No deficiencies were cited as a result of a complaint investigation on 10/1/15 Event ID# F9VH11. Intake NC00107431.

**F 431**

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.
<table>
<thead>
<tr>
<th>ID</th>
<th>PREFIX</th>
<th>TAG</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES</th>
<th>PROVIDER'S PLAN OF CORRECTION</th>
</tr>
</thead>
</table>
| F 431 | Continued From page 1 | F 431 | This REQUIREMENT is not met as evidenced by: Based on observation and staff interviews the facility failed to store refrigerated medications between 36 to 46 degrees Fahrenheit for 1 of 2 medication refrigerators, located in the front medication room for all halls except 600. The findings included: Facility policy and procedure for Medication Storage in the Facility, dated June 2012, stated medications requiring refrigeration are kept in a refrigerator at temperatures between 36 and 46 degrees Fahrenheit. On 9/29/2015 at 1:35 pm an observation of the medication refrigerator showed that the temperature of the refrigerator containing vials of insulin and other medications was 36 degrees. The daily temperature log for September 2015 showed that the temperature for this refrigerator was below 36 degrees Fahrenheit on 12 occasions. The temperature was noted to be at or below freezing on 4 days. 9/9/2015 and 9/10/2015 the temperature was 32 degrees. 9/13/2015 the temperature was 32 degrees and 9/14/2015 the temperature was 30 degrees. This refrigerator was found to have Tuberculin Aplisol injectable, flu vaccines, hepatitis B vaccines, and several vials of insulin. Med Aid #1 was present for the observation and provided a copy of the temperature log at this time. The manufacturers of both Humalog and Lantus recommend storage between 36 and 46 degrees and caution about using the insulin if it has been Refrigerator temperatures checked on 9/30/2015 at 0940 by Regional QA Nurse and noted to be 44 degrees F. Director of Nursing notified pharmacy for further guidance. Pharmacist returned call and requested that all insulin, hepatitis B vaccines, Brovana and Tuberculin skin test to be returned to pharmacy for replacement. All of these were returned on 9/30/15 by the DON. The pharmacy replaced all medications and vaccines that night. All licensed nursing staff have been inserviced beginning on 9/30/2015 by Staff Development Coordinator related to the need to take action if temperature is out of range. They have also been inserviced on the use of the new log form. A new Refrigerator Temperature Log form has been developed and was put in place on 9/30/2015. It includes the required temperature ranges, date, time, temperature and initials of the nurse recording the data. It also includes new instructions to recheck the temperature in 15 minutes if it is out of range and what action to take (adjusting temperature, etc.) The Director of Nursing and the Ass’t DON or SDC will monitor refrigerator temperatures daily for 3 days then weekly.
Continued From page 2

On 9/30/2015 at 8:47 am the DON provided the policy and procedure for storing medications in the refrigerator. The policy states that the temperature should be between 36 and 46 degrees Fahrenheit. It also said that a thermometer should be in place to allow temperature monitoring. The temps should be checked once a day.

On 9/30/2015 8:25 am interview with Charge Nurse #1 was conducted. She said that the temperatures of the medication refrigerators should be between 32 degrees and 38 degrees. Later in the interview she clarified 30 to 34 degrees was acceptable. She stated that she wasn't really sure but she could find out. She stated that if the temperatures were out of range the refrigerator could be adjusted and maintenance could be called if we can't reach the correct temperature. She stated that medicine in the refrigerator would be moved to another refrigerator if the temperature was out of range. When asked specifically about insulin in a refrigerator that was out of range, she stated it could be removed because it is good for 30 days out of the refrigerator.

On 9/30/2015 8:34 am Nurse #1 was interviewed. She stated that she didn't know the temperature parameters on the medication refrigerator. She stated that if it was out of range she could adjust the refrigerator up or down to keep the correct temperature. She stated she would tell maintenance and move the medications to the 600 hall refrigerator if unable to maintain temperatures. When asked about insulin she stated she would move it to 600 hall as well.

for 3 weeks and monthly for 3 months and then periodically thereafter to ensure refrigerator temperatures are within correct range and when recorded otherwise that the action plan is documented as required.

Any area of continued discrepancies will be reviewed with the Quality Assurance Committee for further action plan.
On 9/30/2015 at 8:39 am Nurse #2 was interviewed. She admitted that she did not know the temperatures recommended for the medication refrigerator but that she could show me. She said that if the temperatures were out of range she would make sure the door was shut, readjust the control, document on the log and let the "uppers" know. When asked about what she would do with the medications she stated she would ask pharmacy.

On 9/30/2015 at 8:57 am the DON was interviewed. The copy of the medication refrigerator temperature log was shared with DON. She noted that log said 600 hall. She also asked if the staff had documented anything on the back of the sheet. This copy was of the front of the log only. She stated that the expected range was 36-46 degrees. She expected her staff to document on the back of the sheet if temperatures were out of range and that the refrigerator should be adjusted. They should ask pharmacy what they should do with the medications. When asked about the risk of storing insulin outside of this range she said she would have to ask pharmacy.

On 9/30/2015 at 9:13 am an observation of the medication refrigerator and temperature log was made with Med Aid #1 present. She shared that the medication log says 600 hall because the refrigerator was moved from 600 hall to this front medication room earlier this month. She also made a copy of the front and back of the temperature log, which showed that the back of the sheet was blank.