

APPENDIX F

HOSPITAL MEDICAL ERROR REPORTING RULE

410 IAC 15-1.4-2 Quality assessment and improvement

Authority: IC 16-21-1-7

Affected: IC 16-21-1

Sec. 2. (a) The hospital shall have an effective, organized, hospital-wide, comprehensive quality assessment and improvement program in which all areas of the hospital participate. The program shall be ongoing and have a written plan of implementation that evaluates, but is not limited to, the following:

(1) All services, including services furnished by a contractor.

(2) All functions, including, but not limited to, the following:

(A) Discharge planning.

(B) Infection control.

(C) Medication therapy.

(D) Response to emergencies as defined in 410 IAC 15-1.5-5(b)(3)(L)(i).

(3) All medical and surgical services performed in the hospital with regard to appropriateness of diagnosis and treatments related to a standard of care and anticipated or expected outcomes.

(b) The hospital shall take appropriate action to address the opportunities for improvement found through the quality assessment and improvement program as follows:

(1) The action shall be documented.

(2) The outcome of the action shall be documented as to its effectiveness, continued follow-up, and impact on patient care.

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

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.
 - (CC) Retention of broken microneedles.
 - (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.
 - (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 Stage 4 pressure ulcers acquired after admission to the hospital. Excluded is progression from Stage 2 or Stage 3 if the Stage 2 or Stage 3 pressure ulcer was recognized upon admission or unstageable due to the presence of eschar.

(vii) Patient death or serious disability due to joint movement 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. 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:

(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;
 - (C) be submitted not later than six (6) months after the potential event is brought to the program's attention; and
 - (D) 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) A potentially reportable serious adverse event may be identified by a hospital that receives a patient as a transfer from another health care facility subject to a serious adverse event requirement or admits a patient subsequent to discharge from another health care facility subject to a serious adverse event requirement. In the event that a hospital identifies a potentially reportable event originating from another health care facility subject to a serious adverse event requirement, the identifying hospital shall notify the originating health care facility as soon as they determine an event has potentially occurred for consideration by the originating health care facility's quality assessment and improvement program.

(3) 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.

(4) A quality assessment and improvement program may refrain from making a determination about the occurrence of a serious adverse reportable event that involves a possible criminal act until criminal charges are filed in the applicable court of law.

(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.

(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.

APPENDIX G

AMBULATORY SURGERY CENTER MEDICAL ERROR REPORTING RULE

410 IAC 15-2.4-2 Quality assessment and improvement

Authority: IC 16-21-1-7

Affected: IC 16-21-1

Sec. 2. (a) The center must develop, implement, and maintain an effective, organized, center-wide, comprehensive quality assessment and improvement program in which all areas of the center participate. The program shall be ongoing and have a written plan of implementation that evaluates, but is not limited to, the following:

(1) All services, including services furnished by a contractor.

(2) All functions, including, but not limited to, the following:

(A) Discharge and transfer.

(B) Infection control.

(C) Medication errors.

(D) Response to patient emergencies.

(3) All services performed in the center with regard to appropriateness of diagnoses and treatments related to a standard of care and anticipated or expected outcomes.

(b) The center shall take appropriate action to address the opportunities for improvement found through the quality assessment and improvement program as follows:

(1) The action must be documented.

(2) The outcome of the action must be documented as to its effectiveness, continued follow-up, and impact on patient care.

410 IAC 15-2.4-2.2 Reporting serious adverse events

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

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

Sec. 2.2. (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.

(CC) Retention of broken microneedles.

(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.

(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 or Stage 3 if the Stage 2 or Stage 3 pressure ulcer was recognized upon admission or unstageable due to the presence of eschar.

(vii) Patient death or serious disability due to joint movement 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;

(C) be submitted not later than six (6) months after the potential event is brought to the program's attention; and

(D) 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) A potentially reportable serious adverse event may be identified by a center that receives a patient as a transfer from another health care facility subject to a serious adverse event requirement or admits a patient subsequent to discharge from another health care facility subject to a serious adverse event requirement. In the event that a center identifies a potentially reportable event originating from another health care facility subject to a serious adverse event requirement, the identifying center shall notify the originating health care facility as soon as they determine an event has potentially occurred for consideration by the originating health care facility's quality assessment and improvement program.

(3) 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.

(4) A quality assessment and improvement program may refrain from making a determination about the occurrence of a serious adverse reportable event that involves a possible criminal act until criminal charges are filed in the applicable court of law.

(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.

APPENDIX H

ABORTION CLINICS MEDICAL ERROR REPORTING RULE

410 IAC 26-6-1 Quality assessment and improvement

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

Affected: IC 16-21-1; IC 16-21-2

Sec. 1. (a) The abortion clinic must develop or adopt, implement, and maintain an effective, organized, clinic-wide, comprehensive quality assessment and improvement program in which all areas of the clinic involved in the provision of surgical abortion participate. The program shall be ongoing and have a written plan of implementation that evaluates, but is not limited to, the following:

(1) All services, including services furnished by a contractor.

(2) All functions, including, but not limited to, the following:

(A) Discharge.

(B) Transfer.

(C) Infection control.

(D) Response to patient emergencies.

(3) All services performed in the clinic with regard to the following:

(A) Appropriateness of diagnoses and treatments related to a standard of care.

(B) Anticipated or expected outcomes.

(4) Medical and medication errors.

(b) The clinic shall take appropriate action to address the opportunities for improvement found through the quality assessment and improvement program as follows:

(1) The action must be documented.

(2) The outcome of the action must be documented as to its effectiveness, continued follow-up, and impact on patient care.

(Indiana State Department of Health; 410 IAC 26-6-1; filed May 11, 2006, 9:36 a.m.: 29 IR 3362)

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 1 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.

(CC) Retention of broken microneedles.

(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) Infants discharged to the wrong person.

(ii) Patient death or serious disability associated with patient elopement.

(iii) 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. Excluded are deaths resulting from self-inflicted injuries that were the reason for 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) Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in the clinic. Included are events that occur within forty-two (42) days post-delivery. 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 clinic.

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

(vi) Stage 3 or 4 pressure ulcers acquired after admission to the clinic. Excluded is progression from Stage 2 or Stage 3 if the Stage 2 or Stage 3 pressure ulcer was recognized upon admission or unstageable due to the presence of eschar.

(vii) Patient death or serious disability due to joint movement therapy performed 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;

(C) be submitted not later than six (6) months after the potential event is brought to the program's attention; and

(D) 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) A potentially reportable serious adverse event may be identified by a clinic that receives a patient as a transfer from another health care facility subject to a serious adverse event requirement or admits a patient subsequent to discharge from another health care facility subject to a serious adverse event requirement. In the event that a clinic identifies a potentially reportable event originating from another health care facility subject to a serious adverse event requirement, the identifying clinic shall notify the originating health care facility as soon as they determine an event has potentially occurred for consideration by the originating health care facility's quality assessment and improvement program.

(3) 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.

(4) A quality assessment and improvement program may refrain from making a determination about the occurrence of a serious adverse reportable event that involves a possible criminal act until criminal charges are filed in the applicable court of law.

(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.

APPENDIX I

BIRTHING CENTERS MEDICAL ERRORS REPORTING RULE

410 IAC 27-6-1 Quality assessment and improvement

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

Affected: IC 16-21-1

Sec. 1. (a) The birthing center must develop, implement, and maintain an effective, organized, center-wide, comprehensive quality assessment and improvement program in which all areas of the center participate. The program shall be ongoing and have a written plan of implementation that evaluates, but is not limited to, the following:

(1) All services, including services furnished by a contractor.

(2) All functions, including, but not limited to, the following:

(A) Discharge.

(B) Transfer.

(C) Infection control.

(D) Response to patient emergencies.

(3) All services performed in the center with regard to appropriateness of diagnoses and treatments related to a standard of care and anticipated or expected outcomes.

(4) Medical and medication errors.

(b) The center shall take appropriate action to address the opportunities for improvement found through the quality assessment and improvement program as follows:

(1) The action must be documented.

(2) The outcome of the action must be documented as to its effectiveness, continued follow-up, and impact on patient care.

(Indiana State Department of Health; 410 IAC 27-6-1; filed Feb 3, 2006, 2:00 p.m.: 29 IR 1911)

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 1 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.

(CC) Retention of broken microneedles.

(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.

(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 or Stage 3 if the Stage 2 or Stage 3 pressure ulcer was recognized upon admission or unstageable due to the presence of eschar.

(vii) Patient death or serious disability due to joint movement 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, 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;

(C) be submitted not later than six (6) months after the potential event is brought to the program's attention; and

(D) 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) A potentially reportable serious adverse event may be identified by a center that receives a patient as a transfer from another health care facility subject to a serious adverse event requirement or admits a patient subsequent to discharge from another health care facility subject to a serious adverse event requirement. In the event that a center identifies a potentially reportable event originating from another health care facility subject to a serious adverse event requirement, the identifying center shall notify the originating health care facility as soon as they determine an event has potentially occurred for consideration by the originating health care facility's quality assessment and improvement program.

(3) 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.

(4) A quality assessment and improvement program may refrain from making a determination about the occurrence of a serious adverse reportable event that involves a possible criminal act until criminal charges are filed in the applicable court of law.

(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.