

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

PRINTED: 09/21/2015
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 345358	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED C 08/27/2015
NAME OF PROVIDER OR SUPPLIER LOUISBURG NURSING CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 202 SMOKETREE WAY LOUISBURG, NC 27549		
(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 000	INITIAL COMMENTS There were no deficiencies cited as a result of this complaint investigation survey of 08/27/15. Event ID #HZ1611.	F 000			
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 package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.	F 431		9/5/15	

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

TITLE

(X6) DATE

Electronically Signed

09/08/2015

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	Continued From page 1 This REQUIREMENT is not met as evidenced by: Based on observation, record review and staff interviews the facility failed to store medications at recommended temperatures for 1 of 1 medication refrigerators. Findings included: Review of the Refrigerator Medication Room Record for August 2015 showed 16 of 26 recorded temperatures below 35 degrees. Review of the Tuberculin Purified Protein Derivative (PPD) manufacturer instructions revealed under Storage: "Store at 2 degrees to 8 degrees C (Celsius) (35 degrees to 46 degrees F (Fahrenheit). Do not freeze (bold letters). Discard product if exposed to freezing." Review of the United States Food and Drug Administration literature revealed "According to the product labels from all three U.S. insulin manufacturers, it is recommended that insulin be stored in a refrigerator at approximately 36°F to 46°F. Avoid freezing the insulin. Do not use insulin that has been frozen." Review of the Medication Guide for Forteo showed the medication should be kept "in the refrigerator between 36 to 46 F. Do not freeze ...Do not use Forteo if it has been frozen." Review of the Vaccine Storage Temperatures showed Hepatitis B and pneumococcal vaccines should be "stored at 35-46 degrees. Irreversible loss of potency occurs with exposure to freezing temperatures." Review of the undated Refrigerator Temperatures Policy revealed, "Refrigerator temperatures will be monitored to ensure (they are) maintained at proper range for medications, labs, or food." In an observation on 08/26/15 at 4:05 PM the	F 431	F431 Standard Disclaimer: This plan of correction is provided as a necessary requirement of continued participation in the Medicare and Medicaid program(s) and does not, in any manner, constitute an admission to the validity of the alleged deficient practice. The Medication Room refrigerator has been replaced with a new unit on August 27, 2015 prior to DHSR Survey Team exit. Licensed Nursing Staff have been instructed on appropriate refrigerator temperatures and updated log has been implemented with temperature range noted on log. The 11-7 Licensed Nurses check refrigeration temperatures q night and report any variances noted to DON in AM. The DON, and/or Administrator shall ensure compliance by randomly monitoring refrigerator temps on a weekly basis x 4 weeks and monthly thereafter to ensure compliance with storage of refrigerated medications. Any identified discrepancies shall be remediated. The plan of correction for this alleged deficient practice shall be included as an addendum to the facility's most recent		

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F 431	Continued From page 2 thermometer in the medication refrigerator read 30 degrees. The medication refrigerator contained an injectable pen of Forteo (a medication for osteoporosis), a vial of Tuberculin Purified Protein Derivative, multiple vials of different insulins, multiple vials of hepatitis B vaccine, and multiple vials of pneumonia vaccine. In an interview on 08/26/15 at 4:10 PM the Director of Nursing (DON) stated the Pharmacist Consultant had pointed out to her the previous week that the refrigerator temperature was too low. The DON indicated the Pharmacist Consultant informed her the medications may need to be discarded or returned to the pharmacy. She indicated neither of these actions was done. The DON stated it was the responsibility of the 11-7 nurses to record the medication refrigerator temperatures. In a telephone interview on 08/26/15 at 4:22 PM the Consultant Pharmacist stated she had been at the facility last Thursday (8/20/15). She indicated she told the DON that 32 degrees was considered freezing. She indicated medications should be kept between 36-46 degrees. The Consultant Pharmacist stated medications that had been frozen should not be used. In an observation on 08/26/15 at 4:55 PM the medication refrigerator temperature was 30 degrees. In an interview on 08/26/15 at 4:56 PM the Administrator stated the interior freezer door on the medication refrigerator had broken off approximately 2 weeks ago. She indicated another refrigerator was on order but had not yet arrived. In a telephone interview on 08/26/15 at 5:15 PM the Pharmacist Consultant stated Forteo, insulins, vaccines, and tuberculin PPD should not be frozen. She indicated the medications should be	F 431	Quality Assurance Committee meeting minutes. Additionally, the Administrator and/or DON shall report any episodes of non-compliance with storage of refrigerated medications identified to Quality Assurance Committee monthly for three months and then quarterly thereafter.		

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F 431	Continued From page 3 sent back to the pharmacy. In a telephone interview on 08/27/15 at 5:05 AM Nurse #1 who worked the 11-7 shift, stated the purpose of recording the medication refrigerator temperatures was to make sure medications were stored within the correct ranges. She indicated medications should be stored between 34-46 degrees. She indicated the interior freezer door had been missing from the refrigerator for about one month. She indicated over the last month the temperature readings had not been accurate. Nurse #2 stated if the thermometer was left on the glass shelf the temperature would read lower. She indicated she had not informed the DON or the pharmacy that the medication refrigerator temperatures could not be maintained. In a telephone interview on 08/27/15 at 5:15 AM Nurse #2 who worked the 11-7 shift, stated she now knew the medication refrigerator temperatures should be 36-46 degrees. Prior to the night before she thought the temperatures should just be above 32 degrees. She indicated she did not inform anyone when the refrigerator temperatures were out of range as she had never written an out of range temperature on the log.	F 431			