

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

PRINTED: 06/30/2015
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 345341	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED C 06/04/2015
NAME OF PROVIDER OR SUPPLIER SILVER BLUFF INC			STREET ADDRESS, CITY, STATE, ZIP CODE 100 SILVER BLUFF DRIVE CANTON, NC 28716		
(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	The Mucinex, Latanoprost ophthalmic	6/25/15	

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

TITLE

(X6) DATE

Electronically Signed

06/25/2015

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 remove expired or out of date medications from 2 of 5 medication carts and 1 of 2 medication refrigerators and failed to ensure that Over the Counter (OTC) medications had a manufacturer expiration date on the label. (100 and 300 hall medication carts and Central medication storage room refrigerator). The findings included:</p> <p>Review of manufacturer recommendations for Latanoprost eye drops revealed the ophthalmic solution should not be used more than 42 days after opening.</p> <p>1. Observation on 06/03/15 at 1:58 PM of the 300 Hall Medication Cart revealed 1 bottle of Mucinex 600 milligrams (mg) #500 with approximately half the tablets remaining in the bottle with a manufacturer expiration date of March 2015. The bottle was marked with 2 asterisks after the expiration date and "Please Note" was written on the bottle.</p> <p>An interview on 06/03/15 at 2:13 PM with Nurse #1 about who was responsible for checking expiration dates of medications on the medication cart revealed the nurse working the 11:00 PM to 7:00 AM shift is assigned to check the expiration dates of medications once a week and all the nurses are responsible for checking expiration dates on bottles when they administer medication. Nurse #1 was asked if she had any resident who was currently receiving Mucinex. Nurse #1 stated she just received an order today for Mucinex for a resident and it was scheduled to be started tonight. Nurse #1 confirmed the Mucinex was available for use.</p> <p>2. Observation on 06/03/15 at 2:19 PM of the 100</p>	F 431	<p>solution, Influenza vaccine vial, and the expired Biscacodyl suppositories were immediately removed and discarded. The Catalyn and FerroFood were removed from the cart and replaced with bingo cards with the expiration date on the card. Additionally, the Bisacodyl suppositories were separated by expiration date and placed in individual Ziploc bags by expiration date. The multi-dose box was discarded. Although a procedure for routine inspection of med carts and med rooms was in place for checking labeling and expiration dates, it failed to identify these items on two out of six carts and one out of two med rooms.</p> <p>A mandatory in-service was conducted for licensed nurses to review the role of each nurse and each shift in assuring that: (1) medications are labeled correctly with expiration date, (2) that the nurse labels any multi-dose vial/package with expiration date after opening, and (3) that all items are discarded no later than the date of expiration. The nurses were also instructed on the new sign off procedures (see attached in-service log).</p> <p>A new sign off sheet was implemented for each cart and the med rooms that requires each nurse, each shift will monitor the cart and sign off that they have checked all items and that all items are within date and labeled correctly. The Charge Nurse on each shift is to check the med room and sign off that this has been done (see attached). After implementing this process, it was</p>		

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F 431	<p>Continued From page 2</p> <p>Hall Medication Cart revealed a 2.5 milliliter (ml) bottle of Latanoprost ophthalmic solution 0.005% with a date opened label of 04/07/15 and a manufacturer expiration date of July 2016 which was labeled for a specific resident. The bottle was approximately 1/3 full.</p> <p>An interview on 06/03/15 at 2:48 PM with Nurse #2 about whether or not the Latanoprost was still in use by the resident revealed the medication was still in use. Nurse #2 was asked if he had a reference guide that specified how long medications could remain in use after opening and he checked the front of the controlled substances sign-out book and located a facility reference guide. The reference guide listed Xalatan (Latanoprost) as good for 6 weeks from the date it was opened. Nurse #2 was asked who was responsible for checking expiration dates of medications and he stated he checked the expiration dates when he removed the medication from the medication cart for administration. Nurse #2 offered no explanation for why the ophthalmic solution remained in use.</p> <p>3. a. Observation on 06/03/15 at 2:19 PM of the 100 Hall Medication Cart revealed a bottle labeled "Catalyn" which contained Vitamin A 1200 international units (IU), Vitamin C 4 milligrams (mg), Vitamin D 312 IU, Thiamine 0.2 mg, Riboflavin 0.2 mg and Vitamin B-6 1 mg and the label indicated it contained 360 tablets. The bottle was almost full and a specific resident's name was written on the bottle cap. There was no manufacturer's expiration date on the bottle.</p> <p>3.b. Also, in the 100 Hall Medication Cart was a bottle labeled "Ferrofood" which contained Vitamin C 30 mg, Vitamin B-12 1.7 micrograms (mcg) and Iron 10 mg and the label indicated it</p>	F 431	<p>determined the med room form should be revised. (see attached) This monitoring schedule will continue until the Q.A. Committee determines whether a less frequent schedule can be implemented.</p> <p>The pharmacy was made aware of the expired items that were missed and they have done remedial training with their nurse to ensure that their monthly checks do not miss any out of date items. Pharmacy will continue to send a nurse monthly to check med carts and med rooms (see attached).</p> <p>The nurse managers will do an additional check once a week to make sure that not only are these measures in place but that they are accurate (see attached). The Q.A. Committee will review the documentation every two weeks for a minimum of 8 weeks, then monthly for a minimum of 4 months, to ensure that the new procedures are effective. The Q.A. Committee will continue to monitor the process until it is determined that the new procedure has become routine and that no deficient practices still exist. The Q.A. Committee will then monitor P.R.N.</p>		

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F 431	<p>Continued From page 3</p> <p>contained 150 tablets. The bottle was almost full and had a specific resident's name written on the bottle cap. There was no manufacturer's expiration date on the bottle.</p> <p>An interview on 06/03/15 at 2:48 PM with Nurse #2 about whether the resident was receiving Catalyn and Ferrofood revealed the resident was receiving the medications. Nurse #2 stated the vitamin supplements were supplied by the resident's family and he didn't realize the bottles didn't have an expiration date on them. Nurse #2 was asked who was responsible for checking expiration dates of medications and he stated he checked the expiration dates when he removed the medication from the medication cart for administration.</p> <p>4. Observation on 06/03/15 at 3:13 PM of the Central Medication Storage Room refrigerator revealed a box of Bisacodyl suppositories which contained 8 Bisacodyl 10 milligrams (mg) suppositories with an expiration date of March 2014 which were stored in a box with other Bisacodyl 10 mg suppositories with various expiration dates of August 2015, January, March, July, September, October and December 2016 and March and July 2017. Also, stored in the refrigerator was one 5 milliliter (ml) vial of influenza vaccine afluria with no date opened sticker; approximately half the vial was left. The manufacturer expiration date was 06/30/15.</p> <p>An interview on 06/03/15 at 3:42 PM with Nurse #3 about the expectation for labeling of multidose vials revealed the nurse who opened or first used the vial should label it with the date it was opened. When asked if the Bisacodyl suppositories were available for use for residents,</p>	F 431			

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F 431	<p>Continued From page 4</p> <p>Nurse #3 confirmed that they were. Nurse #3 stated the expired suppositories should have been discarded. When Nurse #3 was asked how long the influenza vaccine could remain in use after opening, she stated: "I'm not sure but I think it is good until the expiration date on the vial. Review of the package insert with Nurse #3 revealed the vial could remain in use for 28 days after opening.</p> <p>An interview on 06/04/15 at 2:47 PM with the Director of Nursing (DON) about the facility's process for checking for expired meds revealed the pharmacy consultant gave her a report on 05/27/15 that indicated all the medication carts had been checked and there were no expired medications. The DON stated every nurse administering medications from the medication cart should be checking for expiration dates and labeling of multidose containers. The DON stated the nurse who works 11:00 PM to 7:00 AM is responsible for checking every medication cart once a week. The DON was asked about her expectation for expired meds and she stated she expected them to be removed from the medication cart and she expected all the nurses to be checking the expiration dates of medications.</p>	F 431			