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**TITLE 410 INDIANA STATE DEPARTMENT OF
HEALTH**

LSA Document #05-326(E)

DIGEST

Temporarily amends provisions and adds provisions to include serious adverse event reporting to the requirements for a hospital's quality assessment and improvement program. Temporarily adds provisions to include serious adverse event reporting to the requirements for an ambulatory outpatient surgical center's quality assessment and improvement program. Temporarily adds various definitions. Authority: IC 4-22-2-37.1; IC 16-19-3-4; IC 16-21-1-7. Effective January 1, 2006.

SECTION 1. The definitions in this document apply throughout this document except as otherwise indicated.

SECTION 2. "ASA Class I patient" means a normal, healthy patient.

SECTION 3. "Biologics" means a biological product (such as a globulin, serum, vaccine, antitoxin, blood, or antigen) used in the prevention or treatment of disease.

SECTION 4. "Burn" means any injury or damage to the tissues of the body caused by exposure to fire, heat, chemicals, electricity, radiation, or gases.

SECTION 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.

SECTION 6. "Hyperbilirubinemia" means total serum bilirubin levels greater than twenty-five (25) mg/dl in a neonate.

SECTION 7. "Hypoglycemia" means a physiologic state in which the blood sugar falls below sixty (60) mg/dl (40 mg/dl in neonates) and physiological and/or neurological dysfunction begins.

SECTION 8. "Immediately postoperative" means within twenty-four (24) hours after induction of anesthesia (if surgery or other invasive procedure is not completed), or within twenty-four (24) hours after completion of surgery or other invasive procedure.

SECTION 9. "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 such surgery or other invasive procedure.

SECTION 10. "Intended use" means the use of a device as described on the label and associated materials provided by the device's manufacturer.

SECTION 11. "Kernicterus" means the medical condition in which elevated levels of bilirubin cause brain damage.

SECTION 12. "Low-risk pregnancy" means a woman aged sixteen to thirty-nine (16-39), with no previous diagnosis of essential hypertension, renal disease, collagen-vascular disease, liver disease, preeclampsia, cardiovascular disease, placenta previa, multiple gestation, intrauterine growth retardation, smoking, pregnancy-induced hypertension, premature rupture of membranes, or other previously documented condition that poses a high risk of pregnancy-related mortality.

SECTION 13. "Neonates" means infants in the first twenty-eight (28) days of life.

SECTION 14. "Serious disability" means:

- (1) significant loss of function including sensory, motor, physiologic, or intellectual impairment not present on admission and requiring continued treatment or for which there is a high probability of long term or permanent lifestyle change at discharge; or**
- (2) unintended loss of a body part.**

SECTION 15. “Spinal manipulative therapy” means all types of manual techniques, including spinal mobilization (movement of a joint within its physiologic range of motion) and 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.

SECTION 16. For purposes of SECTION 18 and SECTION 19 of this document [SECTIONS 18 and 19 of this document], “surgery or other invasive procedure” means surgical or other invasive procedures that involve a skin incision or puncture including, but not limited to, open or percutaneous surgical procedures, percutaneous aspiration, selected injections, biopsy, percutaneous cardiac and vascular diagnostic or interventional procedures, laparoscopies, endoscopies, colonoscopies, and excluding intravenous therapy, venipuncture for phlebotomy, or diagnostic tests without intravenous contract agents.

SECTION 17. “Toxic substance” means chemicals that are present in sufficient concentration to pose a hazard to human health.

SECTION 18. (a) The hospital’s quality assessment and improvement program under 410 IAC 15-1.4-2 shall include:

(1) A process for determining the occurrence of the following serious adverse events within the hospital:

(A) 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. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent.**
- (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. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent.**
- (iv) Retention of a foreign object in a patient after surgery or other invasive procedure. Excludes objects intentionally implanted as part of a planned intervention and objects present prior to surgery that were intentionally retained.**
- (v) Intraoperative or immediately postoperative death in an ASA Class I patient. Includes 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) Product or device events:

- (i) Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the hospital. Includes 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. Includes, but is not limited to:**
 - (AA) catheters;**
 - (BB) drains and other specialized tubes;**
 - (CC) infusion pumps; and**
 - (DD) ventilators.**
- (iii) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in the hospital. Excludes deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.**

(C) 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. Excludes events involving adults with decision making capacity.**
- (iii) Patient suicide or attempted suicide resulting in serious disability, while begin [*sic., being*] cared for in the hospital, defined as events that result from patient actions after admission to the hospital. Excludes deaths resulting from self-inflicted injuries that were the reason for admission to the hospital.**

(D) Care management events:

- (i) Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration). Excludes 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. Includes events that occur within forty-two (42) days postdelivery. Excludes deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or 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. Excludes 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) Environmental events:

- (i) Patient death or serious disability associated with an electric shock while being cared for in the hospital. Excludes 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 contains the wrong gas or 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 *[sic., serious]* disability associated with the use of restraints or bedrails while being cared for in the hospital.

(F) Criminal events:

- (i) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care 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 (i.e., battery) that occurs within or on the grounds of the hospital; and

(2) A process for reporting to the department each serious adverse event listed in subsection (a)(1) *[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) *[sic.]*, 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) *[sic.]*, 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 be made to the department.
- (2) The report shall 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.
- (3) The report shall identify the serious adverse event and the hospital, but shall not include any identifying information for any patient, individual licensed under IC 25, or hospital employee involved, or any other information.
- (4) 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 no less frequently than annually.

SECTION 19. (a) The center's quality assessment and improvement program under 410 IAC 15-2.4-2 shall include:

- (1) A process for determining the occurrence of the following serious adverse events within the center:

(A) 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. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent.**
- (ii) Surgery performed on the wrong patient, defined by 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. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent.**
- (iv) Retention of a foreign object in a patient after surgery or other invasive procedure. Excludes objects intentionally implanted as part of a planned intervention and objects present prior to surgery that were intentionally retained.**
- (v) Intraoperative or immediately postoperative death in an ASA Class I patient. Includes 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) Product or device events:

- (i) Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the center. Includes generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination and/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. Includes, but is not limited to:**
 - (AA) catheters;**
 - (BB) drains and other specialized tubes;**
 - (CC) infusion pumps; and**
 - (DD) ventilators.**
- (iii) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in the center. Excludes deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.**

(C) 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. Excludes events involving competent adults.**
- (iii) Patient suicide or attempted suicide resulting in serious disability, while begin [*sic., being*] cared for in the center, defined as events that result from patient actions after admission to the center. Excludes deaths resulting from self-inflicted injuries that were the reason for admission to the center.**

(D) Care management events:

- (i) Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration). Excludes 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. Includes events that occur within forty-two (42) days postdelivery. Excludes deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or 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 hospital. Excludes 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) Environmental events:

- (i) Patient death or serious disability associated with an electric shock while being cared for in the center. Excludes 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 contains the wrong gas or 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 *[sic., serious]* disability associated with the use of restraints or bedrails while being cared for in the center.

(F) Criminal events:

(i) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care 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; and

(2) A process for reporting to the department each serious adverse event listed in subsection (a)(1) *[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) *[sic.]*, 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) *[sic.]*, 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 be made to the department.

(2) The report shall be submitted as soon as reasonably and practicably possible, but 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.

(3) The report shall identify the serious adverse event and the center, but shall not include any identifying information for any patient, individual licensed under IC 25, or center employee involved, or any other information.

(4) 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 no less frequently than annually.

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