

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  150015	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED  09/19/2012
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NAME OF PROVIDER OR SUPPLIER  FRANCISCAN ST ANTHONY HEALTH - MICHIGAN CITY	STREET ADDRESS, CITY, STATE, ZIP CODE 301 W HOMER ST MICHIGAN CITY, IN 46360
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S0000	<p>This visit was for a standard licensure survey.</p> <p>Facility Number: 005015</p> <p>Survey Date: 9/17-19/2012</p> <p>Surveyors: ReBecca Lair, LCSW Medical Surveyor</p> <p>Jacqueline Brown, RN Public Health Nurse Surveyor</p> <p>Lynnette Smith Medical Surveyor</p> <p>QA: claughlin 09/26/12</p>	S0000		

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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S0362	<p>410 IAC 15-1.4-1 GOVERNING BOARD 410 IAC 15-1.4-1(d)(6)(A)(B)(C)(D)(E)(F)</p> <p>(d) The governing board is responsible for assuring that quality patient care is provided. In accordance with hospital policy, the governing board shall do the following:</p> <p>6) Ensure that the hospital does the following:</p> <p>(A) Establish written protocols to identify potential organ and tissue donors. (B) Has written policies and procedures for the facilitation of organ and tissue donations, including procurement. (C) Inform families or authorized persons of potential organ and tissue donors of the option of donation on admission or at the time of death of a potential donor. (D) Use discretion and sensitivity in contacts with potential organ donor families. (E) Notify the appropriate procurement organization of potential organ donors. (F) Establish membership in the organ procurement and transplantation network if the hospital performs transplants.</p> <p>Based on document review and employee interview, the facility failed to notify the appropriate organ procurement organization, per contract, of all hospital deaths.</p>	S0362	<p><b>1. S0362 <u>Action Plan taken to correct deficiency and prevent reoccurrence with dates of completion:</u> A. Monthly hospital donor council meetings with IOPO are already</b></p>	09/20/2012
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	<p>Thus the facility failed to notify procurement organization of all potential organ donors.</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>1. Review of the contract between the hospital and the Indiana Organ Procurement Organization (IOPO) indicated the hospital shall provide "Timely Referral to IOPO as soon as possible of every individual whose death is imminent or who has died in the hospital".</li> <li>2. Review of Donation 2010 Statistics and Benchmarks indicated 21 deaths occurred in September 2010 and only 19 deaths were reported. Donation 2011 Statistics and Benchmarks indicated 20 deaths occurred in August 2011 and only 19 deaths were reported. Thus the hospital failed to show evidence that all deaths are reported.</li> <li>3. Interview with Employee #A17, and review of the IOPO contract documentation on September 18, 2012 at 4pm, verified the information.</li> </ol>		<p><b>in place and currently scheduled for the 1 st Wednesday of each month at 9:30 am CST in the ICU conference room. All members of the donor council are encouraged to attend. Current process in place. B. IOPO to attend unit meetings in the critical care departments (ICU and ED) quarterly to review clinical triggers for organ, tissue and eye donation as well as review any variances. IOPO will also convey outcomes of any donor process that occurred in that quarter. Will begin with next staff meeting – November 6, 2012. Every critical care nurse will be given an organ referral trigger card badge. Current Action. C. IOPO and ICU staff will update the IOPO and Organ Donation information on the bulletin boards, monthly, in the ICU and ED. Current process in place. D. IOPO will attend new nurse orientations, monthly, to discuss referral triggers and the donation program at Franciscan St. Anthony Health – Michigan City. Current process in place. E. All critical care nursing staff will be required to go to IOPO University, only, and complete the required training sessions. IOPO has been added to the agenda on the competency Day</b></p>		

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			<p><b>on November 6, 2012. All education will be completed by December 30, 2012. F. The Health Unit Clerks (HUC's) have been trained to place a call to the Donor Information Line as a backup to the nursing staff when the nursing staff is occupied with critical patient care activities. Current process in place. G. Monthly dashboards sent to donor council members and Quality Services Department. H. Every referral will be reviewed for donation outcome, quarterly, and each variance tracked and reported. Current process in place. <u>Responsible Party:</u> ICU Manager</b></p>		

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S0754	<p>410 IAC 15-1.5-4 MEDICAL RECORD SERVICES 410 IAC 15-1.5-4(f)(5)</p> <p>(f) All inpatient records, except those in subsections (g), shall document and contain, but not be limited to, the following:</p> <p>(5) Evidence of appropriate informed consent for procedures and treatments for which it is required as specified by the informed consent policy developed by the medical staff and governing board, and consistent with federal and state law.</p> <p>Based on policy and procedure review, medical record review, and staff interview, the facility failed to ensure that informed consents for treatment were completed as required per facility policy and procedure for 4 of 4 (N15, N16, N17 and N18) closed patient medical records reviewed.</p> <p>Findings:</p> <p>1. Policy No.: 9500.2025 titled, "Informed Consents, Obtaining, For Operative or Invasive Procedures" was reviewed on 9/19/12 at approximately 11:41 AM, and indicated on pg.: A. 1, under Policy section, point A, "A properly executed informed consent form for operative and invasive procedures must be on the patient's chart prior to the procedure, except in emergencies."</p>	S0754	<p>2. <b><u>S 0754 Action Plan taken to correct deficiency and prevent reoccurrence with dates of completion:</u></b> Medical Records – Informed consents were not completed for treatment: As part of the pre-incision Timeout, staff will verify that the Operative Consent form is completed and authenticated. Effective September 19, 2012. <b>See attachment A.</b> Method to prevent reoccurrence: See above. Also as a compliance check, the Health Unit Clerk will verify that no spaces are left blank on the operative consent prior to sending chart to be scanned, and will notify surgery manager when not completed. Effective September 19, 2012. Monitor: Chart Audit Frequency: 10 records/month Goal: 100% Compliance X 6 months Report: Quarterly - Hospital Quality Council <b>Responsible Party:</b>Woodland</p>	09/20/2012			

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	<p>B. 2, under Procedure section, point E., "Leave no empty spaces on consent form."</p> <p>2. Review of closed patient medical records on 9/19/12 at approximately 9:30 AM, indicated patient:</p> <p>A. N15:</p> <p>a. underwent a cataract removal of left eye on 9/17/12.</p> <p>b. lacked a complete "Authorization for and Consent to Surgical Operations, Diagnostic and Therapeutic Procedures" form dated 9/17/12 by the patient, with the procedure to be performed documented as "Cataract Left Eye", because the line(s) for:</p> <p>i. number 6, "I consent to the disposal by hospital authorities of any tissues or body parts, which may be removed with the exception of" was blank.</p> <p>ii. date, time, and physician signature for the statement "I have personally explained to the patient, or his or her legal representative, the information set forth in the above on..." were blank.</p> <p>B. N16:</p> <p>a. underwent a colonoscopy on 9/17/12.</p> <p>b. lacked a complete "Authorization for and Consent to Surgical Operations, Diagnostic and Therapeutic Procedures" form dated 9/17/12 by the patient, with the procedure to be performed</p>		Surgery Center Director.				

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	<p>documented as "Colon screening, change in bowel habits; colonoscopy", because the line(s) for date, time, and physician signature for the statement "I have personally explained to the patient, or his or her legal representative, the information set forth in the above on..." were blank.</p> <p>C. N17:</p> <p>a. underwent a colonoscopy on 9/17/12.</p> <p>b. lacked a complete "Authorization for and Consent to Surgical Operations, Diagnostic and Therapeutic Procedures" form dated 9/17/12 by the patient, with the procedure to be performed documented as "Colonoscopy", because the line for time for the statement "I have personally explained to the patient, or his or her legal representative, the information set forth in the above on..." was blank.</p> <p>D. N18:</p> <p>a. underwent a colonoscopy on 9/17/12.</p> <p>b. lacked a complete "Authorization for and Consent to Surgical Operations, Diagnostic and Therapeutic Procedures" form dated 9/17/12 by the patient, with the procedure to be performed documented as "Colonoscopy", because the line(s) for date, time, and physician signature for the statement "I have personally explained to the patient, or his</p>						

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	<p>or her legal representative, the information set forth in the above on..." were blank.</p> <p>3. Personnel P32 was interviewed on 9/19/12 at approximately 9:30 AM and confirmed the above-mentioned patient medical records were lacking complete Informed Consents per facility policy and procedure. They had blank lines as described above.</p>			

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S0788	<p>410 IAC 15-1.5-4 MEDICAL RECORD SERVICES 410 IAC 15-1.5-4(i)(9)</p> <p>(i) Emergency service records shall document and contain, but not be limited to, the following:</p> <p>(9) Copy of transfer form, if patient is referred to the inpatient service of another hospital. If care is not furnished to a patient or if the patient is referred elsewhere, the reasons for such action shall be recorded.</p> <p>Based on policy and procedure review, medical record review, and staff interview, the facility failed to ensure a transfer form was completed for 4 of 4 (N11, N12, N13 and N14) patients transferred to another acute care facility.</p> <p>Findings:</p> <p>1. Policy No.: 6100.0045 titled, "Discharge and/or Transfer of a Patient from Hospital" reviewed on 9/19/12 at 11:47 AM, indicated on pg.:</p> <p>A. 1, under Policy section and Purpose/Explanation section, "All patients will leave the hospital system in a standardized manner. To provide a safe, coordinated discharge or transfer process for all patients."</p> <p>B. 2, under Procedure section, point A.17., "If transfer, complete forms..."</p> <p>2. Review of closed patient medical</p>	S0788	<p>3. <b><u>S 0788Action Plan taken to correct deficiency and prevent reoccurrence with dates of completion:</u></b> Every patient that is to be transferred to another facility from the Emergency Department will have a completed transfer record sent with the patient. In order to insure that the transfer record is complete, the Emergency Department Provider assigned to the patient will check the record to insure that all blanks have been completed. The ED Nurse caring for the patient will check the transfer record to insure that it is completed and if not completed, the ED Nurse will ask the physician/nurse practitioner to complete the form prior to transporting the patient. The ED Unit Clerk will review the record before the patient leaves the facility to insure that the record is complete and is sent with the patient. The Emergency Department Medical Director will</p>	10/16/2012			

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	<p>records on 9/17/12 at 3:00 PM, indicated:</p> <p>a. N11 was transferred via ambulance to another acute care facility on 7/23/12 and was lacking a completed Physician Assessment &amp; Certification (PA&amp;C) form and a Patient Transfer Record (PTR). The PA&amp;C was lacking documentation of number 5 "I hereby certify that this ambulance service is medically necessary for the above name patient due to the following:" (was blank) and it was lacking the time of physician authentication. The PTR was lacking the time the patient was "released/transferred from [facility]".</p> <p>b. N12 was transferred via ambulance to another acute care facility on 3/23/12 and was lacking a completed PA&amp;C form and a PTR. The PA&amp;C was lacking documentation of number 1 "Summary of Risks, if any, of Transfer" and it was lacking the date and time of physician authentication. The PTR was lacking documentation of "vital signs at time of transfer".</p> <p>c. N13 was transferred via air to another acute care facility on 3/13/12 and was lacking a completed PA&amp;C form. The PA&amp;C was lacking the date and time of physician authentication.</p> <p>d. N14 was transferred via ambulance to another acute care facility on 4/16/12 and was lacking a completed PA&amp;C form. The PA&amp;C was lacking documentation of</p>		<p>reinforce this process with the Providers and review it with the providers at the next Department of Emergency Medicine meeting on November 29, 2012. The Emergency Department Manager will reinforce this process with the Emergency Department staff and review it at the next Staff meeting October 16, 2012. The effective date of the process is Tuesday, October 16, 2012.</p> <p>Monitor: Chart Audit Frequency: 10 records/month Goal: 100% Compliance X 6 months Report: Quarterly - Hospital Quality Council <b>Responsible Party:</b> Emergency Department Manager</p>				

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	<p>number 1 "Summary of Benefits of Transfer"; number 2 "time" that transferring physician spoke with receiving physician; number 5 "I hereby certify that this ambulance service is medically necessary for the above name patient due to the following:" (was blank); and it was lacking the time of physician authentication.</p> <p>3. Personnel P16 was interviewed on 9/17/12 at approximately 4:00 PM, and confirmed the above-mentioned closed patient medical records lacked a completed transfer form according to facility policy and procedure.</p>			

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S1024	<p>410 IAC 15-1.5-7 PHARMACEUTICAL SERVICES 410 IAC 15-1.5-7 (d)(2)(C)</p> <p>(d) Written policies and procedures shall be developed and implemented that include the following:</p> <p>(2) Ensure the monthly inspection of all areas where drugs and biologicals are stored and which address, but are not limited to, the following:</p> <p>(C) Detection and quarantine of outdated or otherwise unusable drugs and biologicals from general inventory pursuant to their return to the manufacturer, distributor, or destruction.</p> <p>Based on observation, policy and procedure review, and staff interview, the facility failed to ensure detection and quarantine of outdated medications according to facility policy and procedure for 1 of 11 (Off Premises Surgery Center) areas toured.</p> <p>Findings:</p> <p>1. While on tour of facility on 9/19/12 at approximately 9:00 AM, in the company of P16 and P32, the following was observed in the medication fridge:</p> <p>A. one Novolin R vial, lot #AZF0409, opened on 5/16/12, which was greater than 28 days.</p> <p>B. one Lactated Ringers IV (intravenous) Solution, lot #J9H440,</p>	S1024	<p>4. <b><u>S 1024 Action Plan taken to correct deficiency and prevent reoccurrence with dates of completion:</u></b> Detection and Quarantine of Outdated Medications at hospital off-site: The expired medications were removed from the refrigerator on 9/18/12. In addition to monthly outdated medication inspection of all offsite hospital departments which do not have pharmacy staff, a hospital pharmacist will perform a weekly inspection. The attached policy/procedure has been revised to reflect the addition of a weekly inspection of the medication refrigerator for outdated medications. Policy was revised on 10/8/12 and is moving through the approval process. Pharmacy staff education regarding the new procedure was</p>	09/20/2012			

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	<p>expired on 12/2011, which was over 9 months.</p> <p>2. Policy No.: 7300.0135 titled, "Monthly Floor Audits" was reviewed on 9/19/12 at approximately 11:37 AM, and indicated on pg. 1, under Purpose/Explanation section, "To assure all drugs are properly stored, that outdated drugs are not present and proper quantities of floor stock are available."</p> <p>3. Personnel P32 was interviewed on 9/19/12 at approximately 9:20 AM and confirmed the above-mentioned medications were expired and unusable. Facility policy and procedure related to expired/unusable medications was not followed.</p>		<p>completed on 10/2/12 at the Pharmacy Staff meeting. In addition to the monthly and weekly inspection by a hospital staff pharmacist, designated Woodland Surgery Center nursing staff will also inspect the medication refrigerator on a monthly basis for outdated medications. This will be reported to Hospital Quality Council quality. This task has been added to the Woodland Surgery Center monthly log sheet. <b>See Attachment B and C</b></p> <p><b>Responsible Party:</b> Director of Pharmacy</p>		

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S1118	<p>410 IAC 15-1.5-8 PHYSICAL PLANT 410 IAC 15-1.5-8 (b)(2)</p> <p>(b) The condition of the physical plant and the overall hospital environment shall be developed and maintained in such a manner that the safety and well-being of patients are assured as follows:</p> <p>(2) No condition shall be created or maintained which may result in a hazard to patients, public, or employees.</p> <p>Based on observation, policy and procedure review, and staff interview, the chief executive officer failed to ensure no condition was maintained which may result in a hazard to patients, public, or employees in relation to unlocked Soiled Utility Room doors in 2 of 11 (Emergency Department [ED] and Surgical hallway by the Physician's Lounge) areas toured.</p> <p>Findings:</p> <p>1. While on tour of the:</p> <p>A. ED on 9/18/12 at 10:00 AM, accompanied by P16, P26 and P28, it was observed that two Soiled Utility Room doors were unlocked in patient care areas.</p> <p>B. Surgical hallway by the Physician's Lounge on 9/18/12 at 10:55 AM, accompanied by P16, P26 and P29, it was observed that one Soiled Utility Room</p>	S1118	<p><b><u>5. S 1118 Action Plan taken to correct deficiency and prevent reoccurrence with dates of completion: Unlocked Soiled Utility Rooms – Occurrence #1</u></b> Soiled utility room across from treatment room ED6; combination lockset was replaced on 9/19/12. Soiled utility room next to treatment room ED1 was repaired on 9/19/12. <u>Method to prevent reoccurrence:</u> ED and Environmental Service (housekeeping) staff will be made aware in their departmental staff meetings, to submit a Work Order to Maintenance for any lock problems or any other Maintenance issue. A memo was issued to all staff of the Emergency Department, Surgery Department and Environmental Services staff on October 5, 2012 concerning this issue. See attached memo. <u>Responsible Party:</u> The Emergency Department Manager</p>	09/20/2012			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  150015		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED  09/19/2012	
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	<p>door was unlocked in a patient care area.</p> <p>2. Policy No.: 8500.0179WCC, titled "Infectious Waste, Identification, Handling and Disposal of" reviewed on 9/18/12 at approximately 12:52 PM, indicated on pg.:</p> <p>A. 1, under Procedure section, point B.1., "Biohazard Waste is all waste that contains pathogens or biologically active material in sufficient concentrations or quantity such that exposure to the infectious waste could result in disease."</p> <p>B. 2, under Handling of Biohazard Waste section, point C.2., "To minimize the potential risk of accidental transmission of disease or injury, biohazard waste waiting terminal processing should be stored in an area accessible only to personnel involved in the disposal process."</p> <p>3. Personnel P28 and P29 were interviewed on 9/18/12 at approximately 10:06 AM and 11:00 AM, respectively and confirmed the Soiled Utility Room doors were unlocked as indicated above, which could lead to access by unauthorized individuals. These rooms contained biohazard waste and facility policy and procedure was not followed.</p>		<p>has committed to checking soiled utility doors while rounding the Emergency Department. All staff being made aware of the importance of ensuring that these doors are secured so no authorized personnel can gain entry. <b><u>Unlocked Soiled Utility Rooms – Occurrence #2</u></b> Soiled utility room next to Physician Lounge combination lockset was repaired on 9/20/12. <b><u>Method to prevent reoccurrence with dates of completion:</u></b> Environmental Services (housekeeping) staff will be made aware in the departmental meetings to submit a work order to Maintenance for any lock problems or any other Maintenance issues. A memo was issued to all staff of the Emergency Department, Surgery Department and Environmental Services staff on October 5, 2012 concerning this issue. <b><u>See Attachment D Responsible Party:</u></b> The Director of Environmental Services, Surgery Manager and Supervisor will check these doors during their rounding.</p>				

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

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