

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15C0001129	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 08/19/2014
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NAME OF PROVIDER OR SUPPLIER CARMEL AMBULATORY SURGERY CENTER LLC, THE	STREET ADDRESS, CITY, STATE, ZIP CODE 13421 OLD MERIDIAN ST CARMEL, IN 46032
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S000000	<p>This visit was for a State licensure survey.</p> <p>Facility Number: 003497</p> <p>Survey Date: 8/18/2014 through 8/19/2014</p> <p>Surveyors: Albert Daeger, CFM, SFPIO Medical Surveyor</p> <p>Saundra Nolfi, RN Public Health Nurse Surveyor</p> <p>QA: claughlin 09/11/14</p>	S000000		
S000116	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (b)(2)(A-D)</p> <p>The governing body shall do the following:</p> <p>(2) Ensure the following:</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>(A) The requests of practitioners, for appointment or reappointment to practice in the center are acted upon, with the advice and recommendation of the medical staff.</p> <p>(B) Reappointments are acted upon at least biennially.</p> <p>(C) Practitioners are granted privileges consistent with their individual training, experience, and other qualifications.</p> <p>(D) This process occurs within a reasonable period of time as specified by the medical staff bylaws.</p> <p>Based on documentation review and staff interview, the Governing Board failed to ensure 3 of 3 Allied Health practitioners were granted privileges consistent with their individual training, experience, and other qualifications.(AH1, AH2, and AH3)</p> <p>Findings included:</p> <p>1. Medical Staff Rules & Regulations (Last approved 2/7/2014) section 3 stated, "Allied Health Professional: Physicians utilizing private (non-center employee) allied health professional must submit Allied</p>	S000116	Delineation of Privileges for Allied Health Professionals has been established and will be distributed by Executive Director by 9/30/2014. (Copy Attached) Completed documents will be reviewed and approved at Credentialing Committee meeting on 10/21/14. These will be approved by the Board of Managers at November 21, 2014 meeting. Executive Assistant will be responsible for medical staff files and ensuring compliance in future.	09/17/2014			

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S000176	<p>Health Personnel Applications to the center concerning qualification, licensure certification, malpractice insurance coverage, privileges requested etc. for the assistant prior to their use in the center."</p> <p>2. Three Allied Health Practitioners' credential files were reviewed (AH1, AH2, and AH3). The three practitioners work for physicians that are credentialed to work in the surgery center. In the review of the three Allied Health staff members' credentialed files, there was no evidence of requested or approved privileges to work at the surgery center.</p> <p>3. At 1315 on 8/18/2014, Registered Nurse staff member #5 confirmed the allied staff members do not have requested privileges or approved privileges to work in the surgery center.</p> <p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES</p>						

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	<p>410 IAC 15-2.4-1 (c)(5) (M)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p> <p>(M) Demonstrating and documenting personnel competency in fulfilling assigned responsibilities and verifying in-service in special procedures.</p> <p>Based on policy review, personnel file review, and interview, the facility failed to ensure 7 of 7 registered nurses (RNs) had documentation of competency in medication administration and intravenous (IV) skills (P1, P3, P4, P6, P7, P8, and P9).</p> <p>Findings included:</p> <p>1. The facility policy "Medication Administration", last approved 02/07/14, indicated, "Accurate medication administration is essential in the safe care of the perioperative patient. Measures shall be taken and guidelines followed to ensure the correct administration of all medications based on the five patient rights. Responsibility: Registered Nurses and physicians." The policy outlined procedures to follow for both medications and intravenous fluids.</p> <p>2. The personnel file for RN, P1, with a hire date of 05/02/11, lacked</p>	S000176	The Education Person is responsible to document IV and medication administration competency. The Education person will document current employees by 9/26/14. The IV and medication administration will be an annual mandatory competency in which the Education person is responsible that each appropriate employee complete. The mandatory Inservices are reviewed by the Quality Assurance Committee.	09/26/2014			

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	<p>documentation of IV or medication administration competency.</p> <p>3. The personnel file for RN, P3, with a hire date of 10/12/04, lacked documentation of IV or medication administration competency.</p> <p>4. The personnel file for RN, P4, with a hire date of 06/23/08, lacked documentation of IV or medication administration competency.</p> <p>5. The personnel file for RN, P6, with a hire date of 03/06/07, lacked documentation of IV or medication administration competency.</p> <p>6. The personnel file for RN, P7, with a hire date of 03/01/04, lacked documentation of IV or medication administration competency.</p> <p>7. The personnel file for RN, P8, with a hire date of 11/04, lacked documentation of IV or medication administration competency.</p> <p>8. The personnel file for RN, P9, with a hire date of 05/08, lacked documentation of IV or medication administration competency.</p> <p>9. After review of the personnel files at</p>						

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S000704	<p>12:30 PM on 08/18/14, staff member A5 indicated all nurses received the Medication Administration policy, but confirmed there was no documentation of this or of any orientation or competency in these skills.</p> <p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(a)(1)</p> <p>The medical staff shall do the following:</p> <p>(1) Conduct outcome-oriented performance evaluations of its member at least biennially.</p> <p>Based on documentation review and staff interview, the Medical Staff did not conduct outcome-oriented performance evaluation on 6 of 6 medical staff members that were credentialed to work at the surgery center (P1, P2, P3, P4, P5, and P6).</p> <p>Findings included:</p> <p>1. Six Medical Staff credential files were reviewed (P1, P2, P3, P4, P5, and P6). The six medical staff members' credential files did</p>	S000704	<p>Outcome oriented performance evaluations have been established for Physicians and Allied Health professionals. (See Both Attached.) Executive Director will ensure these are implemented with next credentialing committee meeting on 10/21/14 and approved by the Board at the November 21, 2014 meeting. Executive Assistant will oversee compliance in future by making sure that a completed and signed copy of the Outcome oriented performance evaluation is received in each re-credentialed medical staff file. They will be reviewed by the Credentials Committee and then the Board of Managers for re-credentialing of each medical staff person.</p>	09/17/2014

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S001010	<p>not evidence performance evaluations.</p> <p>2. At 1325 on 8/18/2014, Registered Nurse staff member #5 indicated the surgery center was not conducting performance evaluations on the medical staff that work at the surgery center.</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 policy review, observation, and interview, the facility failed to follow their policies regarding multi-dose vials and medication storage checks in the surgical and pre-op areas.</p> <p>Findings included:</p> <p>1. The facility policy "Pharmacy</p>	S001010	The staff will throw away any vial that is not labeled. Staff was reminded to do so on 9/18/2014 staff meeting conducted by the OR Manager. OR Manager is responsible for compliance in OR Rooms. Pre-Post Op Charge Nurse has reminded the staff of the correct out dates for medication on 8/19/14. The Pre-Post Charge Nurse is	09/18/2014			

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	<p>Services", last approved February 7, 2014, indicated, "Labeling: ...When multidose vials are initially used, they shall be dated with the current date and used within 28 days of opening. ...Quarterly Inspections: ...No outdated or otherwise unusable drugs are stored in the Center."</p> <p>2. During the tour of OR 1 (Operating Room) at 3:00 PM on 08/19/14, accompanied by the OR Manager A8, an open, but not dated, vial of Atropine was observed in the medication drawer of the anesthesia cart.</p> <p>3. During the tour of the pre-op area at 4:00 PM on 08/19/14, accompanied by registered nurse A9, one of one open 20 ml. (milliliter) vial of Labetalol Hydrochloride, with an open date of 06/11/14, was observed in a medication drawer at the nurses' station. The manufacturer's expiration date on the vial was 05/01/15. A multidose vial of Aplisol, with an open date of 06/23/14 and a manufacturer's expiration date of 01/15, and a multidose vial of Tubersol, with an open date of 07/11/14 and a manufacturer's expiration date of 12/15, were observed in the medication refrigerator at the nurses' station.</p> <p>4. At 4:05 PM on 08/19/14, staff</p>		responsible for compliance in pre and post op areas. QA studies will be performed quarterly for the next year to ensure compliance. The studies are reviewed in the Quarterly QA meetings.				

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S001026	<p>member A9 indicated the nurses checked the medication drawers, cabinets, and refrigerator monthly. The log sheet indicated checks of the Labetalol in July and August 2014, but the expiration date was documented as 05/01/15, the manufacturer's expiration date, instead of the 28 day expiration date for an opened multidose vial. The log sheet also indicated checks of the Aplisol and Tubersol in July and August 2014, but the expiration dates were documented as 01/15 and 12/15, the manufacturer's expiration dates, instead of the 28 day expiration date for an opened multidose vial. Staff member A9 confirmed the checks were not done appropriately and the medications should have been discarded.</p> <p>410 IAC 15-2.5-6 PHARMACEUTICAL SERVICES 410 IAC 15-2.5-6(3)(E)(i)</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>(E) Drugs must be accurately and clearly labeled and stored in</p>			

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	<p>specially-designated, well-illuminated cabinets, closets, or storerooms and the following:</p> <p>(i) Drug cabinets must be accessible only to authorized personnel.</p> <p>Based on observation, policy review, and interview, the facility failed to ensure all medications were secured in locked cabinets to prevent unauthorized access.</p> <p>Findings included:</p> <ol style="list-style-type: none"> During the tour of the Procedure Room at 3:15 PM on 08/19/14, accompanied by the OR (operating Room) manager A8, a drawer containing a large quantity of injectable medications, Lidocaine with Epinephrine, Xylocaine, Bupivacaine, Sodium Bicarbonate, Depo-Medrol, and Omnipaque, was observed without any locking device. The room also was not locked. The facility policy titled "Pharmacy Services", last approved February 7, 2014, indicated, "Pharmaceutical supplies and services shall be maintained and controlled in accord with acceptable ethical and professional practices and all legal requirements. Function: Assure effective and proper procurement, storage, preparation, control and dispensing of all drugs and chemicals as approved and authorized by the Medical 	S001026	A lock will be installed on the Procedure Room cabinet drawer for medication by 9/26/2014. No medication will be stored in procedure room until lock is installed. OR Manager will oversee for compliance. The drawer will be locked when not in use.	09/26/2014

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	<p>Staff of the Center. ...Drugs shall be stored in the pharmacy storage cabinet. ...Scheduled drugs shall be stored in a locked cabinet within the locked pharmacy storage cabinet."</p> <p>3. At 3:20 PM on 08/19/14, staff member A 8 indicated the staff from the contracted cleaning service would clean in that room unattended in the evenings and acknowledged the drawer did not lock to secure the medications.</p>				