

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  150100	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED  09/11/2013
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NAME OF PROVIDER OR SUPPLIER  ST MARY'S MEDICAL CENTER OF EVANSVILLE INC	STREET ADDRESS, CITY, STATE, ZIP CODE 3700 WASHINGTON AVE EVANSVILLE, IN 47750
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S000000	<p>This visit was for the investigation of one (1) State complaint.</p> <p>Date of survey: 9-11-13</p> <p>Facility number: 005089</p> <p>Complaint number: IN00133749 Substantiated: State deficiency related to allegations is cited</p> <p>Surveyor: Jennifer Hembree, RN Public Health Nurse Surveyor</p> <p>QA: cloughlin 10/21/13</p>	S000000		
S000420	<p>410 IAC 15-1.4-2.2 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-1.4-2.2 (a)(1)</p> <p>Reportable events</p> <p>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 reportable 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</p>			

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Any deficiency statement ending with an asterisk (\*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (see instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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	<p>patient. Excluded are emergent situations: (AA) that occur in the course of surgery; or (BB) whose exigency precludes obtaining informed consent; or both.</p> <p>(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.</p> <p>(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.</p> <p>(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) Objects not present prior to surgery that are intentionally left in when the risk of removal exceeds the risk of retention, such as microneedles or broken screws. (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.</p> <p>(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</p>			

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	<p>hospital. Included are generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination or product.</p> <p>(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.</p> <p>(iii) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in the hospital. Excluded are deaths or serious disability associated with neurosurgical procedures known to present a high risk of intravascular air embolism.</p> <p>(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.</p> <p>(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</p>			

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	<p>(GG) route of administration.</p> <p>Excluded are reasonable differences in clinical judgment on drug selection and dose. Includes administration of a medication to which a patient has a known allergy and drug-drug interactions for which there is known potential for death or serious disability.</p> <p>(ii) Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA incompatible blood or blood products.</p> <p>(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:</p> <p>(AA) Pulmonary or amniotic fluid embolism.</p> <p>(BB) Acute fatty liver of pregnancy.</p> <p>(CC) Cardiomyopathy.</p> <p>(iv) Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in the hospital.</p> <p>(v) Death or serious disability (kernicterus) associated with the failure to identify and treat hyperbilirubinemia in neonates.</p> <p>(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 because of the presence of eschar.</p> <p>(vii) Patient death or serious disability resulting from joint movement therapy performed in the hospital.</p> <p>(viii) Artificial insemination with the wrong donor sperm or wrong egg.</p> <p>(E) The following environmental events:</p>			

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	<p>(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 or elective cardioversion.</p> <p>(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.</p> <p>(iii) Patient death or serious disability associated with a burn incurred from any source while being cared for in the hospital.</p> <p>(iv) Patient death or serious disability associated with a fall while being cared for in the hospital.</p> <p>(v) Patient death or serious disability associated with the use of restraints or bedrails while being cared for in the hospital.</p> <p>(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.</p> <p>Based on document review and staff interview, the facility failed to ensure patient falls with fracture resulting in serious disability were reported for one (1) patient with a serious disability from a fall (patient #13).</p>	S000420	Preparation and execution of this response and plan of correction do not constitute an admission or agreement by the provider of the truth of the facts alleged or conclusions set forth in the statement of deficiencies. This plan of correction is prepared and/or executed solely because it	12/03/2013			

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	<p>Findings include:</p> <p>1. Review of patient #13 medical record indicated the following:</p> <p>(A) He/she was admitted on 7/29/13 for a scheduled unicompartmental knee replacement.</p> <p>(B) Nurse notes indicated the patient was independent at home with a cane. Nurse notes at 0610 on 7/29/13 indicated the patient was ambulating to the bathroom with a nurse at his/her side when the patient lost their balance and was assisted to the floor. The patient reported increased pain in the right knee and x-rays were ordered and obtained.</p> <p>(C) The x-ray revealed an acute right supracondylar femur fracture which required open reduction and internal fixation with intra-articular extension.</p> <p>(D) He/she was released to longterm care closer to his/her home on 7/31/13 and per transfer form, the patient was no weight bearing on the right leg at the time of the discharge. Additionally, he/she required assistance of 2 with ambulation and toileting which was a significant difference from his/her admission status.</p> <p>2. Review of the log for facility reportable events to ISDH indicated the facility had five (5) reportable events in June/July/August of 2013. There were no reports of a patient fall with fracture.</p>		<p>is required by the provisions of federal and state Credible Allegation of Compliance: For the purpose of any allegation that St. Mary's Medical Center (St. Mary's) is not in substantial compliance with Indiana Administrative Code IAC 15-1.4-2.2 (a)(1) and accompanying regulations, this response constitutes St. Mary's allegations of compliance. Credible Allegation of Correction: St. Mary's submits the following as the credible allegation of correction. For each of the following findings, St. Mary's incorporates by reference its response as set forth above. TAG S 420 Reportable Events St. Mary's recognizes the importance of timely event reporting as required by Indiana Administrative Code 15-1.4-2.2 Quality Assessment and Improvement. Any allegation that this standard is not routinely met represents the exception rather than the norm at St. Mary's. The Indiana Medical Error Reporting Systems procedure for reporting medical errors is as follows: "If the facility's quality assessment and improvement program determines that a reportable event occurred, the facility must report the event within fifteen days of the program's determination that a medical error occurred and not later than six months after the potential event is</p>		

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	<p>3. Facility policy titled REPORTING REQUIREMENTS FOR SERIOUS ADVERSE EVENTS" states on page 1 under definitions: "B. Serious Disability: 1. Significant loss of function including sensory, motor, physiology, or intellectual impairment not present on admission and requiring continued treatment or for which there is a high probability of long-term or permanent life-style change at discharge, or 2. Unintended loss of a body part." Under reportable events, the policy states on page 5: "d. Patient death or serious disability associated with a fall while being cared for in the hospital."</p> <p>4. Staff member #1 indicated the following in interview beginning at 11:45 a.m. on 9/11/13: (A) The facility does not report falls with fracture to ISDH.</p>		<p>brought to the program's attention" By that standard, St. Mary's reported the fall December 3, 2013 within the required timeframe. The event in question was a femur fracture that was surgically repaired. The patient was to be non-weight bearing for 6 weeks. The Joint Commission's list of Sentinel Events describes a serious patient fall as one that "results in death or major permanent loss of function as a direct result of the injuries sustained in the fall". (Attachment A) Additionally, the definition of a disability as described by the Americans with Disabilities Act (1) (C) being regarded as having such as impairment (as described in paragraph (3)) which states: (B) Paragraph (1)(C) shall not apply to impairments that are transitory and minor. A transitory impairment is an impairment with an actual or expected duration of 6 months or less" (Attachment B) Finding #3 of the survey report cites St. Mary's policy titled Reporting Requirements for Serious Adverse Events (Attachment C) related to serious disability as "significant loss of function including sensory, motor, physiology or intellectual impairment not present on admission and requiring continued treatment or for which there is a high probability of long-term or permanent life-style change at discharge". St. Mary's</p>		

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			respectfully submits that non-weight bearing status associated with a femur fracture is not a loss of function, but a requirement for proper healing and bone alignment. Finding #4 states that staff member #1 stated St. Mary's does not report falls with fracture to Indiana State Department of Health. We strongly take exception to the alleged remark. This statement was taken out of context with regards to the conversation between the Indiana State Department of Health surveyor and the St. Mary's staff member. St. Mary's has a duty and obligation to report falls with fracture when it is determined that death or a serious disability has occurred due to the fall. It is our practice to report such events within the expected reportable time frame. All falls are reviewed by the Risk Management Department, as well as, the Quality Department. All falls resulting in death or disability will be reported to the Indiana State Department of Health Medical Error eporting System within the required timeframe. Responsibility for reporting lies with Risk Management within the oversight of the Vice President, Chief Risk and Corporate Responsibility Officer and the Executive Director of Quality.		