

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

PRINTED: 06/19/2015
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 34A001	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 05/21/2015
NAME OF PROVIDER OR SUPPLIER BLACK MOUNTAIN NEURO-MEDICAL TREATMENT CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 932 OLD US HIGHWAY 70 BLACK MOUNTAIN, NC 28711		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
F 431 SS=D	<p>483.60(b), (d), (e) DRUG RECORDS, LABEL/STORE DRUGS & BIOLOGICALS</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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 package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.</p> <p>This REQUIREMENT is not met as evidenced by: Based on observations and staff interview the</p>	F 431	All four identified eye drop bottles were	6/11/15	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Electronically Signed

06/11/2015

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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F 431	<p>Continued From page 1</p> <p>facility failed to label 4 bottles of eye drops on 4 of 10 medication carts with the date the medication was opened and put in use and failed to remove those drops from the medication carts after they had been in use 42 days, as recommended by the manufacturer. (Medication carts: Gravely #1, Raspberry #2 East, Raspberry #3 East and Raspberry #3 West). The findings included:</p> <p>Review of manufacturer recommendations for Xalatan and Lumigan eye drops revealed the ophthalmic solution should not be used more than 42 days after opening.</p> <p>1. Observation of the Raspberry #2 East Medication Cart on 05/19/15 at 3:03 PM revealed it contained a bottle of Xalatan (a medicated eye drop used to treat glaucoma) eye drops with a pharmacy label that indicated it was dispensed on 11/20/14 for Resident #135. The bottle was opened and currently in use. There was no date on the bottle to indicate when it was opened and put into use. A manufacturer stamp on the bottle indicated an expiration date of November 2015.</p> <p>An interview on 05/19/15 at 3:22 PM with Nurse #1 revealed Resident #135 was still receiving the Xalatan eye drops. Nurse #1 was asked if she had a reference tool for expiration dates or knew how long the Xalatan could remain in use after it was opened. Nurse #1 stated she didn't know how long the Xalatan eye drops could remain in use after opening and she didn't have a reference tool as far as she knew. Nurse #1 was asked if staff were expected to label multidoses containers when they were opened and she stated the nurse who opened the container of eye drops should have labeled the bottle with the date it was opened. Nurse #1 was asked if she knew when</p>	F 431	<p>immediately discarded when discovered by Surveyor on 5/19/15 & 5/21/19. New and unopened bottles of ordered eye drops were immediately requisitioned when deficiency noted and refilled by Pharmacy on 5/20/19 and 5/21/19. Nurses administering eye drops from new eye drop bottles documented date and their initials when new bottles opened. Completion Date 5/21/15.</p> <p>All other eye drops and open multi-dose medication bottles in all ten medication carts were checked by Nursing for date and Nurse initial indicating when bottle first opened. No other multi-dose bottles of any other medication were found to be without a date and/or initials. Completion Date 5/22/15.</p> <p>Pharmacy also completed an inspection of all medication carts and removed and properly wasted any product found with date written on label that was past expiration date or a questionably old product with no date. Completion Date 5/28/15.</p> <p>Nursing supervisors met with all Nursing staff and provided in-service review of mandatory documentation of date and Nurse's initials when any multi-dose bottle is opened for the first time and to follow discard dates per Pharmacy. Completion Date 6/11/15.</p> <p>All multi-dose bottles of Ophthalmics will be discarded after 30 days, or as recommended by manufacturer, after</p>		

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F 431	<p>Continued From page 2</p> <p>the Xalatan was opened and she stated she didn't know.</p> <p>2. Observation of Raspberry #3 East Medication Cart on 05/19/15 at 3:45 PM revealed it contained a bottle of Lumigan (a medicated eye drop used to treat glaucoma) eye drops with a pharmacy label that indicated it was dispensed on 03/06/15 for Resident #120. The bottle was opened and currently in use. There was no date on the bottle to indicate when it was opened and put into use. A manufacturer stamp on the bottle indicated an expiration date of October 2016.</p> <p>An interview on 05/19/15 at 3:52 PM with Nurse #2 revealed Resident #120 was still receiving the Lumigan eye drops. Nurse #2 was asked if she had a reference tool for expiration dates or knew how long the Lumigan could remain in use after it was opened. Nurse #2 stated she didn't know how long the Lumigan eye drops could remain in use after opening and she stated she didn't have a reference tool as far as she knew. Nurse #2 was asked if staff were expected to label multidose containers when they were opened and she stated the nurse who opened the container of eye drops should have labeled the bottle with the date it was opened. Nurse #2 was asked if she knew when the Lumigan eye drops were opened and she stated she didn't know.</p> <p>3. Observation of Raspberry #3 West Medication Cart on 05/19/15 at 3:50 PM revealed it contained a bottle of Xalatan eye drops with a pharmacy label that indicated it was dispensed on 03/12/15 for Resident #90. The bottle was opened and currently in use. There was no date on the bottle to indicate when it was opened and put into use. A manufacturer stamp on the bottle indicated an</p>	F 431	<p>being opened. Completion Date 5/21/15.</p> <p>Reference cards placed on the front of all Medication Administration Records and include:</p> <ol style="list-style-type: none"> 1) reminder and prompt for Nurses to date and initial any multi-dose medications when opened 2) to discard all eye drops 30 days after opening 3) to discard all insulin vials 28 days after opening 4) to discard all other liquid medications per manufacturer's expiration date. <p>Completion Date 6/3/15.</p> <p>Nurses to inform the MD/PA of residents who consistently refuse their eye drops, MD/PA will assess individual residents and decide whether to try and continue eye drops or not based on Medical history/need. Eye drops for two residents have been discontinued because of continuous refusals. Completion Date 6/3/15.</p> <p>Pharmacy has added the following to their Monthly Medication Cart Review Checklist: "_____ Eye Drops dated when opened and discarded after 30 days of being opened". Completion Date 6/3/15.</p> <p>As per Medical Procedure 23 "Emergency Equipment", Unit Nursing staff will monitor eye drops and all multi-dose bottles of medication on a weekly basis to ensure date and Nurse's initials are on any opened bottle and will discard any eye drops found in cart 30 days after being</p>		

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F 431	<p>Continued From page 3 expiration date of December 2015.</p> <p>An interview on 05/19/15 at 3:52 PM with Nurse #2 revealed Resident #90 was still receiving the Xalatan eye drops. Nurse #2 was asked if she had a reference tool for expiration dates or knew how long the Xalatan could remain in use after it was opened. Nurse #2 stated she didn't know how long the Xalatan eye drops could remain in use after opening and she didn't have a reference tool as far as she knew. Nurse #2 was asked if staff were expected to label multidose containers when they were opened and she stated the nurse who opened the container of eye drops should have labeled the bottle with the date it was opened. Nurse #2 was asked if she knew when the Xalatan eye drops were opened and she stated she didn't know.</p> <p>4. Observation of Gravelly #1 Medication Cart on 05/21/15 at 9:30 AM revealed it contained a bottle of Lumigan eye drops with a pharmacy label that indicated it was dispensed on 01/26/15 for Resident #12. The bottle was opened and currently in use. There was no date on the bottle to indicate when it was opened and put into use.</p> <p>An interview on 05/21/15 at 10:05 AM with Nurse #3 revealed Resident #12 was still receiving the Lumigan eye drops. Nurse #3 stated she was unaware there was a limitation on how long the medication could be used after opening. Nurse #3 was unable to state when the bottle was opened and put into use and stated it probably was within 3 to 7 days of when it was dispensed.</p> <p>An interview on 05/21/15 at 8:25 AM with the Pharmacy Director about the manufacturer guidelines for Lumigan and Xalatan eye drops</p>	F 431	<p>opened. Completion Date 6/11/15.</p> <p>Second shift Nursing Supervisor will also monitor all bottles of eye drops for Nurse initials and date on a weekly basis. Completion Date 6/3/15.</p> <p>Quality Assurance Performance Improvement Objective will be added to Black Mountain Neuro-Medical Treatment Center's Operational plan: No open eye drops or multi-dose medication bottles will be found on medication carts without Nurse initials and dates indicating when bottle was opened 100% of the time. Completion Date 6/3/15.</p>		

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F 431	<p>Continued From page 4</p> <p>and how long they can be used after opening revealed they can be used for 6 weeks after opening. When asked if the nurses should be labeling the bottle when it was opened, he stated: "that would be a good idea." He stated the eye drops can't be guaranteed sterile beyond 6 weeks after opening.</p> <p>An interview on 05/21/15 at 9:08 AM with Nursing Supervisor #1 about the facility policy or expectation for dating insulin containers or eye drops when they are opened revealed the nurses are expected to date the containers when they are opened. NS #1 was asked about Xalatan & Lumigan eye drops and how long they could remain in use after being opened and she stated she thought it was 6 weeks but she would have to call Pharmacy to be sure. NS #1 was asked if the nurses had a reference guide with expiration dates for insulin and eye drops after they were opened and she stated she was not aware of a reference guide. NS #1 was asked about her expectation for discarding medications that were in use past their expiration date and she stated she expected the medications to be put in the tray and returned to Pharmacy.</p> <p>An interview on 05/21/15 at 9:32 AM with the Director of Nursing (DON) about her expectation for labeling and dating eye drops when they were opened revealed she expected the nurses to label the bottle with the date it was opened & their initials. The DON was asked if there was any reference tool for the nurses to use for expiration dates on how long medications could be used after opening and she stated there wasn't a reference guide but pharmacy staff monitored the dates monthly.</p>	F 431			