STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	345433	A. BUILDING _____ B. WING _____	C 11/04/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CLAY COUNTY CARE CENTER	**86 VALLEY HIDEAWAY DRIVE HAYESVILLE, NC 28904**

(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 No deficiencies were cited as a result of the complaint investigation Event ID # FNBP11.	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		11/28/16

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

Electronically Signed | 11/22/2016

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F 431	Continued From page 1 This REQUIREMENT is not met as evidenced by: Based on observations, record review, staff interviews, manufacturer specifications, and facility policy, the facility failed to follow manufacturer's specifications to discard one opened Humalog and one opened Novolog vial that were kept at room temperature for over 28 days from 1 of 4 medication carts. Findings included: Manufacturer specifications for Humalog per the package insert included, "In-use Humalog vials should be stored at room temperature, below 86° Fahrenheit (F) and must be used within 28 days or be discarded, even if they still contain Humalog." Manufacturer specifications for Novolog per the package insert included, "Novolog lasts up to 28 days without refrigeration after first use. Once in use, Novolog must be kept at room temperature below 86°F for up to 28 days. Opened Novolog vials should be thrown away after 28 days, even if they still have insulin left in them." A review of the facility's Medication Storage Policy dated 01/01/13 indicated "The facility should ensure that all medications and biologics have not been retained longer than recommended by manufacturer or supplier guidelines. Once any medication is opened, the facility should follow manufacturer/supplier guidelines with respect to expiration dates for opened medications. The facility should destroy or return all outdated/expired medications in accordance with Pharmacy return/destruction guidelines and other applicable law." During an observation on 11/02/16 at 3:48 PM, an opened vial of Humalog marked with an open	F 431	Two bottles of insulin were removed immediately from the cart by the licensed nurse. All medication/treatment carts were checked for expired insulin/medications on 11-2-2016 by the Director of Clinical Services. The Director of clinical Services in serviced licensed staff 11-2-2016 thru 11-18-2016, regarding checking for expiration dates and dating of all medications. Director of Clinical Services and/or Nursing supervisor will provide Quality Improvement Monitoring for expired medications three times a week for one month, then two times weekly for one month, then one time a week for one month and then monthly thereafter for one year. The results of the Quality Monitoring will be reported to the Quality Assurance Performance Improvement Committee monthly by the Director of Clinical services. The Quality Assurance Performance Improvement Committee members consists of but not limited to the Executive Director, Director of Clinical Services, Unit Manager, Staff Development, Activities, Medical Director, Social Services, Maintenance Director, Dietary Manager and the MDS nurse	

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F 431	Continued From page 2	F 431		

date of 09/02/16 and a manufacturer expiration date of 09/30/17 and an opened vial of Novolog marked with an open date of 09/07/16 and a manufacturer expiration date of 04/30/18 were found in medication cart #2. Nurse # 1 confirmed that both insulin vials were for Resident #23.
Review of the physician orders dated 06/01/14 indicated Resident #23 was prescribed sliding scale Humalog injected subcutaneously before meals and at bedtime for diagnosis of Diabetes Mellitus (DM). Review of a physician order dated 02/24/16 indicated Resident #23 was also prescribed scheduled Novolog injected subcutaneously 10 units with breakfast, 5 units with lunch and supper. Hold if capillary blood glucose (CBG) was below 100.
Review of the Medication Administration Record (MAR) for Resident #23 indicated that both mentioned insulins were administered as ordered by the nursing staff from 09/01/16 through 11/02/16. Review of Resident #23's CBG from 09/01/16 through 11/02/16 revealed that her CBGs had remained at the baseline. No significant changes in CBG had been observed from September to October 2016.
In an interview conducted on 11/02/16 at 3:48 PM, Nurse #1 admitted that she had administered both outdated insulins to Resident #23 on 11/02/16 for the morning and noon doses. Nurse #1 stated that both insulins should be dated when opened and they should have been discarded from the medication cart at the time of expiration or after 28 days. Nurse #1 acknowledged that both insulins were outdated and they should be removed from the medication cart.
In an interview conducted on 11/02/16 at 3:58 PM, the Director of Nursing (DON) stated that the Unit Manager was responsible for checking all the expired/outdated medications in medication cart

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F 431	Continued From page 3 at least once every week. However, nursing staff who administered medications from the medication cart were expected to check for expired/outdated medication each time before administration. The DON indicated her expectation was for all unopened insulins to be stored in the medication store room refrigerator until they were needed on the medication cart. Once an insulin was opened, it should be dated. The DON specified that the facility's policy was to discard opened vials of Humalog and Novolog insulin 28 days from the date opened in accordance with the manufacturer's recommendations. In an interview conducted on 11/04/16 at 9:13 AM, the Administrator stated the Unit Manager who was responsible for checking expired/outdated medications left 2 weeks ago. The Administrator agreed that the above mentioned outdated insulins should be discarded.	F 431		