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<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</th>
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<td>F 431</td>
<td>SS=D</td>
<td>DRUG RECORDS, LABEL/STORE DRUGS &amp; BIOLOGICALS CFR(s): 483.45(b)(2)(3)(g)(h)</td>
<td>F 431</td>
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<td>11/16/17</td>
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The facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in §483.70(g) of this part. The facility may permit unlicensed personnel to administer drugs if State law permits, but only under the general supervision of a licensed nurse.

(a) Procedures. A facility must provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident.

(b) Service Consultation. The facility must employ or obtain the services of a licensed pharmacist who--

(2) Establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and

(3) Determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.

(g) Labeling of Drugs and Biologicals. 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.

(h) Storage of Drugs and Biologicals. 

(1) In accordance with State and Federal laws,
### Statement of Deficiencies and Plan of Correction

**NAME OF PROVIDER OR SUPPLIER**  
TRINITY OAKS

**STREET ADDRESS, CITY, STATE, ZIP CODE**  
820 KLUMAC ROAD  
SALISBURY, NC  28144

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| **F 431**     |               | PLAN OF CORRECTION TAG  
#483.45(b)(2)(3)(g)(h) F-431 SS=D

The plan to correct specific deficiency and the processes that led to the deficiency cited:

The facility failed to date four (4) multi-dose insulin pens for use in one (1) of three (3) medication rooms. The nurse removed the insulin pens from the stock supply in the medication room refrigerator and did not follow facility policy which states that the nurse will date and label insulin pens with nurse initials when the insulin pen is opened.

The specific procedure for implementing the Plan of Correction:

The Director of Nursing audited all medication rooms and insulin pens that were open to ensure that all insulin pens were dated.

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**Findings included:**

- A review of the facility's policy dated 2/14/02 and revised on 2/20/09, revealed the date opened and the initials of the first person to use the multi-dose insulin vial were recorded on the vials (on the vial label or an accessory label affixed for that person).

- An interview on 10/19/17 at 3:19pm with the DON (Director of Nursing) indicated the facility did not have a specific policy for insulin pens at this time and per the pharmacy followed the above policy for insulin pens.

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**1. A.** An observation on 10/19/17 at 9:45am of the Medication Room for halls C and D revealed 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.

(2) 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, staff interviews, Pharmacy Technician interview, and policy review, the facility failed to date 4 multi-dose insulin pens for use in 1 of 3 medication rooms (Room for C and D Halls).

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**SUMMARY STATEMENT OF DEFICIENCIES**

(Each DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)

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Based on observations, staff interviews, Pharmacy Technician interview, and policy review, the facility failed to date 4 multi-dose insulin pens for use in 1 of 3 medication rooms (Room for C and D Halls).

Findings included:

- A review of the facility's policy dated 2/14/02 and revised on 2/20/09, revealed the date opened and the initials of the first person to use the multi-dose insulin vial were recorded on the vials (on the vial label or an accessory label affixed for that person).

- An interview on 10/19/17 at 3:19pm with the DON (Director of Nursing) indicated the facility did not have a specific policy for insulin pens at this time and per the pharmacy followed the above policy for insulin pens.

1. A. An observation on 10/19/17 at 9:45am of the Medication Room for halls C and D revealed 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.
**SUMMARY STATEMENT OF DEFICIENCIES**

**F 431 Continued From page 2**

A basket for D hall with 2 opened multi-dose Lantus (long-acting insulin) SoloStar Pens 100 units/ml 3 ml labeled for 2 individual residents. Both had a blank sticker label affixed to the pen for open date, discard date, and initials.

An interview on 10/19/17 at 9:55am with Nurse #1 for Hall D stated the label on the insulin pen should be dated and initialed when opened. She explained the insulin pens were stored in the basket once opened and each hall had their own basket. Nurse #1 indicated there were 2 Lantus SoloStar Pens in the basket for Hall D labeled for 2 individual residents and were opened, had been used, and the affixed labels were blank. She stated both affixed labels placed on the insulin pens should have been labeled with the open date, discard date, and initials of the nurse opening the pen.

B. An observation on 10/19/17 at 9:45am of the Medication Room for halls C and D revealed a basket stored on the counter for C hall with 2 opened multi-dose Novolog (fast-acting insulin) Flex Pens 100 units/ml (milliliter) 3 ml labeled for 2 individual residents. Both had a blank sticker label affixed to the pen for open date, discard date, and initials.

An interview on 10/19/17 at 10:10am with the Nurse #2 for Hall C revealed the insulin pens stored in the basket for Hall C had been opened and 2 multi-dose Novolog Flex Pens labeled for 2 individual residents did not have the open date, discard date, and initial of nurse recorded on the insulin pens.

During an interview on 10/19/17 at 10:15am Nurse #3 indicated she was responsible for the

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<td>F 431</td>
<td>were dated and labeled with nurse initials per our policy on October 19, 2017. All licensed nurses will be in-serviced regarding facility policy which states that the nurse will date and place their initials on insulin pens when opened. They will also be in-serviced on the process of checking all insulin pens at the beginning of each shift and documenting compliance. The in-services will be conducted by the Director of Nursing, Staff Development Coordinator and the Wound Care Nurse and completed by November 16, 2017. The monitoring procedure to ensure the the Plan of Correction is effective and deficiency remains corrected: Insulin pens will be checked at the beginning of each shift by a licensed nurse to ensure that insulin pens are labeled per facility policy and document the results of that audit on an audit sheet. This audit will be completed by the Director of Nursing, Staff Development Coordinator, Wound Care Nurse, Hall Nursing Managers and Charge Nurses. The audit will be reviewed daily for two (2) weeks, then biweekly for two (2) weeks, then weekly for six (6) weeks, then monthly for six (6) months and reported quarterly at the Senior Leadership Team / Quality Assurance &amp; Performance Improvement meetings. The title of person responsible for implementing the Plan of Correction:</td>
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**FORM CMS-2567(02-99) Previous Versions Obsolete**

Event ID: IHD111

Facility ID: 923318

If continuation sheet Page 3 of 5
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<td>oversight of halls C and D. She stated that the 2 Novolog Flex Pens from the C Hall basket and the 2 Lantus SoloStar Pens from the basket for D Hall had been opened and were not labeled with an open date, discard date, and initials of the nurse responsible for opening the pen. Nurse #3 explained that hall nurses were responsible for administering insulin to the residents. She revealed that opened insulin pens were stored in the basket for use and discarded after 28 days from the open date labeled on the insulin pen. She indicated there was a list posted in the medication room used as a resource for hall nurses regarding manufacturer guidelines related to discard dates for opened and unopened multi-dose insulin pens. Nurse #3 stated the policy and process for the nurse opening an insulin pen as recording the date opened, discard date, and initials of the nurse on the blank label provided by the pharmacy.</td>
<td>F 431</td>
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<td></td>
<td>The Director of Nursing, Todd Rogers, RN-BC is responsible for implementing the Plan of Correction. Date of Corrective action completed 11/16/2017.</td>
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On 10/19/17 at 3:19pm an interview was conducted with the DON. She indicated her...
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expectation was for all nurses to check for labels verifying an open date prior to each medication administration. She explained that the third shift nurses were to check thoroughly for expired medications, correct label for opened vials, pens, and bottles with open date, discard date, and initials of nursing staff that first opened the medication. The DON stated the pharmacy performed a monthly audit however staff should call the pharmacy if they found an opened insulin vial or pen undated because the medication would need to be discarded and replaced before administered to the resident.