

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15C0001005	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 03/02/2021
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NAME OF PROVIDER OR SUPPLIER SURGICAL CENTER OF NEW ALBANY	STREET ADDRESS, CITY, STATE, ZIP CODE 2201 GREEN VALLEY RD NEW ALBANY, IN 47150
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S 0000 Bldg. 00	<p>This visit was for a state licensure survey of an ambulatory surgery center.</p> <p>Facility number: 005386</p> <p>Dates: 3/1/21 through 3/2/21</p> <p>QA: 3/8/21</p>	S 0000		
S 0030 Bldg. 00	<p>410 IAC 15-2.2-2 SURVEY PROCEDURES 410 IAC 15-2.2-2 (c)(2)</p> <p>(2) A written or electronic register must be kept of all patients treated which provides identification data, treatment rendered, attending surgeon, condition on discharge, transfers to hospital facility, and such other pertinent data deemed needed by the center.</p> <p>Based on document review and interview, the facility failed to ensure it maintained a surgical register.</p> <p>Findings include:</p> <p>1. Daily patient procedure schedules dated 3/1/20 - 3/1/21 were presented to this surveyor upon request of a surgical registry. Review of the daily patient procedure schedules lacked documentation related to the patient's condition on discharge as well as transfer information.</p> <p>2. Staff A1 (Administrator) was interviewed on</p>	S 0030	<p>A Surgical Procedure Log was designed, printed, and entered into a log book. A patient information sticker will be placed along with the items next to it completed. The Pre-op nurse will be responsible for initiating the data and the PACU nurse will be responsible for completing the data and assuring the log is complete. The administrator will check the log book weekly for completion and accuracy. A staff meeting and in-service was held on 3/24/2021 to implement the</p>	03/26/2021

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 other safeguards provide sufficient protection to the patients. (see instructions.) Except for nursing homes, the findings stated above are disclosable 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 disclosed 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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S 0110 Bldg. 00	<p>3/1/21 at approximately 1230 hours and confirmed the facility does not maintain a registry of all surgical patients, either electronic or written, that includes patient identification information, treatment rendered, the attending physician, condition on discharge and transfers. Staff A1 stated he/she uses daily patient procedure schedules to serve as the facility's surgical registry. Staff A1 confirmed the daily procedure schedules lacked documentation related to patient discharge condition and transfer.</p> <p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (a)(5)</p> <p>The governing body shall do the following:</p> <p>(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.</p> <p>Based on document review and interview, the governing body (GB) failed to at least quarterly review reports of management operations, including, but not limited to, the quality assessment and improvement program (QAPI) for the past 4 quarters.</p> <p>Findings include:</p> <p>1. Review of the Quality Assessment Performance Improvement Plan, approved 4/8/2020, indicated the following: COMMITTEE PURPOSE: Documentation of</p>	S 0110	<p>new log book procedure.</p> <p>The Surgical Center will maintain separate Quality Assessment and Improvement (QAPI) committee and minutes reporting on the Surgical Center only. The information will be collected weekly and disseminated to the Governing Board and Medical Advisory Committee, as well as the QAPI committee quarterly. The Administrator will verify the data and oversee the compliance of the process.</p>	03/15/2021

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S 0126 Bldg. 00	<p>the committee activities will be presented to the GB for review.</p> <p>RESPONSIBILITIES: The GB has the overall responsibility for developing, maintaining and supporting the ongoing, comprehensive program.</p> <p>COMMUNICATION: Relevant information...will be disseminated as necessary to the affected individuals and groups in the following ways: Quarterly reports to GB.</p> <p>2. Review of GB meeting minutes dated 1/1/20 (start of new business), 4/8/20, 7/14/20, 10/19/20 and 2/12/21 lacked documentation of the GB review of QAPI reports.</p> <p>3. On 3/2/21 beginning at approximately 11:00am, A1, Administrator, verified that the GB did not have documentation of having reviewed QAPI reports.</p> <p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (b)(5)</p> <p>The governing body shall do the following:</p> <p>(5) Ensure that criteria for selection for medical staff membership are individual character, competence, education, training, experience, and judgement.</p> <p>Based on document review and interview, the Governing Body (GB) failed to ensure that criteria for selection of medical staff (MS) membership included competence and/or experience for 3 of 4 allied health (AH) professionals (AHP) members (AH1, AH3 and AH4).</p> <p>Findings include:</p>	S 0126	<p>Please note the first quarter 4/8/2020, no procedures were performed due to Covid Regulations mandated by the Governor of Indiana.</p> <p>All CRNA's competence and experience is verified by National Practitioners Data Bank (NPDB) and National Board of Certification and Re-Certification of Nurse Anesthetists (NBCRNA). These documents are reviewed and approved by the Governing Board.</p>	03/03/2021

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	<p>1. Review of MS Bylaws, approved 4/8/20, indicated the following: Article II Section 2: The Medical Director or the Medical Director's designee shall make all necessary checks on the following core criteria for appointment, reappointment, and privileges: current license; relevant education, training, or experience; current competence; and ability to perform the requested privileges.</p> <p>2. Review of credential files indicated the following: AHP AH1, Certified Registered Nurse Anesthetist (CRNA). The file lack documentation of appointment by the GB and/or privileges granted. The file lacked documentation of verification of the AH member's competence and/or experience. AHP AH3, Certified Registered Nurse Anesthetist (CRNA). The file lack documentation of appointment by the GB and/or privileges granted. The file lacked documentation of verification of the AH member's competence and/or experience. AHP AH4, Certified Registered Nurse Anesthetist (CRNA). The file lack documentation of appointment by the GB and/or privileges granted. The file lacked documentation of verification of the AH member's competence and/or experience.</p> <p>3. Review of GB meeting minutes dated 10/19/20 indicted The Board accepted the recommendations from the MAC (Medical Advisory Committee) and approved the following: AH1, AH3 and AH4. Review of GB meeting minutes dated 1/1/20 (start of new business), 4/8/20, 7/14/20, 10/19/20 and 2/12/21 lacked documentation of the committee's review of</p>		<p>The administrator will be responsible for overseeing the credentialing files and submit them to the Governing Board for approval and maintain compliance. Note that all CRNA files have been reviewed for verification of the documents maintained in their file as it unknown who AH1, AH3, and AH4 are. There was no key provided on the day of the survey.</p>				

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S 0192 Bldg. 00	<p>appointees, experience or competence.</p> <p>4. In interview, on 3/1/21, beginning at approximately 1:15 PM, A1, Administrator, verified that the credential files for AH1, AH3 and AH4 lacked documentation/verification of their competence and experience in performing the procedures/tasks which they were currently performing in the center.</p> <p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1(c)(5)(P)(iv)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p> <p>Development, implementation, and monitoring of a safety management program include, but not be limited to, the following:</p> <p>(iv) Chemical substances use and storage. Based on observation, document review and interview, the chief executive officer failed to develop and implement policies and programs for safety and monitoring of chemical substance use and storage in 1 (one) facility.</p> <p>Findings include:</p> <p>1. On 3/1/21, during facility tour beginning at approximately 1:30 PM, in the presence of A1, Administrator, the following was observed: In the patient dressing room was an unlocked cabinet containing, but not limited to, the following: a gallon container of "DQM" neutral disinfectant cleaner, an open container of "Bar Keepers Friend</p>	S 0192	The DMQ safety data sheet as well as the sheet for CLR was in the Safety Data Sheet binders which are located in the dictation office. Cavicide and Bar Keepers Friend safety data sheet was added to the binders. An inventory sheet was also added to the beginning of each binder. A staff meeting was held on 3/3/2021 to discuss the state tags and it was re-iterated to all the Safety Data Sheet Binders and their location. A safety officer was appointed and will be responsible	03/02/2021

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	<p>Cleanser & Polish", gallon container of CaviCide (Trademark) and a jug of CLR PRO® CALCIUM, LIME & RUST REMOVER.</p> <p>2. Review of material safety data sheet information indicated the following (not all inclusive):</p> <p>A. DMQ DAMP MOP NEUTRAL DISINFECTANT CLEANER Conditions to Avoid: CAUSES IRRECERSIBLE EYE DAMAGE... HARMFUL TO SKIN...HARMFUL IF SWALLOWED...</p> <p>B. Bar Keepers Friend Cleanser & Polish at https://www.barkeepersfriend.com/wp-content/uploads/2014/12/SDS_BKF_Cleanser_Polish_6-12-15.pdf "HAZARDS IDENTIFICATION CLASSIFICATION OF Skin irritation 3 - H316 THE MIXTURE: Eye irritation 2A - H319 LABEL ELEMENTS: SIGNAL WORD: Warning HAZARD PICTOGRAM: HAZARD STATEMENTS: H316 Causes mild skin irritation H319 - Causes serious eye irritation PREVENTION: P264 Wash hands thoroughly after handling P280 Wear eye protection / face protection RESPONSE: P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing. P337+P313 If eye irritation persists: Get medical advice / attention. If medical advice is needed, have container at hand. P332+P313 If skin irritation occurs, get medical attention. If medical advice is needed, have container in hand."</p>		to maintain the Safety Data Sheet binders.	

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	<p>C. CaviCide (Trademark) at https://www.metrex.com/sites/default/files/content/education-file/education-file-upload/CaviCide%20Canadian%20MSDS%20(7-14-2015).pdf "EMERGENCY OVERVIEW Flammable liquid and vapor. Causes moderate eye irritation. May cause mild skin irritation. Harmful if absorbed through the skin. Inhalation of concentrated vapors may cause irritation of the eyes, nose and throat and dizziness and drowsiness. Prolonged overexposure to ethylene glycol monobutyl ether may affect liver, kidneys, blood, lymphatic system or central nervous system."</p> <p>D. CLR PRO® CALCIUM, LIME & RUST REMOVER "HAZARDS IDENTIFICATION COMPLIES WITH 29CFR 1900.1200 DATED MAY 2012 WARNING ACUTE EYE IRRITATION (Category 2A) ACUTE DERMAL IRRITATION (sic) (Category 4) DO NOT get in eyes, on skin or clothing. DO NOT mix with bleach or other household chemicals harmful; fumes may result. DO NOT ingest. DO NOT breathe vapor or mist. Use in well ventilated areas. Keep container closed when not in use."</p> <p>3. On 3/2/21 beginning at approximately 2:30 PM, A1, Administrator indicated the center did not have a policy/procedure for chemical substance use or storage and that not all MSDS sheets were available for the chemicals observed in the unlocked housekeeping cabinet in the patient changing room.</p>			

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S 0230 Bldg. 00	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1(e)(5)</p> <p>The governing body is responsible for services delivered in the center whether or not they are delivered under contracts. The governing body shall do the following:</p> <p>(5) Provide for a periodic review of the center and its operation by a utilization review or other committee composed of three (3) or more duly licensed physicians having no financial interest in the facility.</p> <p>Based on document review and interview, the governing body (GB) failed to provide for periodic review of the center and its operation by a utilization review (UR) or other committee composed of 3 or more physicians having no financial interest in the facility for the past 4 quarters.</p> <p>Findings include:</p> <ol style="list-style-type: none"> 1. Review of facility documents lacked evidence of UR meeting minutes or periodic review by an appropriate UR or other committee within the past 4 quarters. 2. On 3/2/21, at approximately 2:30 PM, A1, Administrator, verified the center did not have an UR or other committee of 3 or more physicians having no financial interest in the facility to provide periodic review of the center and its operation. 	S 0230	A discussion was held regarding a Utilization Review Board on March 12, 2021. Three physicians were appointed to a Utilization Review Committee by the Governing Board and Medical Director. The committee will review operations as well as charts quarterly and report to the Governing Board as well as the Medical Advisory committee. The Administrator will oversee the process for compliance.	03/25/2021			

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S 0300 Bldg. 00	<p>410 IAC 15-2.4-2 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-2.4-2(a)</p> <p>(a) The center must develop, implement, and maintain an effective, organized, center-wide, comprehensive quality assessment and improvement program in which all areas of the center participate. The program shall be ongoing and have a written plan of implementation that evaluates, but is not limited to, the following: Based on document review and interview, the Center failed to develop, implement and maintain an effective, organized, center-wide, comprehensive quality assessment and performance improvement (QAPI) program in which all areas of the center were evaluated, 8/17 areas (services/functions) were not included (housekeeping, laundry, security, transcription, discharge, transfer, medication errors and response to patient emergency), for the past 4 quarters and the facility failed to annually evaluate the objectives, scope of the organization and effectiveness of the center as per their QAPI Plan.</p> <p>Findings include:</p> <p>1. Review of the document titled Quality Assessment and Performance Improvement Plan, approved 4/8/20, indicated the following: COMMITTEE PURPOSE: A Performance Improvement/Medical Advisory Committee shall be established which shall meet at least once per calendar quarter. MEMBERSHIP: The committee members shall include:</p>	S 0300	<p>QAPI activity and evaluations are listed in each of the areas in the front of each binder. Housekeeping has been performed by staff which is documented daily and reported. Housekeeping is now contracted out and will be added to the list and evaluated quarterly along with Laundry, security, transcription, discharge, transfer, medication errors, and response to patient emergencies. There is also a triennial review of those services performed. The Administrator reports all to the Governing Board, Medical Advisory Board, and QAPI committee in quarterly meetings. The Administrator will be responsible to oversee the compliance.</p>	03/02/2021	

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	<p>Medical Director. Administrative and clinical director(s). At least one other physician.</p> <p>RESPONSIBILITIES:</p> <p>Monitors, coordinates and integrates all committee activities and ensures participation of all disciplines. The committee receives all reports regarding but not limited to, infection control, patient transfers, tissue review, medical records review, safety and fire, medication handling and storage, risk management, and patient safety.</p> <p>COMMITTEE MEMBER FUNCTIONS:</p> <p>Conducts regular meetings to all for staff involvement and to elicit staff ideas and feedback regarding improvement of patient care and services;</p> <p>Reports to the Medical Director on a quarterly basis, the monitoring activities, results, actions and recommendations for further action.</p> <p>COMMUNICATION:</p> <p>The Performance Improvement/Medical Advisory Committee will evaluation the objectives, scope of the organization and effectiveness of the center annually.</p> <p>2. Review of facility documents for all of 2020 through 2/28/21, lacked evidence of a QAPI Committee and/or QAPI Committee meeting minutes. Review of Medical Advisory Committee Meetings dated 4/8/20, 7/14/20, 10/19/20, and 2/12/21 lacked documentation of QAPI monitoring activities, results, actions and/or recommendations for: housekeeping, laundry, security, transcription, discharge, transfer, medication errors and response to patient emergency and lacked documentation of a 2020 annual evaluation of the objectives, scope of the organization and effectiveness of the center.</p> <p>3. On 3/2/21 beginning at approximately 11:00 AM, A1, Administrator, verified the center did not</p>			

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S 0442 Bldg. 00	<p>have documentation of a QAPI Committee or meetings of such, nor did they have evidence of an annual evaluation of the objectives, scope of the organization and effectiveness of the center.</p> <p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(f)(2)(E)(viii)</p> <p>The infection control committee responsibilities must include, but are not limited to:</p> <p>(E) Reviewing and recommending changes in procedures, policies, and programs which are pertinent to infection control. These include, but are not limited to, the following:</p> <p>(viii) An employee health program to determine the communicable disease history of new personnel as well as an ongoing program for current personnel as required by state and federal agencies.</p> <p>Based on document review and interview, the facility failed to ensure their employee health program determined the communicable disease history of personnel in 5 (N1, N3, N6, N7 and N8) of 7 personnel files reviewed.</p> <p>Findings include:</p> <p>1. Review of personnel files, N1 (Registered Nurse [RN]), N3 (Radiology Technician [RT]), N6 (RN), N7 (RN) and N8 (Certified Medical Assistant [CMA]) lacked documentation of a two-step Mantoux tuberculin skin test upon hire as well as</p>	S 0442	Of the 5/7 files reviewed, only 2 staff members were employed over 1 year. They had TB screening questionnaires in their files. According to the Surgery Center policy a TB risk assessment of our area was completed and this area/county was found to be at low risk. Starting April 1, 2021, all new hires will have a TB blood draw and then the yearly TB questionnaire completed. The Infection Control Nurse will be responsible for overseeing the health questionnaires and	03/29/2021

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S 0924 Bldg. 00	<p>documentation of annual tuberculosis screening.</p> <p>2. Review of personnel files, N3, N7 and N8 lacked documentation of history of immunity to communicable diseases including rubella, rubeola and varicella.</p> <p>3. On 3/2/21 at approximately 1330 hours, staff A2 (Registered Nurse/Infection Preventionist) was interviewed and confirmed staff N1, N3, N6, N7 and N8's personnel files lacked documentation of a two-step Mantoux tuberculin skin test upon hire and annual screening. Staff A2 confirmed staff N3, N7 and N8's personnel files lacked documentation of history of immunity to rubella, rubeola and varicella.</p> <p>410 IAC 15-2.5-5 PATIENT CARE SERVICES 410 IAC 15-2.5-5(b)(2)</p> <p>(b) Written patient care policies and procedures shall be available to personnel and shall include, but not be limited to, the following:</p> <p>(2) A requirement that side rails be provided on recovery carts and kept in the upright position when occupied by sedated patients.</p> <p>Based on document review, observation and interview, the facility failed to ensure safe provision of recovery carts with side rails for sedated patients in 2 (Operating Room and Recovery Unit) of 4 areas toured.</p> <p>Findings:</p> <p>1. Review of patient 2's MR indicated: "3/1/21:</p>	S 0924	<p>monitoring the employee health files. The administrator will oversee the files for compliance.</p> <p>As of 3/3/2021 all sedated patients will be transported from the Operating Room to the PACU via stretcher with side rails up. The circulator in that OR will be responsible for overseeing the process of transfer to the stretcher and routing to the PACU area. An in-service was held on 3/3/2021 regarding safe transfers of</p>	03/03/2021	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15C0001005	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 03/02/2021
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NAME OF PROVIDER OR SUPPLIER SURGICAL CENTER OF NEW ALBANY	STREET ADDRESS, CITY, STATE, ZIP CODE 2201 GREEN VALLEY RD NEW ALBANY, IN 47150
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	<p>Procedure Performed: Trigger point injection in the following muscles: lumbar paraspinal, gluteus maximus...Description of Procedures: Monitored Anesthesia: With patient in the prone position...the patient was sedated with direct monitoring by anesthesia personnel".</p> <p>2. Review of patient 2's MR indicated the patient was administered Versed 2 mg and Fentanyl 50 mcg per medical staff D1 (Certified Registered Nurse Anesthetist [CRNA]) on 3/1/21 at 1434 hours in Operating Room (OR) 3.</p> <p>3. On 3/1/21 at approximately 1445 hours, patient 2 was observed in OR 3 undergoing procedure for trigger point injection with monitored anesthesia. Medical staff D1 was observed administering Versed 2 mg and Fentanyl 50 mcg at approximately 1434 hours. At approximately 1440, staff A2 (Registered Nurse/Infection Preventionist) and medical staff D1 were observed assisting the patient from a prone position on the surgical stretcher to a sitting position on the surgical stretcher. Patient 2 was observed to be sedated and unaware of his/her surroundings. Staff A2 and medical staff D1 were then observed assisting the patient from the sitting position on the surgical stretcher to a standing position for pivot to a wheel chair. During the assisted transfer from the surgical stretcher to the wheel chair, patient 2 was observed to be unsteady and unable to stand independently. The patient was then transported from OR 3 to the Recovery Unit per wheel chair where he/she recovered in the wheel chair.</p> <p>4. On 3/1/21 at approximately 1500 hours, staff A2 was interviewed and confirmed patient 2 underwent monitored anesthesia in the OR on 3/1/21 for a trigger point injection procedure and received Versed 2 mg and Fentanyl 50 mcg. Staff</p>		patients. The administrator will oversee the process for compliance.	

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

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NAME OF PROVIDER OR SUPPLIER SURGICAL CENTER OF NEW ALBANY			STREET ADDRESS, CITY, STATE, ZIP CODE 2201 GREEN VALLEY RD NEW ALBANY, IN 47150		
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	A2 confirmed patient 2 was experiencing signs/symptoms of sedation at the time the procedure ended and the patient was assisted from prone position to a sitting position on the surgical stretcher and placed in a wheel chair for transport to the Recovery Unit. Staff A2 stated most patients at the facility that undergo a procedure with monitored anesthesia recover in wheel chairs.				