STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	345001	A. BUILDING _____ B. WING _____	04/07/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HILLCREST CONVALESCENT CENTER	1417 W PETTIGREW STREET DURHAM, NC 27705

(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	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. This REQUIREMENT is not met as evidenced by: Based on observations, record review, and staff	F 431	This plan of correction constitutes	4/18/16

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

Electronically Signed | 04/28/2016

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 interviews, the facility did not maintain medication refrigerator temperatures per the guidelines by the insulin manufacturers in 2 of 2 medication refrigerators observed, compromising the integrity of the insulins. Findings included: On 04/07/2016 at 2:08 PM, a tour of the medication storage room located on "Pinehurst Place" was made with Nurse #1. A review of the Refrigerator Temperature Graph for April 2016 which was attached to the medication refrigerator revealed the recorded temperature was 32 degrees F (Fahrenheit.) on 2 consecutive dates, April 1, 2016, and April 2, 2016. An observation of the refrigerator interior revealed there were 4 unopened vials of insulin inside: two vials of Lantus, one vial of Novolog, and one vial of Humulin. In an interview with Nurse #1 on 04/07/2016 at the time of the observation, she stated the temperature in the medication refrigerators was checked once daily to ensure the temperatures were between the range of 32 degrees F and 40 degrees F as shown on the log. Nurse #1 stated she had never seen any frozen insulin in the refrigerator and that if the temperature were to go down to 31 degrees F, she would call maintenance to repair it. Nurse #1 acknowledged she was not aware of the temperature recommendations for insulin storage. During a tour of the medication storage room located on "Recovery Road" with Nurse #1 on 04/07/2016 at 2:15 PM, a review of the Refrigerator Temperature Graph (log) dated April 2016 revealed the temperature recorded was 32 degrees F on April 1, 2016, April 5, 2016, and April 6, 2016. The same graph revealed the medication refrigerator temperature was 35 degrees F on April 2, 2016, and was 34 degrees F on April 3, 2016, and on April 4, 2016. An	F 431	Hillcrest Convalescent Center's ("Hillcrest") written allegation of compliance for the deficiency cited. However, submission of the Plan of Correction is not an admission that a deficiency exists or that one was cited correctly. This Plan of Correction is submitted to meet requirements established by state and federal law. [F 431] Hillcrest employs a full-time pharmacist, and it is the policy of Hillcrest to provide necessary services to residents regarding drugs and biologicals. Consistent with the lengthy introduction of this Summary Statement, Hillcrest safeguards medications by maintaining a system of records, locking medications in accordance with State and Federal laws, limiting access, disposing of medications appropriately, and labeling medications as they should be labeled. In addition, the Survey Team leader stated the facility had a 0% drug error rate on the medication administration observations. Therefore, Hillcrest attests and the lack of any of other documentation in this Summary Statement makes clear that any other criteria within this regulation are not under question. The insulin in question was discarded despite no indication of crystallization or cloudiness. Staff members were interviewed and no staff member recalls ever seeing any insulin stored in a Hillcrest refrigerator being frozen or showing signs of freezing,	

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F 431	Continued From page 2 observation of the refrigerator interior revealed it contained one unopened vial of Humolog insulin. Nurse #1 stated in an interview during the observation on 04/07/2016 at 2:15 PM that the temperature in the medication refrigerator on " Recovery Road " was maintained at 32 degrees F to 40 degrees F, just as it was for the refrigerator on "Pinehurst Place." Review of the patient package insert for Lantus, revised July 2015, revealed the following: "Store unused Lantus vials in the refrigerator between 36 degrees F and 46 degrees F ... Do not freeze Lantus. If a vial has been frozen or overheated, throw it away." Review of the patient insert for Novolog insulin revealed the following: "Unused Novolog should be stored in a refrigerator between 36 degrees and 46 degrees F. Do not store in the freezer or directly adjacent to the refrigerator cooling element." In bold face type, the patient package insert for storage revealed: "Do not freeze Novolog and do not use Novolog if it has been frozen." Review of the patient package insert for Humulin revealed the following: "unopened Humulin ...vials should be stored in a refrigerator ...36 degrees to 46 degrees F, but not in the freezer." In an interview with the Director of Nursing (DON) on 04/07/2016 at 3:00 PM, she stated she would want the nurses to discard any insulin that might have frozen if the manufacturer of the insulin recommended to do so. The DON also stated she did not know why the refrigerator graphs included a range of 32 degrees F to 40 degrees F to be initialed, and that she would check the facility's policy related to medication refrigerator temperatures. The facility's pharmacist stated in an interview on 04/07/2016 at 3:15 PM if the temperature in the	F 431	such as crystallization, or cloudiness that might indicate the insulin had been frozen. Nothing indicates the temperature in the refrigerators in question were below 32 degrees Fahrenheit. Also no one has ever questioned the effectiveness of insulin treatment received in the facility. In addition to discarding the insulin in question, all other medication refrigerators log forms were checked throughout the building and no other temperature below 36 was noted to have been recorded. To address the concern, a revised form was created that indicates what steps to take if a temperature lower than 36 degrees should be observed. Staff in-services were conducted for nurses who check medication refrigerator temperatures. Also, new digital thermometers were installed in medication refrigerators for easier temperature readings and recordings. Daily temperature monitoring of medication refrigerators will continue by nurses. The Director of Nurses or her designee will check temperature logs weekly for 4 weeks and monthly for 4 months. And finally, this allegation and the quality initiative described above will be addressed at the next scheduled Quality Assurance meeting as well as the monitoring of results of this quality initiative. The committee will review the study results and revise the action plan as	

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F 431	Continued From page 3 medication refrigerator registered 32 degrees F, the nurse should check for signs of freezing and then check the insulin manufacturer's package insert. The pharmacist referred to the insulin manufacturers ' package inserts and stated that if the refrigerator temperature was freezing, it should not be used, and he would expect the nurse to call him to determine if the insulin was not an appropriate temperature. He stated he would want the facility to follow the instructions provided on the package insert. The DON stated in an interview on 04/07/2016 at 3:40 PM, she stated she had not been able to find a facility policy related to medication refrigerator temperature for guidance. The DON stated she did not know why the temperatures on the Refrigerator Temperature Graph were set to have the range of 32 degrees F to 40 degrees F, especially if insulins should not be kept below 36 degrees per the insulin manufacturer. The DON stated she would expect the facility to follow the guidelines provided for insulin use. In an interview with the Administrator on 04/07/2016 at 4:04 PM, he stated that the insulin vials that were stored in the 2 medication storage refrigerators would be discarded per the manufacturer recommendations for use and that the temperatures in the refrigerators would be adjusted.	F 431	necessary to ensure continued compliance.	