



IDAHO DEPARTMENT OF
HEALTH & WELFARE

C.L. "BUTCH" OTTER – Governor
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BUREAU OF FACILITY STANDARDS
3232 Elder Street
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RECEIVED
MAY 01 2012
DIV. OF MEDICAID

April 18, 2012

David Orchard, Administrator
Les Bois Surgery Center
8950 W Emerald Street, Suite 168
Boise, ID 83704

RE: Les Bois Surgery Center, Provider #13C0001036

Dear Mr. Orchard:

This is to advise you of the findings of the Medicare survey of Les Bois Surgery Center, which was conducted on April 11, 2012.

Enclosed is a Statement of Deficiencies/Plan of Correction Form CMS-2567, listing Medicare deficiencies. In the spaces provided on the right side of each sheet, please provide a Plan of Correction. It is important that your Plan of Correction address each deficiency in the following manner:

An acceptable plan of correction (PoC) contains the following elements:

- Action that will be taken to correct each specific deficiency cited;
- Description of how the actions will improve the processes that led to the deficiency cited;
- The plan must include the procedure for implementing the acceptable plan of correction for each deficiency cited;
- A completion date for correction of each deficiency cited must be included;
- Monitoring and tracking procedures to ensure the PoC is effective in bringing the ASC into compliance, and that the ASC remains in compliance with the regulatory requirements;
- The plan must include the title of the person responsible for implementing the acceptable plan of correction; and
- The administrator's signature and the date signed on page 1 of the Form CMS-2567.

David Orchard, Administrator
April 18, 2012
Page 2 of 2

After you have completed your Plan of Correction, return the original to this office by **May 1, 2012**, and keep a copy for your records.

Thank you for the courtesies extended to us during our visit. If you have questions, please call this office at (208) 334-6626.

Sincerely,



TERESA HAMBLIN
Health Facility Surveyor
Non-Long Term Care



NICOLE WISENOR
Co-Supervisor
Non-Long Term Care

TH/srm
Enclosures

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

PRINTED: 04/18/2012
FORM APPROVED
OMB NO. 0938-0391

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| NAME OF PROVIDER OR SUPPLIER LES BOIS SURGERY CENTER | | | STREET ADDRESS, CITY, STATE, ZIP CODE 8950 W EMERALD STREET, SUITE 168 BOISE, ID 83704 | |
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| Q 000 | INITIAL COMMENTS The following deficiencies were cited during the recertification survey of your Ambulatory Surgical Center. Surveyors conducting the survey were: Teresa Hamblin, RN, MS, HFS, Team Leader Aimee Hastriter, RN, BS, HFS Acronyms used in this report include: cc - Cubic Centimeter CDC - Centers for Disease Control and Prevention CLIA - Clinical Laboratory Improvement Amendments H&P - History and Physical INH - Isoniazid hydrochloride (a drug for people with Tuberculosis) PPD - Purified Protein Derivative RN - Registered Nurse | Q 000 | | |
| Q 162 | 416.47(b) FORM AND CONTENT OF RECORD The ASC must maintain a medical record for each patient. Every record must be accurate, legible, and promptly completed. Medical records must include at least the following: (1) Patient identification. (2) Significant medical history and results of physical examination. (3) Pre-operative diagnostic studies (entered before surgery), if performed. (4) Findings and techniques of the operation, including a pathologist's report on all tissues removed during surgery, except those exempted by the governing body. (5) Any allergies and abnormal drug reactions. (6) Entries related to anesthesia administration. | Q 162 | Q 162 – This standard will be corrected by updating the medical record content to reflect both post-op diagnosis and also allergic reactions. The physicians will asked/trained to update the electronic medical records system so that all patients' procedural notes will include the correct post-op diagnosis. The EMR policy | |

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FACILITY STANDARDS

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE _____ TITLE _____ (X6) DATE **4/30/12**

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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| Q 162 | <p>Continued From page 1</p> <p>(7) Documentation of properly executed informed patient consent.</p> <p>(8) Discharge diagnosis.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, policy review and staff interview, it was determined the facility failed to ensure medical records included comprehensive information for 16 of 21 patients (#1 - #8, #12, and #14 - #20) whose records were reviewed. This resulted in a lack of information related to patients' post-operative diagnoses and/or drug reactions which resulted in potential negative impacts to patients. Findings include:</p> <p>1. Facility policy, "MEDICAL RECORD CONTENT," effective February, 2011, stated operative reports were to contain post-operative diagnosis. However, post-operative diagnoses were not present in the medical records of Patients #1, #2, #4, #6, #7, #12, #14, #16, #17, #18, and #19 whom Physician B treated.</p> <p>Physician B was interviewed on 4/11/12 at 10:30 AM. He confirmed the template he had been using to write his procedure reports did not include a place to enter post-operative diagnoses and none of the above listed patient records included post-operative diagnoses. The facility failed to ensure post-operative diagnoses were present in the patients' medical records.</p> <p>2. The facility's policy, "MEDICAL RECORD CONTENT," effective February, 2011, indicated staff were to verify and update patient allergy</p> | Q 162 | <p>will be updated to state the need for a post-op diagnosis. Also, the patient's medical records will be verified and updated to reflect allergies, including any adverse reactions, at each visit. The allergies and adverse reactions will be documented in red pen on the ASC pre-op assessment sheet to alert medical personnel of any potential concerns. The EMR policy will be updated to include documenting the adverse reactions. Making both these changes will help avert possible negative impact on patient care. The policy will be updated by May 15th by the Office Manager and appropriate staff will be trained on the new procedure. Chart audits are performed on a monthly basis and will include verifying the inclusion of post-op diagnosis and adverse allergic reactions.</p> | | |

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| Q 162 | <p>Continued From page 2</p> <p>information each visit. It also stated a comprehensive H&P was to include allergies to medication and foods. The policy did not address the need to document the type of adverse drug reactions to all or specified types of medications/products. Further, patient medical records were reviewed. The records documented patient allergies but did not consistently specify the type of allergic reactions patients had experienced as follows:</p> <p>a. Patient #19 was 73 year old female admitted to the facility on 1/11/12. An RN's pre-operative assessment, dated 1/11/12 at 8:07 AM, documented Patient #19's allergy to novocaine and demerol. A physician's H&P report, dated 1/11/12, documented the same two allergies. According to www.drugs.com, novocaine can result in cardiovascular system reactions including low blood pressure (hypotension), low heart rate (bradycardia), and even cardiac arrest. Patient #19's record did not include documentation that described the type of allergic reaction Patient #19 had to these medications.</p> <p>According to the physician's progress note, dated 1/11/12, Physician B anesthetized Patient #19's skin with a combination of 1% lidocaine and .25% bupivacaine with a total of 5 cc of the mixture to the depth of approximately 2.5 inches. After the administration of the drug mixture, Patient #19's heart rate and blood pressure dropped (bradycardia and hypotension). In response to Patient #19's changing symptoms, staff administered intravenous fluids, removed her from the surgical suite and placed her on monitors until she recovered. Subsequently, she was transported (via emergency medical service)</p> | Q 162 | | |

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| Q 162 | <p>Continued From page 3</p> <p>to a local hospital for a complete evaluation of the cardiac episode.</p> <p>Physician B was interviewed on 4/11/12 at 10:30 AM. He stated he had evaluated Patient #19's reaction to novocaine in the office prior to scheduling the procedure. He stated he did not write down the assessment. He said it was more typical for a patient who reacted to novocaine to be reacting to the epinephrine mixed in with the novocaine, which could cause a fast heart rate, instead of a slow heart rate. He stated he would not have given Patient #19 the lidocaine and bupivacaine if Patient #19 had a history of developing bradycardia and hypotension from lidocaine exposure.</p> <p>The facility failed to ensure the type of allergic reactions Patient #19 experienced were documented in her record.</p> <p>b. Patient #20 was an 81 year old female admitted to the facility on 4/10/12. Patient #20's pre-operative nursing assessment was observed on 4/10/12 beginning at 10:20 AM. The RN was observed to ask Patient #20 if she had any allergies. Patient #20 said she had an allergy to medical tape. When asked what type of reaction she had to medical tape, Patient #20 stated her skin got itchy and red. The allergy to medical tape was written down in the nursing notes. However, the type of reaction Patient #20 had to the medical tape was not written down. Similarly, a physician's progress note, dated 4/05/12, documented the allergy to tape, but did not document the type of adverse reaction.</p> <p>The RN who did the pre-operative assessment</p> | Q 162 | | | |

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| Q 162 | <p>Continued From page 4</p> <p>was interviewed on 4/11/12 at 12:05 PM. She stated if Patient #20 had reported blistering from the tape, she would have written it down. She confirmed she performed the assessment but did not document her findings related to the reaction to tape.</p> <p>The facility failed to ensure the type of allergic reaction Patient #20 experienced was documented in her record.</p> <p>c. Patient #4 was a 34 year old male admitted to the facility on 3/01/12. An untimed physician progress note, dated 2/23/12, and a nursing note, dated 3/01/12 at 2:07 PM, documented allergies to milk and IVP (intravenous pyelogram) dye. The medical record did not contain documentation of what type of adverse reaction milk and IVP caused in Patient #4.</p> <p>d. Patient #8 was a 67 year old female admitted to the facility on 3/12/12. An untimed physician progress note, dated 3/12/12, and an RN note, dated 3/19/12 at 2:18 PM, documented Patient #8 had allergies to erythromycin, tape, sulfa, and talwin. The medical record did not contain documentation of what type of adverse reaction the medications and tape caused in Patient #8.</p> <p>e. Patient #15 was a 79 year old female admitted to the facility on 3/26/12. Her medical record contained a H&P, completed by the physician on 3/21/12, and nursing notes, completed on 3/26/12, that indicated Patient #15 had an allergy to INH found in the PPD tuberculosis testing subcutaneous injection. The medical record did not contain documentation of what type of adverse reaction the INH caused in Patient #15.</p> | Q 162 | | | |

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| Q 162 | Continued From page 5 f. Patient #5 was a 36 year old female admitted to the facility on 3/12/12. Her medical record contained a H&P, completed by the physician on 2/23/12, and nursing notes, completed on 3/12/12, that indicated Patient #5 was allergic to Sulfa and Imitrex. The medical record did not contain documentation to describe Patient #5's allergic response to the medications. g. Patient #3 was a 76 year old female admitted to the facility on 3/05/12. Her medical record contained a H&P, completed by the physician on 2/27/12, and nursing notes, completed on 3/05/12, that indicated Patient #3 was allergic to Compazine, Zymar, Quinine, Citric Acid, Zantac, and Vitamin C. The medical record did not contain documentation of Patient #3's allergic response to the medications. h. Patient #18 was a 48 year old male admitted to the facility on 3/14/12. His medical record contained a H&P, completed by the physician on 3/14/12, and nursing notes, also completed on 3/14/12, that indicated Patient #18 was allergic to Demerol, Ibuprofen, and Morphine. The medical record did not contain documentation regarding Patient #18's allergic response to the medications. i. Patient #17 was an 85 year old female admitted to the facility on 3/15/12. Her medical record contained a H&P, completed by the physician on 3/15/12, and nursing notes, also completed on 3/15/12, that indicated Patient #17 was allergic to Penicillin, Diclofenac, and Prednisone. The medical record did not contain documentation regarding Patient #17's allergic | Q 162 | | | |

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| Q 162 | Continued From page 6 response to the medications. During an interview on 4/11/12 between 11:40 and 11:55 AM, the RN reviewed records for Patients #3, #4, #5, #8, #15, #17, #18 and confirmed they did not contain documentation to indicate the type of allergic reaction the patients experienced. She stated this was something she typically asked the patient but confirmed that the information was not always documented. | Q 162 | | |
| Q 201 | 416.49(a) LABORATORY SERVICES If the ASC performs laboratory services, it must meet the requirements of Part 493 of this chapter. If the ASC does not provide its own laboratory services, it must have procedures for obtaining routine and emergency laboratory services from a certified laboratory in accordance with Part 493 of this chapter. The referral laboratory must be certified in the appropriate specialties and subspecialties of services to perform the referral test in accordance with the requirements of Part 493 of this chapter. This STANDARD is not met as evidenced by: Based on review of facility policies and interview, it was determined the facility failed to ensure procedures for obtaining routine and emergency laboratory services from a certified laboratory were developed. This had the potential to result in the facility utilizing laboratory services from a laboratory that did not meet quality standards. Findings include: | Q 201 | Q 201 – The standard will be corrected by updating our policy for obtaining routine and emergency laboratory services from a certified laboratory. The changes will include the procedures for obtaining lab services, language that requires the incorporation of lab reports in to patient records and also proof of CLIA certification from the lab that will be used. The policy will be updated on a routine basis and a proof of CLIA | |

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| Q 201 | Continued From page 7 The Practice Manager was interviewed on 11/10/12 at 11:00 AM. He confirmed the facility had no contract or written agreement with a laboratory used to process lab samples. He provided a "CLIA Certificate Policy," dated 1/11/11, which indicated the facility did not perform tests on "materials derived from the human body," and indicated all samples and tests were sent to an outside facility for processing. He confirmed an outside laboratory processed laboratory specimens for the facility. He confirmed the policy did not specify which laboratory was used to process the specimens. During an interview on 4/11/12 at 3:45 PM, the RN explained the process for labeling and packaging specimens for laboratory evaluation. She stated most often the specimens sent for laboratory evaluation were tubes of cerebrospinal fluid from a lumbar puncture. She stated occasionally a blood sample was collected at the same time. She confirmed the facility did not obtain routine or emergency blood draws and did not send tissues for examination. She explained that when they performed a lumbar puncture, the laboratory supplied pre-printed labels which were then affixed to the tubes provided by the laboratory. She confirmed that each tube was labeled with the patient's name, date of procedure, and the contents of the tube. She stated all of the tubes were placed in a biohazard bag and the bag was collected by an individual for transfer to the laboratory. The Practice Manager was interviewed on 11/11/12 at 3:50 PM. He reviewed the facility policy, "PATHOLOGY SPECIMENS," dated | Q 201 | certification will be maintained by the Office Manager. These changes and proof of certification will be completed by May 15 th , 2012, including the training of appropriate staff. Making these changes will well ensure that proper collection services are being used and the laboratory meets quality standards. | | |

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| Q 201 | Continued From page 8 4/01/11, and confirmed that the policy did not outline the procedures currently used to prepare laboratory specimens for transport to the laboratory. He also confirmed the policy did not indicate what pathology specimens were sent for laboratory testing (i.e. cerebrospinal fluid rather than tissue samples). He confirmed that the facility did not have documentation to ensure the laboratory used was a CLIA-approved laboratory or a method in place to monitor the services provided by the laboratory. | Q 201 | | |
| Q 241 | 416.51(a) SANITARY ENVIRONMENT The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice. This STANDARD is not met as evidenced by: Based on observation, policy review, and interview, it was determined the facility failed to ensure the availability of a method to sanitize hands in 1 of 2 patient care areas toured. This resulted in the inability of physician and nursing staff to sanitize their hands when in the procedure room behind closed doors. This had the potential to interfere with the prevention of infection. Findings include: The facility was toured on 4/10/12 at 2:35 PM. There were two patient care areas. One area was used for pre-operative preparation and for patient recovery after procedures. The second | Q 241 | Q 241 – This standard was already corrected on April 11 th , 2012 by placing an alcohol-based sanitizer in the procedure room. Hand washing hygiene posters will be made, including the guidelines from the CDC and posted at each station. Staff will be reminded of proper | |

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| Q 241 | Continued From page 9 area was used for procedures and surgeries. The procedure room/surgical suite did not have a sink or any hand sanitizer present in the room. The RN confirmed this information at the time of the tour. Physician A was interviewed on 4/10/12 between 3:30 PM and 4:00 PM. He stated the door to the procedure room was usually, but not always, kept open during procedures. When asked how he would sanitize his hands when the procedure room door was closed and his hands became contaminated during a procedure, he stated he would change gloves. A facility policy, "HAND HYGIENE - CDC GUIDELINES," effective 4/01/11, stated all personnel were expected to use the hand-hygiene techniques recommended by the CDC. This included washing hands with soap and water or using an alcohol-based hand rub "after coming in contact with patient's intact skin, i.e. taking a patient's blood pressure, pulse, lifting/moving the patient...after contact with medical equipment/supplies in patient areas... [and] before applying sterile gloves." | Q 241 | hygiene technics. This will be done by May 15 th , 2012 by the Nurse Manager. Adding the sanitizer provides a functional and sanitary environment for the provision of surgical services. | |
| Q 242 | 416.51(b) INFECTION CONTROL PROGRAM The procedure room did not include a method for sanitizing hands. The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevent program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines. | Q 242 | | |

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| Q 242 | Continued From page 10 This STANDARD is not met as evidenced by: Based on observation, policy review, and staff interview, it was determined the facility failed to ensure the infection control program was sufficiently developed and implemented to ensure proper sterilization of equipment and hand hygiene was completed. These failures directly impacted 2 of 2 patients (#20 and #21) whose procedures were observed and had the potential to impact all patients receiving care at the facility. The lack of sufficient infection control program development and implementation resulted in the potential for patients to experience increased exposure to infectious agents. Findings include: 1. A facility policy, "HAND HYGIENE - CDC GUIDELINES," effective 4/01/11, stated all personnel were expected to use the hand-hygiene techniques recommended by the CDC. This included washing hands with soap and water or using an alcohol-based hand rub "after coming in contact with patient's intact skin, i.e. taking a patient's blood pressure, pulse, lifting/moving the patient...after contact with medical equipment/supplies in patient areas... [and] before applying sterile gloves." This policy was not followed by Physicians A and B during two procedures that were observed, as follows: a. On 4/10/12 at approximately 11:00 AM, Physician A was observed to enter the pre-operative area and cleanse his hands with an alcohol-based hand rub. After cleansing his | Q 242 | Q 242 – (Part 1) This standard will be met by performing additional training with the ASC staff regarding proper hand hygiene techniques. The facility policy on Hand Hygiene – CDC Guidelines will be reviewed with staff. The Nurse Manager will ensure that staff are properly trained by May 15 th , 2012. The additional training will help reduce the risk for patients of potential exposure to infectious agents. | |

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

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 13C0001036 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | (X3) DATE SURVEY COMPLETED 04/11/2012 | |
|--|--|--|--|----------------------|
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| Q 242 | <p>Continued From page 11</p> <p>hands, he interviewed Patient #20 and conducted a physical examination including listening to Patient #20's heart and lungs. After entering the procedure room, he put on a lead apron and assisted the surveyor with applying a lead apron. Physician A then donned sterile gloves and proceeded with prepping Patient #20, cleansing her back with betadine and then inserted needles into her lower back.</p> <p>During an interview with the RN on 4/10/12, after the procedure, she confirmed Physician A sanitized his hands upon entering the pre-operative area, but not after examining the patient and prior to putting on sterile gloves.</p> <p>b. Patient #21's care was observed from admission to discharge on 4/11/12 from 1:30 PM to 2:45 PM. At 2:00 PM, Physician B was observed to perform hand hygiene and begin an assessment of Patient #21 which included listening to Patient #21's heart and lungs with a stethoscope. At approximately 2:18 PM, Physician B was observed donning sterile gloves and preparing items needed for the procedure, including drawing up medications and preparing the skin prep materials. Physician B was not observed to perform hand hygiene after completing the examination of Patient #21 and prior to putting on sterile gloves for the procedure.</p> <p>During an interview on 4/11/12 at 4:00 PM, Physician B acknowledged that hand hygiene had not been performed prior to putting on the sterile gloves for the procedure.</p> <p>The facility failed to ensure facility policy and CDC guidelines were sufficiently implemented</p> | Q 242 | <p>(Part 2) This standard will be met by performing onsite sterilization of medical instruments. Our autoclave will undergo an onsite inspection for compliance and functionality. A policy will be created for proper maintenance and use of the autoclave equipment. The onsite inspection took place on April 30th, 2012 and a policy will be created and implemented by June 1st, 2012. Instrument</p> | |

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| Q 242 | <p>Continued From page 12 necessary to ensure hand hygiene was performed.</p> <p>2. The Practice Manager was interviewed on 4/10/12 at 1:20 PM. He stated the facility did not perform on-site sterilization. He stated the facility mechanically cleaned and packaged the instrument for sterilization and transported the item to a nearby hospital for the sterilization process. He stated this arrangement had been in place for over a year and confirmed there was no written agreement or contract between the facility and the hospital. He provided a document titled, "Possible Agreement with [name of hospital] for the processing of Medical Instruments in use at [name of facility]." He confirmed this documented was in the process of being developed and was not yet approved by the governing body. He stated the agreement was being developed to assist the facility in monitoring the sterilization services provided by the hospital.</p> <p>The facility failed to ensure the infection control program was sufficiently developed to address sterilization process utilized by the facility and how the sterilization process would be monitored for compliance with nationally recognized guidelines.</p> | Q 242 | <p>Washing/Autoclave posters will be placed at the appropriate stations. An autoclave log book will be created and updated to reflect the procedures in the policy. The policy and procedure will be developed by the Office Manager and Nurse Manager to follow nationally recognized guidelines. By developing and addressing the sterilization process of medical equipment, we will help reduce the risk of exposure to infectious agents.</p> | | |