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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15C0001151 | | X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____ | | X3) DATE SURVEY COMPLETED 03/07/2012 | |
| NAME OF PROVIDER OR SUPPLIER BROADWEST SPECIALTY SURGICAL CENTER LLC | | | | STREET ADDRESS, CITY, STATE, ZIP CODE 315 W 89TH AVE MERRILLVILLE, IN 46410 | | | |
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| Q0000 | <p>This visit was for a recertification survey.</p> <p>Facility Number: 011094</p> <p>Survey Date: 03/06-07/2012</p> <p>Surveyors: ReBecca Lair, LCSW Medical Surveyor</p> <p>Jacqueline Brown, RN Public Health Nurse Surveyor</p> <p>QA: claughlin 03/15/12</p> | O0000 | | | | | |

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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| Q0181 | <p>416.48(a) ADMINISTRATION OF DRUGS Drugs must be prepared and administered according to established policies and acceptable standards of practice.</p> <p>Based on observation, policy and procedure review, document review, and staff interview, the facility failed to implement its policies and procedures related to drug storage, labeling, and handling in 3 of 3 (Post Anesthesia Care Unit {PACU}, Clean Supply Room, and Pharmacy Room) areas toured.</p> <p><u>Findings:</u></p> <p>1. While on tour 3/7/12 at 8:30 AM while in the company of personnel P1 and P2, the following was observed:</p> <p>A. in the PACU area Malignant Hyperthermia (MH) cart:</p> <ul style="list-style-type: none"> a. eighteen vials of Dantrium (dantrolene), 20 mg IV. b. five 8.4% sodium bicarbonate 50mEq, lot #87-531-DK, expiration 3/1/12. c. four 2.7 ml blue top BD Vacutainers, lot #1034873, expiration 11/2011. d. one 4.5 ml green top BD Vacutainers, lot #8064514, expiration 4/2009. e. ten 4.5 ml green top BD Vacutainers, lot #unknown, expiration 12/2011. f. six 5.0 ml yellow top BD Vacutainers, lot #0343334, expiration 11/2011. g. two 4.0 ml red top BD Vacutainers, lot #0316091, expiration 2/2012. h. two 20 ml BacT/Alert PF, lot #1027898, expiration 2/15/12. i. two 40 ml BacT/Alert SA, lot #1027805, expiration 2/1/12. j. two 40 ml BacT/Alert SN, lot #1027981, expiration 2/25/12 and lot #1027602, expiration 1/7/12. | 00181 | <p>#1 The Peds Crash and Malignant Hyperthermia cart will be assigned to Danielle Feddeler, RN and Connie Fieldhouse, RN and will be monitoring for all meds/supply outdated and restocking of all expired items on the first day of every month. Debbie Terpstra, RN, PACU Manager will be responsible for making sure this is implemented. On March 8, 2012, the blood collection supplies were replaced and outdated items were removed.#2 On March 7th 2012, during the inspection of the Malignant Hyperthermia cart the 18 vials of Dantrium were delivered and placed on the cart in the presence of the surveyor.#3 J. Gatlin will ensure that 36 vials are ordered 0instead of 2 shipments of 18 and our policy will reflect that change as well. The pharamcist, Bert Gonnella, will document this in his monthly report as well. #4 Revised Policy for Infection Prevention & Control & Safety#285 to include the "Removal of Medications at the beginning of the expiration month" to avoid any descrapancies when medications should be removed. This policy will be sent for Board Approval at the April 23rd committee</p> | 04/01/2012 |

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| | <p>B. in the Clean Supply Room Fridge:</p> <p>a. two 10 ml Rocuronium (high alert medication, multi-dose vial), lot #RT108X, expiration 2/2013, opened and lacking a date item was opened.</p> <p>b. one 10 ml Anectine (high alert medication, multi-dose vial), lot #7003789, expiration 2/2012, opened and lacking a date item was opened.</p> <p>c. fourteen 10 ml Anectine (high alert medication), lot #7003789, expiration 2/2012.</p> <p>C. in the Pharmacy Room, one 1 ml Ketorolac, lot #86-370DK, expiration 2/1/12.</p> <p>2. Policy No. ANE#345, titled "Malignant Hyperthermia" reviewed at 11:00 AM on 3/7/12, indicated on pg. 1, under Procedure section, point A.(3.), "A designated cart containing 36 vials of dantrolene and the ancillary medications and equipment as recommended by MHAUS (Malignant Hyperthermia Association of the United States) immediately is available in the anesthetizing and recovery areas."</p> <p>3. Review of Malignant Hyperthermia Association of the United States Medical Professional document titled, "Drugs, Equipment, and Dantrolene - Managing MH" on 3/7/12 at 11:30 AM, indicated:</p> <p>a. on pg. 4, "All facilities, including ambulatory surgery centers and offices, where MH triggering anesthetics...are administered, should stock a minimum of 36 vials of dantrolene, along with the other drugs and devices necessary to treat an MH reaction..."</p> <p>4. Policy No. InfPrev&Safety#285, titled "Expiration Dates" reviewed at 11:13 AM on 3/7/12, indicated on pg. 1, under Procedure section, point A.(1.), "If an expired item is found, it must be removed from stock and segregated from all other supplies and medications."</p> | | <p>meeting.#5 Revision of Policy #464 Storage and Administration of Medications that will include "only dated multi-dose vials can be stored". Staff will be instructed to only put away MDV vials if they are dated, otherwise discard them. Sharpies will be placed in all anesthesia carts to ensure proper dating by Anesthesia staff. A QI study will be continued on this. J. Gatlin, RN, OR Supervisor and Debbie Terpstra, RN, PACU Manager will oversee this and will report findings to Dr. Gupta.ADDENDUM: The three policies (#285, 464 and 324) listed in our Plan of Correction will be approved by the Board on April 23, 2012 and incorporated into the Policy and Procedure Manual.</p> | |

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| | <p>5. Policy No. PHARM#464, titled "Storage and Administration of Medications" reviewed at 11:23 AM on 3/7/12, indicated on pg. 2, under Procedure section, point C. Preparation (4.)(a.), "Multi-dose vials...If aseptic technique is used consistently, an uncontaminated multi-dose vial may be used for 28 days after it is opened or until the manufacturer's expiration date, whichever comes first."</p> <p>6. Personnel P1 was interviewed at 9:03 AM on 3/7/12 and indicated, facility policy and procedure and recommendations from the MHAUS are not being followed because the MH cart was lacking 18 of the 36 vials of Dantrolene required. In addition, facility policy and procedure is not being followed related to the removal of expired supplies and medications. And the above-mentioned multi-dose vials were not labeled when opened, therefore, it cannot be determined whether or not they were past 28 days from the date opened as required per facility policy and procedure.</p> | | | | | | |

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| S1010 | <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, policy and procedure review, document review, and staff interview, the facility failed to implement its policies and procedures related to drug storage, labeling, and handling in 3 of 3 (Post Anesthesia Care Unit {PACU}, Clean Supply Room, and Pharmacy Room) areas toured.</p> <p><u>Findings:</u></p> <p>1. While on tour 3/7/12 at 8:30 AM while in the company of personnel P1 and P2, the following was observed:</p> <p>A. in the PACU area Malignant Hyperthermia (MH) cart:</p> <p>a. eighteen vials of Dantrium (dantrolene), 20 mg IV.</p> <p>b. five 8.4% sodium bicarbonate 50mEq, lot #87-531-DK, expiration 3/1/12.</p> <p>c. four 2.7 ml blue top BD</p> | S1010 | J. Gatlin, RN, OR Supervisor and D. Terpstra, RN, PACU Manager will instruct the employees on the written policies and procedures regarding Drug handling, storing, labeling and dispensing. On March 7, 2012 during the insepction of the Malignant Hyperthermia cart, the 18 vials of Dantrium were delivered and placed on the cart in the presence of the Surveyor. J. Gatlin will be in charge of ordering the 36 vials required rather than splitting the order into 18 vials at a time.High Risk/High Alert Medications throughout the facility are noted by colored stickers. The clean supply room refrigerator will now contain red plastic containers that are labeled high risk/high alert for the muscle relaxant and insulin to ensure the proper dating of Multi-dose vials.Sharpie markers will be placed in all anesthesia carts and Dr. Gupta will instruct all anesthesia staff on dating the | 04/01/2012 | | | |

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| | <p>Vacutainers, lot #1034873, expiration 11/2011.</p> <p>d. one 4.5 ml green top BD Vacutainers, lot #8064514, expiration 4/2009.</p> <p>e. ten 4.5 ml green top BD Vacutainers, lot #unknown, expiration 12/2011.</p> <p>f. six 5.0 ml yellow top BD Vacutainers, lot #0343334, expiration 11/2011.</p> <p>g. two 4.0 ml red top BD Vacutainers, lot #0316091, expiration 2/2012.</p> <p>h. two 20 ml BacT/Alert PF, lot #1027898, expiration 2/15/12.</p> <p>i. two 40 ml BacT/Alert SA, lot #1027805, expiration 2/1/12.</p> <p>j. two 40 ml BacT/Alert SN, lot #1027981, expiration 2/25/12 and lot #1027602, expiration 1/7/12.</p> <p>B. in the Clean Supply Room Fridge:</p> <p>a. two 10 ml Rocuronium (high alert medication, multi-dose vial), lot #RT108X, expiration 2/2013, opened and lacking a date item was opened.</p> <p>b. one 10 ml Anectine (high alert medication, multi-dose vial), lot #7003789, expiration 2/2012, opened and lacking a date item was opened.</p> <p>c. fourteen 10 ml Anectine (high alert medication), lot #7003789, expiration 2/2012.</p> <p>C. in the Pharmacy Room, one 1 ml Ketorolac, lot #86-370DK, expiration</p> | | <p>vials. To ensure this policy is followed Staff RNs are now instructed to only put away dated vials and discard if no date appears. In addition, the policy on medications outdated will be reviewed and state that a medication will be removed from stock at the beginning of the month it expires. Bert Gonnella, Pharmacists, will also be required to perform a vial by vial inspection bi-annually as to ensure no outdates are in stock rotation.</p> | | | | |

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| | <p>2/1/12.</p> <p>2. Policy No. ANE#345, titled "Malignant Hyperthermia" reviewed at 11:00 AM on 3/7/12, indicated on pg. 1, under Procedure section, point A.(3.), "A designated cart containing 36 vials of dantrolene and the ancillary medications and equipment as recommended by MHAUS (Malignant Hyperthermia Association of the United States) immediately is available in the anesthetizing and recovery areas."</p> <p>3. Review of Malignant Hyperthermia Association of the United States Medical Professional document titled, "Drugs, Equipment, and Dantrolene - Managing MH" on 3/7/12 at 11:30 AM, indicated:</p> <p>a. on pg. 4, "All facilities, including ambulatory surgery centers and offices, where MH triggering anesthetics...are administered, should stock a minimum of 36 vials of dantrolene, along with the other drugs and devices necessary to treat an MH reaction..."</p> <p>4. Policy No. InfPrev&Safety#285, titled "Expiration Dates" reviewed at 11:13 AM on 3/7/12, indicated on pg. 1, under Procedure section, point A.(1.), "If an expired item is found, it must be removed from stock and segregated from all other supplies and medications."</p> | | | | | | |

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