does not have a definitive number of these centers. The ISDH estimates the number of birthing centers to be five. The North American Industry Classification System classifies these institutions as midwives' offices or centers (NAICS 621399).

In summary, the number of small businesses impacted by this rule is likely less than 44.

2. Estimate of the average annual reporting, record keeping, and other administrative costs that small businesses will incur to comply with the proposed rule.

The economic impact of the serious adverse event reporting rule on ambulatory surgery centers, abortion clinics, and birthing centers is minimal. Ambulatory surgery centers are federally certified and state licensed. Abortion clinics and birthing centers are state licensed. Pursuant to existing certification and licensing standards, the health care facilities regulated by this rule are required to maintain records and ensure quality care. Existing rules and regulations require the regulated businesses to have a quality assurance committee and system. Each facility's quality assurance program is required to review and address quality of care issues. Existing rules and regulations would therefore require that the health care facility review serious adverse events and develop and implement a plan to address those events.

Initial start-up expenses:

This rule will require ambulatory surgery centers, abortion clinics, and birthing centers to gather and report serious adverse event data. To implement and achieve compliance with the rule, the facilities may have to modify current reporting policies and procedures in order to add the serious adverse event reporting. The facilities will need to ensure preparation, completion, and submission of required data. Because the reports will be submitted through the ISDH Web-based portal system, the facility will need to designate an individual to submit the reports and that individual will need to register on the system. The total estimated employee compensated time per facility for initial start-up compliance during the first year is 20 hours. The ISDH expects these activities to be coordinated and performed by a compliance officer or director of nursing. The estimated total start-up expense based on estimated labor rates is $500 [20 hours × $25/hour].

Recurring expenses:

The rule will require the health care facility to determine whether a reportable serious adverse event occurred and, if so, report that event to the ISDH. The reporting of a serious adverse event is essentially a two-step process. The rule requires that the facility quality assessment and improvement program review reported medical errors to determine whether a reportable serious adverse event occurred. Under existing facility licensing rules, the facility quality assessment and improvement program is already required to review this kind of information so that component of the rule should not result in an added expense for the facility. If the program determines that a reportable serious adverse event occurred, the rule requires the facility to report serious adverse events within 15 working days of the determination by the quality assessment and improvement program. Reporting occurs through a Web-based portal system and only takes a couple of minutes to do per reportable event. The time required for gathering the information, determining whether reportable, and filing the report is likely no more than two hours per serious adverse event. For facilities with few or no reportable errors, the cost is proportionately lower. Facilities reporting a significant number of errors would incur costs proportionately higher. Assuming one event per month, the estimated recurring annual expense is $600 [12 events × 2 hours × $25/hour].

3. Estimate of the total annual economic impact that compliance with the proposed rule will have on all small businesses subject to the rule.

Based on the above assumptions, the average first year expense is $1,100 [$500 start-up costs plus $600 recurring expenses] per facility. The total annual cost on small businesses for the initial year is therefore $48,400 [44 small businesses × $1,100 per facility].

The average expense for subsequent years is $600 per facility. The annual ongoing cost to the small businesses is therefore approximately $26,400 [44 small businesses × $600].

4. Statement justifying any requirement or cost that is imposed on small businesses by the rule; and not expressly required by the statute authorizing the agency to adopt the rule; or any other state or federal law.

IC 16-21 requires the ISDH to license and regulate ambulatory surgery centers, abortion clinics, and birthing centers. The statute requires the ISDH to adopt rules to ensure quality assurance standards at the regulated facilities. Additionally, rules and regulations require the facilities to maintain a quality assurance program. The ISDH believes the proposed rules are within the requirements established in applicable statutes, rules, and regulations.

Patient safety is of significant concerns to all Hoosiers. Medical errors have been identified in studies such as the Institute of Medicines 2000 report entitled *To Err is Human* as a significant problem in ensuring health care quality. The ability to collect data on serious adverse events is an important step towards analyzing information in order to improve health care quality through decreasing medical errors. The reduction of serious adverse events would decrease operating costs for health care facilities.

5. Regulatory Flexibility Analysis

A. Establishment of less stringent compliance or reporting requirements for small businesses.

In order to ensure the ability to obtain complete data, the reporting requirements are the same for all health care providers. The reporting requirement is very minimal. The facility is only required to report the classification of the serious adverse event and the quarter in which it occurred.

B. Establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses.

Because the reporting requirements are minimal, there was no need to establish less stringent schedules or deadlines for small business compliance.

C. Consolidation or simplification of compliance or reporting requirements for small businesses.

It is expected that the health care facility's quality assessment and improvement program will meet periodically and review any serious adverse events gathered during the period since their last meeting. The program will therefore be able to consolidate events in an efficient manner. There are no other reporting requirements imposed by the proposed rule.

D. Establishment of performance standards for small businesses instead of design or operational standards imposed on other regulated entities by the rule.

There are accreditation and certification organizations that have established performance standards for these health care facilities. The standards imposed by this rule were developed by the National Quality Forum in collaboration with health care providers.

E. Exemption of small businesses from part or all of the requirements or costs imposed by the rule.

The health care facilities already have quality assurance programs in place pursuant to other requirements. This proposed rule adds a minimal reporting requirement that is negligible.

Conclusion

The economic impact of the proposed rule on small businesses is minimal. If the health care facility has no serious adverse events, there would be no economic impact on small businesses.

410 IAC 15-2.4-3
410 IAC 26-1-1
410 IAC 26-1-3.5
410 IAC 26-1-4.6
410 IAC 26-1-4.8
410 IAC 26-1-9.5
410 IAC 26-1-12.5
410 IAC 26-1-12.6
410 IAC 26-1-12.7
410 IAC 26-1-12.8
410 IAC 26-1-12.9
410 IAC 26-1-13.5
410 IAC 26-1-17.5
410 IAC 26-1-17.8
410 IAC 26-1-19
410 IAC 26-6-2
410 IAC 27-1-1
410 IAC 27-1-1.5
410 IAC 27-1-2.5
410 IAC 27-1-3.5
410 IAC 27-1-9.5
410 IAC 27-1-13.4
410 IAC 27-1-13.5
410 IAC 27-1-13.6
410 IAC 27-1-13.7
410 IAC 27-1-13.8
410 IAC 27-1-13.9
410 IAC 27-1-15.5
410 IAC 27-1-16.5
410 IAC 27-1-21.5
410 IAC 27-1-23
410 IAC 27-1-24
410 IAC 27-6-2

SECTION 1. 410 IAC 15-2.4-3 IS ADDED TO READ AS FOLLOWS:

410 IAC 15-2.4-3 Reporting serious adverse events
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 3. (a) The center'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 center:

(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 center. 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 center. 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 center, defined as events that result from patient actions after admission to the center. Excluded are deaths resulting from self-inflicted injuries that were the reason for admission to the center.

(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 center. 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 center.

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

(vi) Stage 3 or 4 pressure ulcers acquired after admission to the center. 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 center.

(E) The following environmental events:

(i) Patient death or serious disability associated with an electric shock while being cared for in the center. 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 center.

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

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

(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 center.

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

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

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

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

(i) patient;

(ii) individual licensed under IC 25; or

(iii) center 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 center'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 center. 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 center 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 15-2.4-3)*

SECTION 2. 410 IAC 26-1-1, PROPOSED TO BE ADDED AT 29 IR 85, SECTION 1, IS AMENDED TO READ AS FOLLOWS:

410 IAC 26-1-1 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 26-1-1)*

SECTION 3. 410 IAC 26, PROPOSED TO BE ADDED AT 29 IR 85, SECTION 1, IS AMENDED BY ADDING A NEW SECTION TO READ AS FOLLOWS:

410 IAC 26-1-3.5 "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. 3.5. "ASA Class I patient" means a normal, healthy patient. *(Indiana State Department of Health; 410 IAC 26-1-3.5)*

SECTION 4. 410 IAC 26, PROPOSED TO BE ADDED AT 29 IR 85, SECTION 1, IS AMENDED BY ADDING A NEW SECTION TO READ AS FOLLOWS:

410 IAC 26-1-4.6 "Biologics" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 4.6 "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 26-1-4.6)*

SECTION 5. 410 IAC 26, PROPOSED TO BE ADDED AT 29 IR 85, SECTION 1, IS AMENDED BY ADDING A NEW SECTION TO READ AS FOLLOWS:

410 IAC 26-1-4.8 "Burn" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 4.8. "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 26-1-4.8)

SECTION 6. 410 IAC 26, PROPOSED TO BE ADDED AT 29 IR 85, SECTION 1, IS AMENDED BY ADDING A NEW SECTION TO READ AS FOLLOWS:

410 IAC 26-1-9.5 "Elopement" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 9.5. "Elopement" means any situation in which a registered or admitted patient, excluding adults with decision making capacity, leaves the clinic without staff being aware that the patient has done so. *(Indiana State Department of Health; 410 IAC 26-1-9.5)*

SECTION 7. 410 IAC 26, PROPOSED TO BE ADDED AT 29 IR 85, SECTION 1, IS AMENDED BY ADDING A NEW SECTION TO READ AS FOLLOWS:

410 IAC 26-1-12.5 "Hypoglycemia" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 12.5. "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 26-1-12.5)

SECTION 8. 410 IAC 26, PROPOSED TO BE ADDED AT 29 IR 85, SECTION 1, IS AMENDED BY ADDING A NEW SECTION TO READ AS FOLLOWS:

410 IAC 26-1-12.6 "Immediately postoperative" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 12.6. "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 26-1-12.6)

SECTION 9. 410 IAC 26, PROPOSED TO BE ADDED AT 29 IR 85, SECTION 1, IS AMENDED BY ADDING A NEW SECTION TO READ AS FOLLOWS:

410 IAC 26-1-12.7 "Informed consent" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 12.7. "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 26-1-12.7)*

SECTION 10. 410 IAC 26, PROPOSED TO BE ADDED AT 29 IR 85, SECTION 1, IS AMENDED BY ADDING A NEW SECTION TO READ AS FOLLOWS:

410 IAC 26-1-12.8 "Intended use" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 12.8. "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 26-1-12.8)*

SECTION 11. 410 IAC 26, PROPOSED TO BE ADDED AT 29 IR 85, SECTION 1, IS AMENDED BY ADDING A NEW SECTION TO READ AS FOLLOWS:

410 IAC 26-1-12.9 "Kernicterus" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 12.9. "Kernicterus" means the medical condition in which elevated levels of bilirubin cause brain damage. *(Indiana State Department of Health; 410 IAC 26-1-12.9)*

SECTION 12. 410 IAC 26, PROPOSED TO BE ADDED AT 29 IR 85, SECTION 1, IS AMENDED BY ADDING A NEW SECTION TO READ AS FOLLOWS:

410 IAC 26-1-13.5 "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. 13.5. "Low-risk pregnancy" means a woman sixteen (16) to thirty-nine (39) 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 26-1-13.5)

SECTION 13. 410 IAC 26, PROPOSED TO BE ADDED AT 29 IR 85, SECTION 1, IS AMENDED BY ADDING A NEW SECTION TO READ AS FOLLOWS:

410 IAC 26-1-17.5 "Serious disability" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 17.5. "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 26-1-17.5)

SECTION 14. 410 IAC 26, PROPOSED TO BE ADDED AT 29 IR 85, SECTION 1, IS AMENDED BY ADDING A NEW SECTION TO READ AS FOLLOWS:

410 IAC 26-1-17.8 "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. 17.8. "Surgery or other invasive procedure", for purposes of 410 IAC 26-6-2, 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 26-1-17.8)

SECTION 15. 410 IAC 26, PROPOSED TO BE ADDED AT 29 IR 85, SECTION 1, IS AMENDED BY ADDING A NEW SECTION TO READ AS FOLLOWS:

410 IAC 26-1-19 "Toxic substance" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 19. "Toxic substance" means chemicals that are present in sufficient concentration to pose a hazard to human health.
(Indiana State Department of Health; 410 IAC 26-1-19)

SECTION 16. 410 IAC 26, PROPOSED TO BE ADDED AT 29 IR 85, SECTION 1, IS AMENDED BY ADDING A NEW SECTION TO READ AS FOLLOWS:

410 IAC 26-6-2 Reporting serious adverse events
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 2. (a) The clinic'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 clinic:
(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 clinic. 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 clinic. Excluded are deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

(C) The following patient protection events:

(i) 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.

(ii) Patient suicide or attempted suicide resulting in serious disability, while being cared for in the clinic, defined as events that result from patient actions after admission to the clinic.

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

(E) The following environmental events:

(i) Patient death or serious disability associated with an electric shock while being cared for in the clinic. 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 clinic.

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

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

(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 clinic.

(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 clinic.

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

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

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

(i) patient;

(ii) individual licensed under IC 25; or

(iii) clinic 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 clinic'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 clinic. 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 clinic 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 26-6-2)*

SECTION 17. 410 IAC 27-1-1, AS ADDED AT 29 IR 1904, SECTION 1, IS AMENDED TO READ AS FOLLOWS:

410 IAC 27-1-1 Applicability

Authority: IC 16-21-1-7; IC 16-21-2-2.5

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 27-1-1; filed Feb 3, 2006, 2:00 p.m.: 29 IR 1904)*

SECTION 18. 410 IAC 27, AS ADDED AT 29 IR 1904, SECTION 1, IS AMENDED BY ADDING A NEW SECTION TO READ AS FOLLOWS:

410 IAC 27-1-1.5 "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. 1.5. "ASA Class I patient" means a normal, healthy patient. *(Indiana State Department of Health; 410 IAC 27-1-1.5)*

SECTION 19. 410 IAC 27, AS ADDED AT 29 IR 1904, SECTION 1, IS AMENDED BY ADDING A NEW SECTION TO READ AS FOLLOWS:

410 IAC 27-1-2.5 "Biologics" defined

Authority: IC 16-19-3-4; IC 16-21-1-7

Affected: IC 16-19-3; IC 16-21-1

Sec. 2.5 "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 27-1-2.5)*

SECTION 20. 410 IAC 27, AS ADDED AT 29 IR 1904, SECTION 1, IS AMENDED BY ADDING A NEW SECTION TO READ AS FOLLOWS:

410 IAC 27-1-3.5 "Burn" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 3.5. "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 27-1-3.5)

SECTION 21. 410 IAC 27, AS ADDED AT 29 IR 1904, SECTION 1, IS AMENDED BY ADDING A NEW SECTION TO READ AS FOLLOWS:

410 IAC 27-1-9.5 "Elopement" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 9.5. "Elopement" means any situation in which a registered or admitted patient, excluding adults with decision making capacity, leaves the center without staff being aware that the patient has done so. *(Indiana State Department of Health; 410 IAC 27-1-9.5)*

SECTION 22. 410 IAC 27, AS ADDED AT 29 IR 1904, SECTION 1, IS AMENDED BY ADDING A NEW SECTION TO READ AS FOLLOWS:

410 IAC 27-1-13.4 "Hyperbilirubinemia" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 13.4. "Hyperbilirubinemia" means total serum bilirubin levels greater than twenty-five (25) mg/dl in a neonate. *(Indiana State Department of Health; 410 IAC 27-1-13.4)*

SECTION 23. 410 IAC 27, AS ADDED AT 29 IR 1904, SECTION 1, IS AMENDED BY ADDING A NEW SECTION TO READ AS FOLLOWS:

410 IAC 27-1-13.5 "Hypoglycemia" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 13.5. "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 27-1-13.5)

SECTION 24. 410 IAC 27, AS ADDED AT 29 IR 1904, SECTION 1, IS AMENDED BY ADDING A NEW SECTION TO READ AS FOLLOWS:

410 IAC 27-1-13.6 "Immediately postoperative" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 13.6. "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 27-1-13.6)

SECTION 25. 410 IAC 27, AS ADDED AT 29 IR 1904, SECTION 1, IS AMENDED BY ADDING A NEW SECTION TO READ AS FOLLOWS:

410 IAC 27-1-13.7 "Informed consent" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 13.7. "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 27-1-13.7)*

SECTION 26. 410 IAC 27, AS ADDED AT 29 IR 1904, SECTION 1, IS AMENDED BY ADDING A NEW SECTION TO READ AS FOLLOWS:

410 IAC 27-1-13.8 "Intended use" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 13.8. "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 27-1-13.8)*

SECTION 27. 410 IAC 27, AS ADDED AT 29 IR 1904, SECTION 1, IS AMENDED BY ADDING A NEW SECTION TO READ AS FOLLOWS:

410 IAC 27-1-13.9 "Kernicterus" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 13.9. "Kernicterus" means the medical condition in which elevated levels of bilirubin cause brain damage. *(Indiana State Department of Health; 410 IAC 27-1-13.9)*

SECTION 28. 410 IAC 27, AS ADDED AT 29 IR 1904, SECTION 1, IS AMENDED BY ADDING A NEW SECTION TO READ AS FOLLOWS:

410 IAC 27-1-15.5 "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. 15.5. "Low-risk pregnancy" means a woman sixteen (16) to thirty-nine (39) 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 27-1-15.5)

SECTION 29. 410 IAC 27, AS ADDED AT 29 IR 1904, SECTION 1, IS AMENDED BY ADDING A NEW SECTION TO READ AS FOLLOWS:

410 IAC 27-1-16.5 "Neonates" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 16.5. "Neonates" means infants in the first twenty-eight (28) days of life. *(Indiana State Department of Health; 410 IAC 27-1-16.5)*

SECTION 30. 410 IAC 27, AS ADDED AT 29 IR 1904, SECTION 1, IS AMENDED BY ADDING A NEW SECTION TO READ AS FOLLOWS:

410 IAC 27-1-21.5 "Serious disability" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 21.5. "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 27-1-21.5)

SECTION 31. 410 IAC 27, AS ADDED AT 29 IR 1904, SECTION 1, IS AMENDED BY ADDING A NEW SECTION TO READ AS FOLLOWS:

410 IAC 27-1-23 "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. 23. "Surgery or other invasive procedure" means, for purposes of 410 IAC 27-6-2, 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 contract agents.
(Indiana State Department of Health; 410 IAC 27-1-23)

SECTION 32. 410 IAC 27, AS ADDED AT 29 IR 1904, SECTION 1, IS AMENDED BY ADDING A NEW SECTION TO READ AS FOLLOWS:

410 IAC 27-1-24 "Toxic substance" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 24. "Toxic substance" means chemicals that are present in sufficient concentration to pose a hazard to human health.
(Indiana State Department of Health; 410 IAC 27-1-24)

SECTION 33. 410 IAC 27, AS ADDED AT 29 IR 1904, SECTION 1, IS AMENDED BY ADDING A NEW SECTION TO READ AS FOLLOWS:

410 IAC 27-6-2 Reporting serious adverse events
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 2. (a) The center's quality assessment and improvement program under section 2 of this rule shall include:
(1) A process for determining the occurrence of the following serious adverse events within the center:
(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 center. 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 center. 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 center, defined as events that result from patient actions after admission to the center.

(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 center. 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 center.

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

(E) The following environmental events:

(i) Patient death or serious disability associated with an electric shock while being cared for in the center. 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 center.

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

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

(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 center.

(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 center.

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

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

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

(i) patient;

(ii) individual licensed under IC 25; or

(iii) center 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 center'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 center. 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 center 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 27-6-2)*

Notice of Public Hearing

Under IC 4-22-2-24, notice is hereby given that on April 24, 2006 at 9:00 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 require ambulatory outpatient surgical centers, abortion clinics, and birthing centers to implement a medical errors reporting system and report medical errors reporting data to the department.

This rule imposes additional requirements in order to comply with Executive Order 5-10 of Governor Daniels.

Copies of these rules are now on file at the Health Care Regulatory Services 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