

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING	X3) DATE SURVEY COMPLETED 06/26/2014
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NAME OF PROVIDER OR SUPPLIER  TERRE HAUTE HEART CENTER OUTPATIENT CATH LAB	STREET ADDRESS, CITY, STATE, ZIP CODE 455 E HOSPITAL LN TERRE HAUTE, IN 47802
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S000000	This visit was for a standard licensure survey.  Facility Number: 009610  Survey Date: 6/24/14 to 6/26/14  Surveyor: Trisha Goodwin, RN BSE Public Health Nurse Surveyor  QA: cloughlin 07/08/14	S000000		
S000110	410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (a)(5)  The governing body shall do the following:  (5) Review, at least quarterly, reports of management operations, including, but not limited to, quality assessment and improvement program, patient services provided, results attained, recommendations made, actions taken, and follow-up. Based on document review and interview, the governing board failed to	S000110	Nursing, Radiology, Discharge, Medication errors, Response to patient errors, reportable events along with transcription and	07/14/2014

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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S000320	<p>review quality activities for six directly-provided services/activities (nursing, radiology, discharge, medication errors, response to patient errors, and reportable events) and two contracted services (transcription and patient transfer) in calendar year 2013.</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>1. Review of governing board minutes for calendar year 2013 indicated there were no reports of quality activities reviewed by the governing board for the directly-provided services of nursing, radiology, discharge, medication errors, response to patient errors, and reportable events.</li> <li>2. Review of the governing board minutes for calendar year 2013 indicated there were no reports of quality activities reviewed by the governing board for the contracted services of transcription and patient transfer.</li> <li>3. In interview on 6/24/14 at 3:30 pm, employee #A1 confirmed the above and no further documentation was provided prior to exit.</li> </ol>		<p>patient transfer have been added to the QA documentation list to be reviewed by the governing board on a quarterly bases and also have been specifically added to the QA policy as reviewable QA. It is the responsibility of the Cath lab director to see that the above is documented and presented to the Board.</p>				

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	<p><b>QUALITY ASSESSMENT AND IMPROVEMENT</b> 410 IAC 15-2.4-2(a)(2)</p> <p>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 and transfer. (B) Infection control. (C) Medication errors. (D) Response to patient emergencies.</p> <p>Based on document review and interview, the center failed to include all functions in its quality assessment and performance improvement (QAPI) program (activities of nursing, internal radiology, transcription, discharge, transfer, medication errors, response to patient emergencies or reportable events). Findings:</p> <p>1. Review of the facility's QAPI program indicated it did not include the activities of nursing, internal radiology, transcription, discharge, transfer, medication errors, response to patient emergencies or reportable events.</p> <p>2. In interview, on 6/24/14 at 3:30pm, employee A1 confirmed the above. No further documentation was provided prior</p>	S000320	<p>A written plan of QAPI has been added to the QA poilicy for Nursing, internal radiology, transcription, discharge, transfer, medication errors, response to patient emergencies and reportable events. The policy has been written and presented to the Board of Directors and approved. The policy will be followed and it is the responsibliy of the Cath Lab director to see the plan is followed and presented to the Board of Directors on a quarterly bases.</p>	07/14/2014

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S000408	<p>to exit.</p> <p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(d)</p> <p>(d) The center shall designate a person qualified by training or experience as responsible for the ongoing infection control activities and the development and implementation of policies governing control of infections and communicable diseases. Based on document review and interview, the center failed to ensure a person designated as infection control officer who was qualified by training or experience.</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>Review of the personnel file for A1, identified as the infection control officer, failed to include documentation of specialized infection control training or experience.</li> <li>In interview on 6/26/14 at 1:15pm, A1 confirmed having no specialized infection control training or experience.</li> </ol>	S000408	The Cath Lab director has been signed up for an online infection control class to be certified as an infection control officer. This will be completed by 09/01/2014.	07/21/2014

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S000624	<p>410 IAC 15-2.5-3 MEDICAL RECORDS, STORAGE, AND ADMIN. 410 IAC 15-2.5-3(c)(7)</p> <p>An adequate medical record must be maintained with documentation of service rendered for each patient of the center as follows:</p> <p>(7) The center shall ensure the confidentiality of patient records. The center must develop, implement, and maintain the following:</p> <p>(A) A procedure for releasing information or copies of records only to authorized individuals, in accordance with federal and state laws.</p> <p>(B) A procedure that ensures that unauthorized individuals cannot gain access to patient records.</p> <p>Based on document review and interview, it could not be determined that the center implemented a procedure for ensuring against unauthorized access to patient electronic records in any instance.</p> <p>Findings:</p> <p>1. Review of 1 of 1 medical staff (MS) credential files indicated no provision for protection of computer password for medical record entry by MD#1.</p>	S000624	A policy has been written, presented and approved by the Board of Directors for the unauthorized access to patient electronic records. A statement has been added to the reappointment application requiring the physician to attest that he will not give his password to anyone. A Policy has been written and approved by the Board of Directors for releasing information or copies of records to authorized individuals, in accordance to federal and state	06/27/2014

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S000900	<p>2. In interview on 6/26/14 at 1:00pm employee #A1 confirmed the above and provided no further documentation prior to exit.</p> <p>410 IAC 15-2.5-5 PATIENT CARE SERVICES 410 IAC 15-2.5-5(a)</p> <p>(a) All patient care services must meet the needs of the patient, within the scope of the service offered, in accordance with acceptable standards of practice. Patient care services must be under the direction of a qualified person or persons. Patient care services must require the following: Based on document review, observation and interview, the facility failed to provide patient care services to meet the need of the patient in accordance with their policy and procedure (P&amp;P) in 10 (1A, 11A, 12A, 14A, 17A, 19A,22A, 25A, and 28A) of 10 instances. Findings: 1. Review of policy 5.09 titled CARE OF DIABETIC PATIENT, reviewed 07/06, indicated in paragraph 3. Once the patient returns from the Cath Lab,</p>	S000900	<p>laws. This is the responsibility of the director of cath lab to monitor and enforce this policy.</p> <p>A review of the Policy 5.09 was done with the staff and physician. A space has been added to the post cath recovery document for documentation of post cath blood sugar. This is the responsibility of the staff nurse to complete the Accucheck. This has also been added to the QA program for monitoring. This will be carried out quarterly and by the cath lab director and reported to the Board of Directors.</p>	06/27/2014

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S001000	<p>monitor patient for signs of hypoglycemia. Obtain a set of vital signs. If the patient is an insulin-dependent diabetic, perform an accucheck to check their blood sugar.</p> <p>2. Review of 30 closed medical records (MR) on 6/24/14 and 6/25/14 indicated nine (9) diabetic patients (11A, 12A, 14A, 17A, 19A,22A, 25A, and 28A) to have procedures at the center without having blood glucose level checked prior to, during or after procedures.</p> <p>3. On 6/25/14 beginning at 11:30am, in observation of patient 1A, glucose checks were not observed.</p> <p>4. Review of MR for patient 1A did not include evidence of glucose monitoring.</p> <p>5. In interview on 6/25/14 at 4:00pm, employee A1 confirmed blood sugar checks not being done per policy and no further documentation was provided prior to exit.</p> <p>410 IAC 15-2.5-6 PHARMACEUTICAL SERVICES</p>						

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410	<p>IAC 15-2.5-6</p> <p>The center shall provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice, and under the direction of an individual designated responsible for pharmaceutical services. Pharmaceutical services must have the following: Based on observation, document review and interview, the center failed to maintain pharmaceuticals in a safe and effective manner in one (1) instance.</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>During tour of the facility on 6/26/14 beginning at 9:30am, in the presence of A1, it was observed in the clean utility room inside an unlocked cabinet, 10 bottles of 25mg 250ml Nitroglycerin in 5% Dextrose Injection (100 mcg/ml) Exp. May 12.</li> <li>In interview on 6/26/14 at 9:40am, employee A1 confirmed improper storage of the above mentioned Nitroglycerin. Policy for storage of outdated medications was requested at that time.</li> <li>Review of Policy 8.01 titled PHARMACEUTICAL SERVICES, reviewed 07/06, under section titled Pharmacy Storage Cabinet, it is indicated that: Drugs shall be stored in the</li> </ol>	S001000	Policy 8.01 was reviewed with the staff. All medications including those that have expired and waiting for disposal have been placed in a locked cabinet. This will be monitored by the cath lab supervisor. It has been brought to the attention of the Pharmacy consultant and he will monitor during his quarterly inspections.	06/26/2014

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S001010	<p>pharmacy storage cabinet... No further documentation was provided prior to exit.</p> <p>410 IAC 15-2.5-6 PHARMACEUTICAL SERVICES 410 IAC 15-2.5-6(3)(A)</p> <p>Pharmaceutical services must have the following:</p> <p>(3) Written policies and procedures developed, implemented, maintained, and made available to personnel, including, but not limited to, the following:</p> <p>(A) Drug handling, storing, labeling, and dispensing.</p> <p>Based on observation, interview and document review, the center failed to implement policy and procedure (P&amp;P) for drug labeling in one (1) instance.</p> <p>Findings:</p> <p>1. During tour of the facility on 6/26/14 beginning at 9:30am, in the presence of A1 in the procedure room narcotic cabinet, one (1) opened medication vial Midazolam 50mg/10ml (5mg/ml) was</p>	S001010	The policy 8.01 was reviewed with the staff and labels are being kept as per policy on all opened vials. This will be monitored by the cath lab director and the pharmacy consultant. It is now placed on the QA list to be monitored quarterly.	06/26/2014

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S001152	<p>noted without an adjunct label. P&amp;P for labeling multi-dose vials after opening was requested of A1 at that time.</p> <p>2. In interview on 6/26/14 at 10:00am, employee A1 confirmed center P&amp;P requires labeling of opened medication vials.</p> <p>3. Review of Policy No. 8.01 titled PHARMACEUTICAL SERVICES, reviewed 07/06, in the section titled <u>Labeling</u> it indicates ...When multidose vials are initially used they shall be dated with the current date and will have an effective expiration date 30 days from the date of initial use or the expiration date printed on the vial, whichever is sooner.</p> <p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)(3)(B)</p> <p>(b) The condition of the physical plant and the overall center environment must be developed and maintained in such a manner that the safety and well-being of patients are assured as follows:</p> <p>(3) Provision must be made for the</p>			

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	<p>periodic inspection, preventive maintenance, and repair of the physical plan and equipment by qualified personnel as follows:</p> <p>(B) All mechanical equipment (pneumatic, electric, sterilizing, or other) must be on a documented maintenance schedule of appropriate frequency in accordance with acceptable standards of practice or the manufacturer's recommended maintenance schedule.</p> <p>Based on document review and interview, the center failed to maintain appropriate frequency of maintenance per manufacturers' recommended schedule in one instance.</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>1. Review of the emergency generator manufacturer's manual in section 3.3 titled Service Schedule, a chart of system inspections and frequencies indicated weekly checks requiring action.</li> <li>2. Review of facility documents included no weekly checks of the emergency generator.</li> <li>3. In interview on 6/26/14 at 1:00pm, employee A1 confirmed no weekly maintenance of the generator and no further documentation was provided prior to exit.</li> </ol>	S001152	The manufacturers' manual was reveiwed with the maintenance person. A new maintance schedule and chart has been put in place. This will be monitored by the cath lab director and reviewed by the board of directors.	07/14/2014

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S001198	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(c)(6)</p> <p>(c) A safety management program must include, but not be limited to, the following:</p> <p>(6) Emergency and disaster preparedness coordinated with appropriate community, state, and federal agencies. Based on document review and interview, the center failed to participate in emergency and disaster preparedness with an appropriate agency on a regular basis. Findings: 1. Review of 18 months of documents dated from January 2013 to present failed to show evidence of participation in emergency and disaster preparedness. 2. In interview on 6/26/14 at 1:00pm, A1 confirmed no regular activity or drill participation for emergency and disaster preparedness.</p>	S001198	As stted in our policy 14.01, we will work with the Vigo County Health Department and the Vigo County Department of Emergency Management Services to participate in the Medical Reserve Corp. We were added to their list 2 years ago. The Cath Lab Director will be attending the District 7 Disaster Preparedness group on Aug 6. and become a more active member. This will be documented and presented at the Board of Director's meeting.	07/14/2014			
S001210	<p>410 IAC 15-2.5-8 RADIOLOGY SERVICES 410 IAC 15-2.5-8(c)(1)</p> <p>(c) All centers shall comply with all regulations set forth in this rule and</p>						

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	<p>with 410 IAC 5, when radiology services are provided on-site by the center, including, but not limited to the following:</p> <p>(1) Radiology services must be supervised by a radiologist or radiation oncologist.</p> <p>Based on document review and interview, the center failed to ensure supervision of radiology services by a radiologist or radiation oncologist.</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>1. Review of center documents failed to include documentation of supervision for radiology services by a radiologist or radiology oncologist.</li> <li>2. In interview on 6/26/14 at 12:00pm, employee A1 indicated the medical director (MD#1) to be the supervisor over radiology services.</li> <li>3. Review of the credential file for MD#1 indicated no radiologist or radiology oncologist license/certification.</li> <li>4. In interview on 6/26/14 at 1:15pm, employee A1 confirmed the above and no further documentation was provided prior to exit.</li> </ol>	S001210	A radiologist or radiation oncologist will be contacted by the Medical Director to consult/supervise the radiology services. This is delayed due to Vacationing Medical Director and Radiologist.	07/28/2014