

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 150012	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 03/01/2012
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NAME OF PROVIDER OR SUPPLIER SAINT JOSEPH REGIONAL MEDICAL CENTER	STREET ADDRESS, CITY, STATE, ZIP CODE 5215 HOLY CROSS PKWY MISHAWAKA, IN 46545
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S0000	<p>This visit was for a standard licensure survey.</p> <p>Facility Number: 005012</p> <p>Survey Date: 2/27, 28, 29 & 3/1/2012</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>Deborah Franco, RN Public Health Nurse Surveyor</p> <p>QA: claughlin 03/13/12</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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S0178	<p>410 IAC 15-1.3-2 POSTING OF LICENSE 410 IAC 15-1.3-2(a)</p> <p>(a)The license shall be conspicuously posted on the hospital premises in an area open to patients and public. A copy shall be conspicuously posted in an area open to patients and public on the premises of each separate hospital building of a multiple hospital building system.</p> <p>Based on observation, the facility failed to post the hospital license in an area conspicuous and open to patients and the public in 3 of 3 instances.</p> <p>Findings:</p> <ol style="list-style-type: none"> On February 29, 2012 at 9:45am, at the Rehabilitation Institute offsite area, and in the presence of Employee #A1, it was observed that the posting of the hospital license was in the Administration Office, area not open to all patients and public. On February 29, 2012 at 10:45am, at the Sleep Lab offsite area, and in the presence of Employee #A1, it was observed that there was no posting of the hospital license. On March 1, 2012 at 10:00am, 	S0178	<p>Response to Findings:</p> <ol style="list-style-type: none"> The hospital license was hanging in the Administrative Office suite just off the front entrance/lobby at the Rehab Institute offsite. While the surveyor was onsite, the license was moved to a glass cabinet in the front lobby next to the entrance at the Rehab Institute. Date Completed: February 29, 2012. There was not a hospital license hanging at the Sleep Lab during the surveyor visit. A copy of the hospital license was made, a frame and security brackets were purchased to hang the license. The license was hung on March 28, 2012. The hospital license was moved to the front lobby by the elevator bank and secured, so it will be in a conspicuous and public area. Date completed: March 15, 2012. During the Environment of Care rounds, the licenses will be noted and presence documented. The EOC rounding tool has been 	03/28/2012			

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	at the main hospital campus/lower level near Administration area, and in the presence of Employee #A1, it was observed that the posting of the hospital license was in the Administration Office, area not open to all patients and public.		updated with a question noting the presence of the hospital license. The Director of Facilities is responsible for the EOC rounding results. The managers responsible for the offsite departments are aware that the hospital license must be posted in a public area within their departments. If either the managers or the Director of Facilities notes that that the license has been removed/ is not present, they will notify the Manager of Accreditation for a replacement. The presence of the hospital licenses in the main lobby and at the off sites will be tracked and reported at the EOC committee and the PI Steering Committee quarterly. Person Responsible: Manager of Accreditation		

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S0408	<p>410 IAC 15-1.4-2 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-1.4-2 (a)(2)(A)(B)(C)(D)</p> <p>(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:</p> <p>(2) All functions, including but not limited to the following:</p> <p>(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).</p> <p>Based on policy and procedure review, document review, and staff interview, the facility failed to ensure that all areas of the hospital participate in an effective, organized, comprehensive quality assessment and performance improvement program for infection control that includes off-site locations under the hospital's license for 2 of 2 (Outpatient Services and Rehabilitation Institute, located on Bodnar Drive and Bodnar Blvd., respectively) departments toured.</p>	S0408	<p>Response to Findings:</p> <p>1. The Rehab Institute located at Bodnar Blvd, is an inpatient unit and has all of their reportables and microbiology reports reviewed by Infection Prevention. This data is included in the quarterly data reported at the IP meetings. The Outpatient Therapy, across the parking lot on Bodnar Drive, has any reportables go through IP for review. All IP policies and procedures are systemwide and cover all SJRMC entities. All data reported at IP committee whether it is the EOC report or system wide data, includes the Rehab</p>	04/12/2012
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	<p>Findings:</p> <p>1. Policy titled, "Infection Control Program" was reviewed on 2/27/12 at 11:00 AM, and indicated on pg. 2, 3, and 5, under Procedure section, point:</p> <p>A. O.(3) Authority, "Reports: Through the Performance Improvement Structure to the Committees of the Medical Staff, and the Medical Center Administration."</p> <p>B. Q.(2) Specific Responsibilities: The Infection Prevention Committee, "Review and make recommendations, when indicated, for all departments' infection prevention policies and procedures."</p> <p>C. R.(11) Specific Responsibilities of Infection Prevention Manager and Coordinator, "Provides Infection Control Committee with written reports, including analysis of Hospital Acquired Infections and summary of surveillance and monitoring activities."</p> <p>D. V.(3)(b) Identification Process of Infections - Patients...Infection Prevention Coordinator, "Generates the appropriate reporting mechanisms to the Infection Control Committee and/or to the chairman of the Infection Control Committee and the local Public Health Department and Environment of Care Committee."</p> <p>2. Infection Prevention Meeting Minutes dated 11/22/11, 1/26/12, and 2/23/12</p>		<p>Institute and outpatient sites as appropriate.. The Rehab Institute has been on the IP committee, the outpatient therapy unit, has a new director who will be attending the April 26, 2012 IP meeting.</p> <p>2.At the April 26, 2012 IP meeting, the 2011 summary report will continue have the inpatient Rehab Institute included and will be broken out from the hospital report per recommendations for HAIs, so that there is a differentiation.</p> <p>3.The IC data collecting and reporting has been ongoing for the Rehab Institute and the outpatient therapy. The IP scorecard is currently reported to the Quality Committee of the Board quarterly and will also be reported to PI Steering Committee quarterly. Person Responsible: IPC</p>		

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	<p>were reviewed on 2/27/12 at 2:47 PM and indicated off-site facilities under the hospital's license were not documented as being reported on.</p> <p>3 . Personnel P3 was interviewed on 2/27/12 at 1:42 PM and confirmed the above-mentioned off-site facilities under the hospital's license were not documented as being reported on during Infection Prevention meetings.</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, document 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 6 of 7 (N3-N5, N10, N13, and N20) closed patient medical records reviewed for patients requiring informed consent for treatment.</p> <p>Findings:</p> <p>1. Policy titled, "Documentation in the Medical Record" was reviewed on 3/1/12 at 11:00 AM, and indicated on pg. 1: A. under Policy section, point 1., "To define requirements for an accurate, legible, and timely medical record in conjunction with the Medical Staff Rules and Regulations and other policies."</p>	S0754	<p>Response to Findings:</p> <p>1.The Consent for Procedure/ Sedation and Other Medical Services was reviewed by the VP of Legal Counsel and a modification to the consent was made regarding the blood transfusion during a procedure/surgery was made to make the consent clearer. The consent now reads: My physician has fully explained to me or my legal representative: the risks, benefits, complications and reasonable alternatives of transfusing blood or blood products. I consent to the transfusion of blood or blood products for the procedure and any post procedure need, up to the time of discharge. The verbiage on the consent is the same as before the modification, just the order of the two statements has been modified and the checkbox box before the</p>	04/12/2012			

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	<p>B. under Contents of the Medical Record section, point g., "Evidence of appropriate informed consent."</p> <p>2. Policy titled, "Informed Consent" was reviewed on 3/1/12 at 11:15 AM, and indicated on pg. 5:</p> <p>A. under Requirements for a Legally Valid Consent Form section, point 2.:</p> <p>a. d., "A legally valid Consent Form must include each of the following...The complete name of the Proposed Treatment to be performed which must also be identically recorded on the Hospital's Operating Room schedule and on the Physician's Order Sheet by the Treating Practitioner responsible for obtaining the Informed Consent, abbreviations shall be avoided..."</p> <p>b. g., "The name(s) of all Treating Practitioners who will be responsible for the performance of the Proposed Treatment..."</p> <p>B. under Medical Record Documentation section, point 1. a., "Documentation of the Informed Consent process shall be included in any of the following...The signed Consent Form, on file in the Patient's medical record..."</p> <p>3. Policy titled, "Blood and Blood Product Administration" was reviewed on 3/1/12 at 11:30 AM, and indicated on pg. 1, under Policy section, point 1.,</p>		<p>"I consent".....has been removed. There is a check box refusing the transfusion of blood/ blood products just below these statements. This covers patients during the procedure as well as post procedure if they need a transfusion as the consent is valid through the hospitalization.</p> <p>2.A Patient Care Alert that will go to all departments that witness the consents. The expectation is that the information will be reviewed in Daily Huddles and at staff meetings. The content of the Patient Care Alert will focus on the completion of the consents and not have missing elements, and no use of abbreviations. The Patient Care Alert was approved on March 27, 2012 and will go to the managers for use in daily Huddles and staff meetings in April.</p> <p>3.The annual I-Learn on Informed Consent has been reviewed and updated. The I-Learn will be assigned after the update is loaded into the software and assigned to the staff responsible for completing the consent forms, on or before April 9 th .</p> <p>4.HIM is auditing 50 charts each month for consent compliance. The results of the monthly audits will be reported to PI Leadership.</p> <p>5.Compliance Goal: 90% Person Responsible: CNO</p>				

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	<p>"Informed consent is required for blood and blood product administration and must be signed prior to administration..."</p> <p>4. Review of Medical Staff Rules and Regulations of [facility] on 3/1/12 at 11:45 AM indicated, on pg.:</p> <p>A. 10, under Section 2. Authentication, point b., "All entries in the medical record shall be dated, timed and authenticated by the person making the entry."</p> <p>B. 11, under Section 3. Contents, point 6., "evidence of informed consent when required by hospital policy."</p> <p>5. Review of closed patient medical records on 3/1/12 at 9:30 AM, indicated patient:</p> <p>A. N3:</p> <p>a. underwent a PICC (Peripherally Inserted Central Catheter) insertion per PICC Procedure Flow Sheet dated 3/18/11.</p> <p>b. lacked a complete "Consent for Procedure/Sedation and Other Medical Services" form dated 3/18/11 by the patient, with the procedure to be performed documented as Peripherally Inserted Central Catheter, because it was missing the physician name performing the procedure in the statement, "I hereby authorize Doctor (blank line for physician name) his/her associates and such assistants as may be selected by him/her</p>			
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	<p>to perform upon [patient N5] the following procedure..."; and physician authentication with date and time.</p> <p>B. N4:</p> <p>a. underwent a left heart catheterization; coronary angiography; angiogram of the internal mammary graft to the LAD (Left Anterior Descending); angiogram of the vein graft to the ramus intermedius; and selective bilateral renal arteriography on 5/24/11 per Operative Report.</p> <p>b. had an abbreviation of PTA in the proposed procedure description on the "Consent for Procedure and Other Medical Services in Cardiac Cath Lab" dated 5/24/11.</p> <p>C. N5:</p> <p>a. underwent an exploratory laparotomy with right hemicolectomy and side-to-side, functional end-to-end stapled ileocolostomy on 9/7/11 per Operative Report.</p> <p>b. lacked a complete "Consent for Procedure/Sedation and Other Medical Services" form dated 9/7/11, because it was missing the physician name performing the procedure in the statement, "I hereby authorize Doctor (blank line for physician name) his/her associates and such assistants as may be selected by him/her to perform upon [patient N5] the following procedure..."</p> <p>c. underwent an IVC (Inferior Vena</p>			

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	<p>Cava) filter placement on 9/7/11 per Progress Notes.</p> <p>d. had abbreviations of IVC and IV in the proposed procedure description on the "Consent for Procedure/Sedation and Other Medical Services" dated 9/7/11.</p> <p>D. N10:</p> <p>a. underwent a left heart catheterization with coronary angiography; left ventriculography; and insertion of a sheath in the right femoral vein and insertion of intra-aortic balloon pump on 2/8/12 per Operative Report.</p> <p>b. lacked a complete "Consent for Procedure/Sedation and Other Medical Services in Cardiac Cath Lab" form dated 2/8/12 by the patient, with the procedure to be performed documented as left heart catheterization with coronary angiogram, left ventriculography...possible stent placement, possible intra-aortic balloon placement..., because it was missing the time of physician authentication.</p> <p>E. N13:</p> <p>a. underwent an esophagogastroduodenoscopy on 11/10/11 per Operative Report.</p> <p>b. lacked a complete "Consent for Procedure/Sedation and Other Medical Services" form dated 11/10/11 by the patient, with the procedure to be performed documented as esophagogastroduodenoscopy, because it was missing physician authentication with</p>						

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	<p>date and time for the Physician Certification section.</p> <p>F. N20:</p> <p>a. received 4 units of fresh frozen plasma, 1 unit at a time, per physician order on 2/28/12 at 8:29 am, 8:36 am, 9:15 am, and 9:19 am per Transfusion Records.</p> <p>b. lacked a Consent for Blood and Blood Product Administration form.</p> <p>6. Personnel P2 was interviewed on 3/1/12 at 11:30 AM and confirmed the above-mentioned patient medical records were lacking complete Informed Consents per facility policy and procedure. They were lacking: name of physician performing the procedure; physician authentication with date and time; consent for blood products; and/or had abbreviations for the proposed procedure.</p> <p>7. Personnel P37 was interviewed on 2/28/12 at 1:30 PM and confirmed an informed consent had not been signed prior to the administration/transfusion of blood products for fresh frozen plasma. Patient N20 did receive 4 units per physician orders as described above. Facility policy and procedure requires that consent be obtained in this instance and that it was not emergent circumstances. Administration/Transfusion without signed consent violated facility policy.</p>			

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S0952	<p>410 IAC 15-1.5-6 NURSING SERVICE 410 IAC 15-1.5-6(d)</p> <p>(d) Blood transfusions and intravenous medications shall be administered in accordance with state law and approved medical staff policies and procedures. If the blood transfusions and intravenous medications are administered by personnel other than physicians, the personnel shall have special training for these procedures in accordance with subsection (b)(6).</p> <p>Based on review of "Blood and Blood Product Administration" policy and procedure, patient blood administration records, and staff interview, blood transfusions failed to be administered in accordance with approved medical staff policies and procedures for 3 of 10 patient records reviewed.</p> <p>Findings included:</p> <ol style="list-style-type: none"> On 2-28-12 between 11:35 AM and 1:00 PM, review of "Blood and Blood Product Administration" policy / procedure, approved on "11/11/2011" read: "Vital signs (TPR & BP) are to be taken and recorded...15 minutes after start of each unit...." Review of patient blood administration records on 2-28-12 between 11:35 AM and 1:00 AM and between 2:00 PM and 	S0952	<p>Response to Findings:</p> <ol style="list-style-type: none"> The Blood and Blood Product Administration Policy that was in draft was reviewed by the ISDH surveyor during survey. The policy has been reviewed and updated and will be taken to the next Provision of Care Meeting on April 4 for approval. The staff that perform transfusions will be re-educated on the 15 minute vital signs to be completed after the transfusion has been initiated by a Patient Care Alert that will be covered in Daily Huddles and staff meetings The Patient Care Alert was approved on March 27, 2012 and will go to the managers for use in daily Huddles and staff meetings in April. The annual Blood Transfusion and Blood Reaction I-Learn was reviewed and focus was placed on the 15 minute VS and blood reactions. The I-Learn will be assigned after the update is loaded into the software and 	04/12/2012			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 150012	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 03/01/2012
NAME OF PROVIDER OR SUPPLIER SAINT JOSEPH REGIONAL MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 5215 HOLY CROSS PKWY MISHAWAKA, IN 46545		
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	<p>4:00 PM revealed the following:</p> <p>a. Patient #L1 had a blood transfusion initiated on 2-27-12 at "22:55". The fifteen minute vital signs were taken at "2304", nine minutes after the transfusion had been initiated.</p> <p>b. Patient #L2 had a blood transfusion initiated on 2-27-12 at "12:09". The fifteen minute vital signs were taken at "13:00", fifty-one minutes after the transfusion had been initiated.</p> <p>c. Patient #L10 had a blood transfusion initiate on 2-27-12 at "0938". The fifteen minute vital signs were taken at "10:02", twenty-four minutes after the transfusion had been initiated.</p> <p>3. In interview on 2-28-12 between 2:00 PM and 4:00 PM, Staff Member #L12 acknowledged the above findings.</p>		<p>assigned to the staff responsible for transfusing blood, on or before April 9 th .</p> <p>4.The compliance of the 15 minute vital signs completion will be audited monthly. The results of the audits will be reported to Provision of Care Committee.</p> <p>5.Compliance Goal: 90%. Person responsible: CNO</p>		