

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  150090	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED  03/15/2012
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NAME OF PROVIDER OR SUPPLIER  FRANCISCAN ST MARGARET HEALTH - DYER	STREET ADDRESS, CITY, STATE, ZIP CODE 24 JOLIET ST DYER, IN 46311
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S0000	<p>This visit was for a standard licensure survey.</p> <p>Facility Number: 005080</p> <p>Survey Date: 3/12, 13, 14 &amp; 15/2012</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: cloughlin 03/26/12</p>	S0000	<p>A000The filing of this Plan of Correction does not constitute an admission that the alleged violation of Indiana Statutes or Regulations, as referenced in the Department's letter of April 3, 2012 conveying the state licensure survey reoprtd dated March 15, 2012 did in fact exist. Rather, this Plan of Correction is filed as evidence of the Hopsital's desire to comply with the applicable statutes and reuglations, the survey process and reporting procedures as well as to continue to provide quality of care in the delivery of its service. We intend for the Plan of Correction to serve as our Credible Allegation of Compliance.</p>	
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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Any defenciystatement ending with an asterisk (\*) denotes a defidency which the institution may be excused from correcting providing it is determined that other safegaurds 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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S0332	<p>410 IAC 15-1.4-1 GOVERNING BOARD 410 IAC 15-1.4-1(c)(6)(L)</p> <p>(c) The governing board is responsible for managing the hospital. The governing board shall do the following: (6) Require that the chief executive officer develops policies and programs for the following:</p> <p>(L) Demonstrating and documenting personnel competency in fulfilling assigned responsibilities and verifying inservicing in special procedures.</p> <p>Based on document review and staff interview, the facility failed to notify the appropriate organ procurement organization, per contract, of all hospital deaths. Thus the facility failed to notify procurement organization of potential organ donors.</p> <p>Findings:</p> <p>1. On March 13, 2012 at 1:00pm, review of the contract between the hospital and the Gift of Hope Organ &amp; Tissue Donor Network indicated the hospital shall "Provide Gift of Hope...with a Timely Notification for Tissue Donation or Timely Notification for Organ Donation, as applicable, of all individuals who have died or whose death is Imminent".</p>	S0332	<p>S0332 The facility, Franciscan Saint Margaret Health-Dyer failed to notify the appropriate organ procurement organization, per contract, of all hospital deaths. Thus, Franciscan Saint Margaret Health-Dyer failed to notify procurement organization of potential organ donors.1.0 PLAN- to notify organ procurement organization of all deaths. 1.1 Amended policy #299.01 "Organ/Tissue Donation" which includes requirement to notify Gift of Hope of all cardiac deaths as soon as possible. (see attached) 1.2 The nurse or Hospital Designated Requestor initiates the "Organ, Tissue and Eye Referral Tracking" form. (see attached) 1.2.1 Form amended to include checkbox: _____ Call Gift of Hope with time of death. 1.3 A new form was developed, "Expiration Checklist"</p>	04/15/2012			

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	<p>2. On March 13, 2012 at 1:00pm, review of the documentation presented failed to show all deaths were reported. Donation Activity Report for the 4th Quarter 2011, giving also a Year End Summary, indicated 15 deaths occurred in April 2011 and only 14 deaths were reported. Further the report indicated 18 deaths occurred in September 2011 and only 17 deaths were reported. Thus the hospital failed to show evidence that all deaths are reported.</p> <p>3. Interview with Employee #A8 on March 13, 2012 at 1:30pm, at which time review of the Gift of Hope contract documentation and the Year End 2011 data verified the information.</p>		<p>(see attached) which is completed by the Admitting Department. The Admitting Department will ask Nursing if Gift of Hope was called (Line 16), by whom and if patient is an Organ / Tissue / Eye donor.-- -Policy amended and approved - April 2012---Forms amended/developed/approved - April 2012Approvals: Organ Tissue Donation Committee April 20122.0 EDUCATIONPolicy and Forms will be in-serviced at unit and departments meetings in April 2012 by Clinical Directors and Nursing Managers along with Admitting Department Managers.3.0 MONITORING Every death will be monitored for the appropriate call to Gift of Hope by Nursing Unit with the attached "Real-Time QA Monitoring Tool for Organ and Tissue Donation for 90 days (see Attached) May 1 to July 31, by Nursing Managers, Access Coordinator and Nursing Service Directors.4.0 QA Report will be completed and summarized by Senior Director of Patient Servies and reported at the monthly Quality Meetings as part of the Housewide Quality Committee, June, July and August of 2012.</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 2 of 2 patients having an incomplete informed consent (N4 and N6) and dictation of an operative report immediately after surgery for 1 of 8 patients undergoing a surgical procedure (N6) in closed patient medical records reviewed.</p> <p>Findings:</p> <p>1. Policy titled, "Informed Consents" was reviewed on 3/15/12 at approximately 9:07 AM, and indicated on pg.:</p> <p>A. 1, under Statements of Policy section, point 2.4, "It is the physician's responsibility prior to a procedure and</p>	S0754	<p><b>S 754CONSENTS</b> Correction of the deficiency will be accomplished via contact by the Vice President Medical Affairs with each performing surgeon to advise of the deficiency, and to direct for completion of the required consent authentications by April 15, 2012Systemic action to identify, correct and prevent recurrence of the deficient process will be accomplished by: Implementation of a revised preoperative checklist, including verification of consent prior to procedure (completed 4/4/12);</p> <ul style="list-style-type: none"> <li>·Reorientation of procedural support staff to standard procedure prohibiting patient transfer from Holding Area without authentication of all consents by 4/15/12</li> <li>·Reorientation of the Medical Staff, via an educational packet</li> </ul>	04/14/2012			

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	<p>before obtaining written consent to explain any proposed treatment or procedure to the patient, and, when appropriate, the family..."</p> <p>B. 3, under Surgical Treatment/Special Procedures and Anesthesia Consents section, points 4.2 and 4.2.1, "The physician performing the surgery or procedure is responsible for discussing with the patient the risks, benefits, potential complications and alternatives of the contemplated surgery/procedure, and obtaining the patient's informed consent.. The physician is responsible for documenting these discussions and the patient's informed consent in the patient's medical record..."</p> <p>2. Policy titled, "Non-Electronic Medical Record Documentation" was reviewed on 3/15/12 at approximately 9:17 AM, and indicated on pg.:</p> <p>A. 1, under:</p> <p>a. Purpose section, points 1.0 and 1.3, "The purposes of the medical record are to...Document communication between the practitioner responsible for the patient and any other health care professional contributing to the patient's care."</p> <p>b. Statement of Policy section, point 2.0, "All entries are authenticated with a signature or initials and time/shift of entry by the nurse/designee utilizing military time."</p>		<p>from the Medical Staff Office disseminated by June 2, 2012, to the processes of consent authentication, so as to include</p> <ul style="list-style-type: none"> <li>·explanation of the deficiency issue and</li> <li>·copy of the revised pre-op checklist</li> </ul> <p>Monitoring against recurrence of the deficient practice will be accomplished via concurrent audit by procedural staff of 20 surgical/procedural records per week beginning week of April 15, 2012 for authentication of consents prior to procedure with results reported to Quality Services for monthly presentation to Department of Surgery and Quality Council. <b>IMMEDIATE POST OPERATIVE REPORT</b></p> <p>Correction of the deficiency for each cited client will be accomplished via contact by the Vice President Medical Affairs with the performing surgeon to advise of the deficiency, direct for correction, and reinforce Medical Staff requirement for immediate postoperative documentation by April 13, 2012 (completed).Systemic action to identify, correct and prevent recurrence of the deficient process will be accomplished by:</p> <ul style="list-style-type: none"> <li>·Placement of post-op note templates in the ICU to facilitate their use in open heart cases (which are recovered in ICU in lieu of Post Anesthesia Care Unit) by April 15</li> <li>·Establish immediate deficiency</li> </ul>		

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	<p>B. 2, under Statement of Policy section, point 3.1.1, "Blank spaces, boxes or lines indicate the assessment, intervention, evaluation or treatment did not occur."</p> <p>3. Review of Medical Staff Rules and Regulations on 3/15/12 at approximately 9:30 AM, indicated on pg. 10, under Section IV Medical Records, point C., "A complete operative report shall be dictated or written in the medical record immediately after each surgical case..."</p> <p>4. Review of closed patient medical records on 3/13/12 at approximately 2:45 PM, indicated patient:</p> <p>A. N4:</p> <p>a. underwent a "triple lumen central venous catheter insertion and removal of a tunneled central venous catheter" per Cardiology Operative Report dictated 2/17/12.</p> <p>b. lacked a complete "Authorization for and Consent to Surgical Operations, Diagnostic and Therapeutic Procedures" form dated 2/17/12 by the patient, with the procedure to be performed documented as "Removing tunneled central line and placement of triple lumen catheter", because the lines for date 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</p>		<p>notice in OneChart/Epic EMR for omission of post-op note during implementation in June, 2012 Monitoring against recurrence of the deficient practice will be accomplished via concurrent audit by procedural staff of 20 surgical records per week beginning week of April 15, 2012 for presence of post op notes per template vs. notation of completed dictation, with results reported to Quality Services for monthly presentation to Department of Surgery and Quality Council.</p>				

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	<p>2/17/12" were blank.</p> <p>B. N6:</p> <p>a. underwent a "coronary artery bypass grafting x4; left internal mammary to the left anterior descending, saphenous vein graft aorta to diagonal, saphenous vein graft aorta to obtuse marginal left ventricular branch; placement of right heart catheter; and placement of radial arterial line" on 2/24/12 per Operative Report dictated 3/11/12.</p> <p>b. Operative Report was dictated 23 days after the procedure was performed.</p> <p>c. lacked a complete "Surgical Treatment/Anesthesia Consent for CABG (Coronary Artery Bypass Graft)" form dated 2/24/12 by the patient, with the procedure to be performed documented as "Coronary Artery Bypass Graft", because the lines 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 above on" were blank.</p> <p>d. underwent a "Percutaneous endoscopic gastrostomy" per Operative Report dictated 3/7/12.</p> <p>e. lacked a complete "Authorization for and Consent to Surgical Operations, Diagnostic and Therapeutic Procedures" form dated 3/6/12 by the patient, with the procedure to be performed documented as "Percutaneous endoscopic gastrostomy</p>			

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	<p>insertion", because the lines for 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 3/7/12" were blank.</p> <p>5. Personnel P17 was interviewed on 3/15/12 at approximately 9:10 AM and confirmed the above-mentioned patient medical records were lacking complete Informed Consents per facility policy and procedure. They had blank lines where the date, time, and/or physician signature were to be documented as described above. Also, patient N6 lacked a dictated operative report immediately following their surgical case on 2/24/12 as required per Medical Staff Rules and Regulations.</p>			

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S1022	<p>410 IAC 15-1.5-7 PHARMACEUTICAL SERVICES 410 IAC 15-1.5-7 (d)(2)(B)</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>(B) Appropriate storage conditions.</p> <p>Based on observation, policy and procedure review, and staff interview, the facility failed to ensure appropriate storage conditions for high alert medications according to facility policy and procedure for 1 of 10 (Operating Room Medication Room) areas toured.</p> <p>Findings:</p> <p>1. While on tour of facility on 3/14/12 at approximately 3:15 PM, in the company of P15 and P16, the following was observed in the medication fridge:</p> <p>A. one Succinylcholine 200 mg vial, lot #95-311-EV, expired on 2/1/12 was located in the wrong bin. It was in bin #7 with Pontocaine 1% ampules for injection.</p> <p>B. two Atracurium 100 mg vials, lot #196083.</p> <p>C. two Rocuronium 10 mg vials, lot</p>	S1022	<p>S1022 Failure to ensure appropriate storage conditions for high alert medications according to facility policy &amp; procedure. The old process was to use individual containers with high alert stickers to each vial of high alert drugs (e.g. paralytics). This process was dependent on nurses returning the containers to pharmacy upon use and pharmacy recycling the containers to replenish stock. Upon investigation, the nurses did not know the containers were supposed to be returned to pharmacy so it was disposed. Over time, the individual containers were not returned to pharmacy, leading to insufficient number of containers to replenish high alert drug storage. On April 2, 2012, we adopted a new process to increase compliance of storage and labeling of high alert drug (e.g. paralytics). We have replaced individual containers to hinged with a lid,</p>	04/02/2012			

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	<p>#RB5074.</p> <p>D. the above-mentioned medications lacked a blue sticker designating them as high alert medications.</p> <p>2. Policy titled, "High Risk Medications" was reviewed on 3/15/12 at approximately 9:22 AM, and indicated on pg.:</p> <p>A. 1, under Procedure section, points 1.3 and 1.6, "High risk medications will have mechanisms in place to minimize the risk of patient harm. These actions may include, but are limited to...special packaging and/or labeling...The list is shown in Attachment A..."</p> <p>B. 2, Attachment A High Risk Medications, "Neuromuscular Blocking Agents (NMB), 'Location in the Hospital' in Pharmacy and ER (Emergency Room), NMB's in ER are sequestered in a 'lock box' in the refrigerator that is clearly marked. All NMB's prepared in Pharmacy are placed in a brown plastic overwrap sleeve with a blue warning sticker 'Do not infuse as an IVPB (intravenous piggy back)'. All NMB's are physically separated from other medications in Pharmacy. Available outside the Pharmacy in ICU (Intensive Care Unit), ER, and OR (Operating Room)."</p> <p>3. Policy titled, "Disposal of Unusable Medications and Devices" was reviewed</p>		<p>high alert bins. Each vial of paralytic will be stocked in a zip lock bag with "warning" and "paralytic" stickers. The paralytics drugs in the zip lock bag will then be stored inside the enclosed bin that will have stickers with "Warning, Paralytics" on the bin. This high alert storage bins will be easily differentiated from regular storage bins in all patient care areas where we stock paralytic agents. Policy 7300-119, labeling and storage of high alert medications have been revised to reflect above changes. Policy 7300-603, attachment A (location of neuromuscular blocking agents in the hospital) have been updated to reflect all the storage locations so the information is consistent and identical. Staff education on importance of following high alert medications policy and procedure have been provided On March 15, 2012, the pharmacy management and staff reviewed storage of all high alert medications throughout the hospital. We took proper measures to label and store the high alert medications appropriately per policy when deficiency was identified. Pharmacy leadership or designee will audit the revised process quarterly to measure compliance on proper labeling and storage of high alert medications as our quality assurance metrics. Quarterly audit will be tracked by</p>		

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	<p>on 3/15/12 at approximately 9:22 AM, and indicated on pg. 1, under Statement section, points 1.0, 1.1, 2.0, and 2.1, "Unusable medications and devices shall be handled and disposed of in accordance with this policy...Unusable medications and devices include those that are...Mislabeled (improper, illegible, missing, or worn)...Unusable medications and devices shall not be distributed or administered. Pharmacy, Nursing, and other personnel who discover unusable medications and devices shall return them to the Pharmacy for proper disposition."</p> <p>4. Personnel P13 was interviewed on 3/14/12 at approximately 3:30 PM and confirmed Succinylcholine, Atracurium, and Rocuronium are neuromuscular blocking agents and are considered high risk/alert medications. Protocol is to designate all high alert medications by either putting a blue sticker on a bag that states "warning paralytic agent" and placing the medication in the bag or placing the medication in a clear, square container and placing the same blue sticker on it. Facility policy and procedure related to high risk/alert medications was not followed. Also, there is a typo on Attachment A of the High Risk Medications policy in the "Location in the Hospital" section. It reads Pharmacy and ER, but should include OR as well.</p>		using pharmacy monthly dashboard tracker program.				

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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 10 (Operating Room Medication Room) areas toured.</p> <p>Findings:</p> <p>1. While on tour of facility on 3/14/12 at approximately 3:15 PM, in the company of P15 and P16, the following was observed in the medication fridge:</p> <p>A. three Succinylcholine 200 mg vials, lot #95-311-EV, expired on 2/1/12.</p> <p>B. one Pontocaine 1% for injection vial, lot #63575DD, expired on 3/1/12.</p>	S1024	<p><b>S 1024: Failure to ensure detection and quarantine of outdated medications according to facility policy and procedure</b> On March 16, 2012, a report was generated to identify all outdated drugs within the automated medication dispensing area. The pharmacy management and staff audited drugs stored in patient care areas and removed any outdated drugs. The old process had one staff member audit the entire facility for outdated drugs. We adopted the new process was implemented on March 19, 2012 where multiple team members are now assigned to audit assigned areas. A checklist was created to standardize the audit process. Staff education was provided to auditing personnel on</p>	03/16/2012	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  150090		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED  03/15/2012	
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	<p>2. Policy titled, "Disposal of Unusable Medications and Devices" was reviewed on 3/15/12 at approximately 9:22 AM, and indicated on pg. 1, under Statement section, points 1.0, 1.1, 2.0, and 2.1, "Unusable medications and devices shall be handled and disposed of in accordance with this policy...Unusable medications and devices include those that are...expired (outdated)...Unusable medications and devices shall not be distributed or administered. Pharmacy, Nursing, and other personnel who discover unusable medications and devices shall return them to the Pharmacy for proper disposition."</p> <p>3. Personnel P13 was interviewed on 3/14/12 at approximately 3:30 PM and confirmed the above-mentioned medications were expired and unusable. Facility policy and procedure related to expired/unusable medications was not followed.</p>		<p>outdating process and hospital policy. On March 16, 2012, we changed policy 7300-429 and revised monitoring of expired medication by the pharmacy staff. The following week, we educated staff on new procedure of timely monitoring of expired medications. The education will be on-going for pharmacy and nursing. A monthly report will be generated through automated medication dispensing system and bar-code drug scanning software to monitor expiration date. The report will be used in expiration date surveillance program. Pharmacy leadership or designee will audit the revised process quarterly to measure compliance on proper disposal of expired medications. Pharmacy staff failing to follow the hospital policy shall receive appropriate counseling and corrective action if appropriate. The audits will be tracked by using pharmacy monthly dashboard tracker program.</p>				