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

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FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	34A001	A. BUILDING ______ B. WING ______	01/24/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
BLACK MOUNTAIN NEURO-MEDICAL TREATMENT CENTER	932 OLD US 70 HIGHWAY BLACK MOUNTAIN, NC 28711

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F 157 SS=D

483.10(b)(11) NOTIFY OF CHANGES (INJURY/DECLINE/ROOM, ETC)

A facility must immediately inform the resident; consult with the resident's physician; and if known, notify the resident's legal representative or an interested family member when there is an accident involving the resident which results in injury and has the potential for requiring physician intervention; a significant change in the resident's physical, mental, or psychosocial status (i.e., a deterioration in health, mental, or psychosocial status in either life threatening conditions or clinical complications); a need to alter treatment significantly (i.e., a need to discontinue an existing form of treatment due to adverse consequences, or to commence a new form of treatment); or a decision to transfer or discharge the resident from the facility as specified in §483.12(a).

The facility must also promptly notify the resident and, if known, the resident's legal representative or interested family member when there is a change in room or roommate assignment as specified in §483.15(e)(2); or a change in resident rights under Federal or State law or regulations as specified in paragraph (b)(1) of this section.

The facility must record and periodically update the address and phone number of the resident's legal representative or interested family member.

This REQUIREMENT is not met as evidenced by:
Based on staff, family member, nurse practitioner and medical director interviews, and record review, the facility failed to notify a family

F 157 (Provider's Plan of Correction)

As soon as deficiency noted regarding failure to notify identified resident's guardian of change in resident's condition and order for antibiotic therapy (resident's MOST indicated "Determine use or limitation of antibiotics when infection occurs), resident's guardian/brother was contacted and change in condition and treatment provided discussed. Call documented in resident's chart. — 1/23/2014

On all charts with MOST forms, the MOST Form and Physician Orders (written after January 1, 2014) will be reviewed by Nursing Staff for evidence that orders written for a change in residents medical status have correlating documentation of notification of legal representative. If Physician orders for medical change are noted without documentation of notifying legal representative, the Physician will provide immediate follow up. — 2/21/2014

New policy (MED048) written "Notification of Changes in Resident Medical Status" which outlines a systematic process to prevent recurrence of deficient practice, to inform the resident's legal representative when there is: — 2/21/2014
* An incident/accident resulting in injury
* Acute illness or significant change in resident's physical, mental, or psychosocial status
*A need to alter treatment significantly
*A decision to transfer or to discharge the resident
*A situation/condition in which the resident/family/legal representative has requested notification or
*When it is necessary to discuss scope of treatment with the resident's legal representative

Procedure:
A. Notifications to legal representatives/family members/significant others shall be made in accordance with confidentiality rules and regulations governing state owned and operated facilities and directives of the competent resident, family, legal representative regarding notifications.
B. Notification of legal representative should be documented in the medical record by the health care professional providing the information.
C. Discussion of general medical conditions, gradual decline or routine review of scope of treatment should occur through the care planning process and be reviewed with the legal representative through the routine care plan process.

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Lauri Hollingsworth
TITLE: Facility Director
(X6) DATE: 1.21.14

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F 157	Continued From page 1 member of a significant change in condition which required antibiotic therapy for 1 of 3 sampled residents with a significant change in condition (Resident #36). The findings included: Resident #36 was admitted to the facility on 10/09/12 with diagnoses which included profound intellectual disability. Review of Resident #36's Medical Orders for Scope of Treatment form dated 04/01/13 revealed the use or limitation of antibiotics would be determined when an infection occurred. This form was signed by Resident #36's family member who was also the Resident's legal guardian. Review of Resident #36's quarterly Minimum Data Set dated 10/24/13 revealed an assessment of severely impaired decision making ability with a life expectancy of less than 6 months. Review of a nursing note dated 01/07/14 revealed Resident #36's temperature was 102 degrees Fahrenheit with agitated behavior. The physician received notification. Review of telephone physician's orders dated 01/07/14 at 8:00 PM revealed direction to administer Levaquin (antibiotic) 750 milligrams (mg.) for one dose and obtain a chest x-ray. Review of Nurse Practitioner's orders dated 01/09/14 revealed direction to administer Levaquin 500 mg. daily for 7 days for possible pneumonia.	F 157	D. Changes in resident's medical status which has direct and immediate implications for scope of treatment (MOST/DNR) will be communicated by the physician/physician extender. E. During regular business hours it is the Physician/Physician Extender's responsibility to advise the legal representative of a significant medical change. Medical interventions after hours or transfers to the hospital will be communicated and documented by the nurse with any needed follow-up by the Physician/Physician Extender as needed. F. Efforts should be made to reach the legal representative as soon as practical when there is any change in medical status of a nature which falls under the purview of this policy. The expectation is that this would occur within the 8-hour shift in which medical changes occur. If medical staff is unable to contact the legal representative this will be communicated to the social worker on the unit who will continue to attempt to contact legal representative as outlined in ADM 68. Policy reviewed and approved in Medical Meeting 2/10/2014, BMNTC Physicians Dr. Jolley and Dr. Moomaw, & Cathy Rankine, DON present at meeting. Dr. Jolley met with and reviewed new "Notification Policy" with Susan Casar, PE, upon her return to work. Executive Committee to approve policy on 2/12/2014 and DON to inservice all Nursing Staff.. * Policy revision for additional clarification of staff responsible related to notification of legal representative when a resident has significant medical change. Revision approved by Executive Committee on 2/21/2014. Revisions inserviced to all physicians and nurses. Medical Director/designee and DON/designee will attend "Quality Events Report Meeting" every weekday morning at 8:30 for the next 12 months along with Facility Director, Assistant Director, Program Director and Quality Assurance Director to review and discuss changes in resident's physical, mental or psychosocial status, scope of treatment and how communication with resident's legal representative occurred. Changes that occur on a weekend or holiday will be reviewed and discussed as above on the next business day.	2/12/2014 2/21/2014 2/14/2014

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F 157	Continued From page 2 Telephone interview with Resident #36's family member and legal guardian on 01/23/14 at 10:56 AM revealed the facility did not notify him of Resident#36's possible pneumonia and order for antibiotic therapy. The family member reported he did not know if he would have agreed to antibiotic therapy but wanted to be informed and consulted when Resident #36 became ill. Interview with Nurse #1 on 01/23/14 at 11:29 AM revealed the physician or nurse practitioner would notify family members when a resident condition changed. Nurse #1 did not know if Resident #36's family member received notification of the possible pneumonia and antibiotic therapy. Interview with the Nurse Practitioner (NP) on 01/23/14 at 12:34 PM revealed she did not notify Resident #36's family member. The NP explained she was not in the facility at the time the significant change or orders for treatment occurred. Interview with the acting Director of Nursing on 01/23/14 at 1:35 PM revealed Resident #36's family member should receive notification of the significant change in condition but did not know who was responsible for the notification. Interview with the Quality Assurance (QA) Director on 01/23/14 at 1:48 PM revealed the medical staff notified family members and legal representatives when a significant change occurred. The QA Director explained there was no written policy which designated responsibility of notification. Interview with the Medical Director on 01/23/14 at	F 157	Medical Director/designee and DON/designee will perform routine weekly chart audits for the next 12 months to identify if documentation is present reflecting communication with legal representative about significant change in resident status and scope of treatment. A Quality Assurance Performance Improvement (QAPI) objective will be initiated to assure that resident/legal representative will be contacted 100% of the time to discuss changes to resident status and treatment as applicable. Review of objective will occur at least quarterly with QAPI Team in Executive Committee for 1 year and then reevaluated.	2/14/2014 2/14/2014

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F 157	Continued From page 3 2:03 PM revealed the facility's medical staff notified family members of significant changes unless the change occurred after work hours or on weekends. The Medical Director reported Resident #36's family member should have received notification of the condition change and order for antibiotics.	F 157		
F 431 SS=D	483.60(b), (d), (e) DRUG RECORDS, LABEL/STORE DRUGS & BIOLOGICALS The facility must employ or obtain the services of a licensed pharmacist who establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled. Drugs and biologicals used in the facility must be labeled in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions, and the expiration date when applicable. In accordance with State and Federal laws, the facility must store all drugs and biologicals in locked compartments under proper temperature controls, and permit only authorized personnel to have access to the keys. The facility must provide separately locked, permanently affixed compartments for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse, except when the facility uses single unit	F 431	Once identified, the two inaccurately filled Lacosamide (Vimpat) oral syringes were removed from theR1 floor stock and replaced with accurately filled syringes.	1/22/2014
			Once the initial error was identified, all remaining pre-filled Lacosamide syringes in the R1 floor stock were inspected for accuracy. No other errors were found. No other Unit currently uses this product.	1/22/2014
			To ensure that the deficient practice does not reoccur, Pharmacy Services will implement the following corrective measures: G) All manually filled control syringes of will be inspected by a second Pharmacy staff member to ensure accuracy prior to being labeled.	2/14/2014
			H) After this second inspection, the syringes will be properly labeled with both the volume and strength dispensed.	2/14/2014
			I) Once labeled, a tamper-resistant seal will be placed on each syringe.	2/14/2014
			J) A compounding log record, containing both the initials of the staff member who filled the syringes and who inspected the syringes will be kept for inspection.	2/14/2014
			K) Upon requisition, the Pharmacy will deliver to the Unit Nurse. With his/her signature on the Control Substance sign-out sheet, the Nurse verifies that the correct quantity has been delivered, that each pre-filled syringes is accurately filled as labeled, and that every tamper-resistant seal is intact.	2/14/2014

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F 431	Continued From page 4 package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected. This REQUIREMENT is not met as evidenced by: Based on observations and staff interviews the facility failed to accurately ensure the correct volume for in-house pharmacy prefilled syringes of a controlled medication in 1 of 5 controlled medication drawers. The findings included: On 01/22/14 at 3:40 PM, an observation of the controlled medication drawer in the medication storage room on R1 Unit revealed a plastic bag with 10 syringes labeled lacosamide (Vimpat) 200 milligrams (mg) / 20 milliliters (mL); an anti-epileptic seizure medication. In the bag, 2 of the syringes were noted to have less than the 20mL volume. One syringe had a volume of 17ml and the second syringe had a volume of 18mL. On 01/22/14 at 3:42 PM, an interview was conducted with Nurse #2. She stated when the pharmacist brought controlled medications to the unit the pharmacist would sign the requisition verifying the number of syringes being delivered and the unit nurse would sign the requisition verifying the number of filled syringes with the controlled medication was received from the delivering pharmacist to the unit. She further stated neither the pharmacist nor the unit nurse would verify the volume amount in each syringe, only the number of syringes received. She indicated in shift change two unit nurses were	F 431	L) Nursing will continue to count quantities shift-to shift as before, however, the syringes should be inspected to ensure the tamper-resistant seals are intact. If a seal is found broken, the Nursing Supervisor and Director of Pharmacy should be immediately notified. M) As always, the final check for accuracy of volume of the syringe will be done by the Nurse prior to administration. N) All pharmacy and nursing staff will be inserviced on review of procedure; A Quality Assurance Performance Improvement objective will be initiated with a goal that 100% of the time all controlled substance syringes will have the correct volume present. This corrective measure will be monitored by the following: A) The double-check during the syringe filling process and recorded in the compounding log. B) The Nurse receiving the pre-filled syringe will inspect for accurately filled syringes and only sign for such on the Control Substance sign-out sheet. C) At the time of administration, the Nurse will make a final inspection of the syringe that the volume of the medicine is the correct volume being administered. This will be recorded in the MAR. Review of objective will occur at least quarterly with QAPI Team in Executive Committee for 1 year and then reevaluated.	2/14/2014 2/14/2014 2/14/2014 2/14/2014

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F 431	Continued From page 5 responsible for counting the medications in the controlled medication drawer and were verifying the number of syringes in the drawer and not the volume in the syringes. Nurse #2 verified the 2 syringes did not contain the 20mL volume amount as indicated on the label of the controlled medication, lacosamide. On 01/22/14 at 3:51 PM, an interview was conducted with Pharmacist #1. She stated the number of controlled medication syringes was counted when delivered to the unit by the pharmacist and was counted a second time with the unit nurse. She further stated the volume amount in each syringe would be verified by the pharmacist before delivering the controlled medication to the unit. She verified the label on the lacosamide syringes should have a total volume of 20mL in each syringe. She further verified one syringe had a volume of 17mL and the other syringe had a volume of 18mL of lacosamide. She revealed the syringes should not have been delivered from pharmacy with less than the 20mL of volume as indicated on the medication syringe. On 01/24/14 at 11:15 AM, an interview was conducted with the Pharmacy Director. He demonstrated the steps that would be taken when an order for a controlled medication requisition was received and how the pharmacist would fill the syringes. He revealed the controlled medication syringes would be counted by the pharmacist and the number of syringes ordered would be delivered to the unit with the order requisition. He further revealed the pharmacist would count the number of syringes delivered to the unit and sign his/or her name at the top of the requisition for verification and the unit nurse	F 431		

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F 431	Continued From page 6 would sign the top of the requisition verifying the number of syringes received to the unit. He stated a pharmacist would verify the volume in the syringe when the syringe was being filled with the controlled medication and labeled accordingly. He further stated the actual volume in the medication syringes would not be counted by the delivering pharmacist or the unit nurse. He indicated there was no expectation for the pharmacy department and/or the nursing units to count the volume of controlled medication in the syringes. He further indicated he was unaware of a system for volume count of controlled medication in syringes. On 01/24/14 at 12:01 PM, an interview was conducted with the Quality Assurance Director. She stated she was unaware of a policy and procedure and/or a system in place for volume count of controlled medication in syringes and/or the dispensing of controlled medications.	F 431		