### SUMMARY STATEMENT OF DEFICIENCIES

<table>
<thead>
<tr>
<th>ID</th>
<th>PREFIX</th>
<th>TAG</th>
<th>PROVIDER'S PLAN OF CORRECTION</th>
<th>COMPLETION DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>F 431</td>
<td></td>
<td>SS=D</td>
<td>(EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</td>
<td>11/14/14</td>
</tr>
</tbody>
</table>

**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 the observation, record review of the

Submission of this response to the

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

*Electronically Signed*

**DATE** 11/26/2014
### SUMMARY STATEMENT OF DEFICIENCIES

**F 431** Continued From page 1

Manufactures’ instructions and interviews with staff the facility failed to date medications when opened. The facility failed to remove a medication from the cart of a discharged resident. This was evident in 3 of 4 medication carts observed on units 100, 200 and 300.

Findings included:

A review of the manufactures instructions revealed Budesonide Inhalation solution vials can be stored for 2 weeks after opening the protective aluminum foil envelope. Throw away Budesonide Inhalation solution vials if not used within 2 weeks of opening the protective aluminum foil envelope. The manufacturer info specifies to "protect from light."

A review of the manufactures instructions for Albuterol Inhalation solution revealed the unit dose vials should remain stored in the protective foiled pouch at all times. Once the foiled package is opened the vials should be used within 1 week.

Observation of the 300 hall medication cart on 11/5/14 at 9:49 am with Nurse #1 revealed an open undated foil package containing three (3) vials of Ipratropium Bromide and Albuterol Sulfate inhalation solution 0.5 mg /3 mg per 3 ml dispensed for Resident #63. Lidocaine with 2% jelly topical dispensed for Resident #116 was opened but not dated when opened. Nurse #2 could not indicate when the foil pouch was opened.

Observation on 11/5/14 at 10 am of the 200 medication cart with Nurse #2 Budesonide 0.5 mg /2 ml unit dose bullet package dispensed for Resident #57 was opened

### PROVIDER’S PLAN OF CORRECTION

Statement of deficiencies does not constitute an admission that the deficiencies exist and/or were correctly cited or required correction.

The following corrective action was accomplished for those residents found to have been affected by the practice:

During the survey, on 11/5/14, all open nebulizer medications that were not dated, without regard for the delivery date or uses per MAR (which indicated that the medications were within the expiration date) were discarded by the licensed nurses. This was verified by the DON on 11/5/14. The inhaler for the resident who was discharged on 10/29/14 was returned to the pharmacy on 11/5/14 by the licensed nurse and was verified by the Director of Nursing. To be noted, there is not a pharmacy policy nor a regulation that dictates the time frame for returning medications to the pharmacy for discharged residents. The Lidocaine jelly was not returned to the pharmacy because Lidocaine, per policy and consultation with the Pharmacist, is discarded based on the manufacturer’s expiration date and is printed on the tube itself. The date it is opened is irrelevant.

The following corrective action was accomplished for those residents found to have been affected by the practice:

Licensed nursing staff was in-serviced during the survey on 11/5-7/14 by the Director of Nursing regarding medication
F 431 Continued From page 2

and not dated. There was (one) 1 vial left in package.
There was a Ventolin HFA inhaler in the medication cart dispensed for Resident #86 who was discharged on 10/29/14.
Budesonide 0.5 mg /2 m-3 (2.5) was dispensed in a box containing foiled packages of 5 vials for Resident #65. The foiled package was opened and undated. There were three (3) vials still in the foil.
Albuterol Sulfate Inhalation Solutions 0.083% 2.5 mg/3ml was dispensed in a box and stored in a foiled container for Resident #96. The foiled package was opened and undated with 2 vials left in the opened foiled package and one (1) in the bottom of the box outside the foiled package.

Interview on 11/05/14 at 11am with Nurse #1 indicated she was not aware that the opened foiled package needed to be dated and was not aware of when the pouch was opened.

Observation on 11/5/14 at 10:30 am of Unit 100's medication cart revealed an open box Ipratropium Bromide and Albuterol Sulfate inhalation solution 0.5 mg /3 mg per 3 ml vials. There were foiled packages of 5 vials each. One foiled package was opened and undated with (2) (two) vials remaining in the foiled package. One vial was noted in the bottom of the box under 5 unopened foiled packages.

Interview on 11/5/14 at 10.55 am with Nurse #3 revealed medications should be dated when opened. Nurse #3 indicated she did not usually date when foiled packages were opened. Not aware of when the packages were opened. Continued interview with Nurse #3 indicated she was not aware that the foiled packages once

storage. This in-service included the dating and removing of nebulizer medications per manufacturer's instructions, keeping nebulizer medications stored in the manufacturer's foil packs and returning medications to the pharmacy when residents are discharged.

All medication carts were checked on 11/6/14 by the Director of Nursing and the Assistant Director of Nursing to ensure all open foil nebulizer packets were dated when opened and were within the expiration date per manufacturer's instructions, and that no medication belonging to discharged residents were present in the medication carts. This audit revealed no negative findings.

The following measures have been put in place and systemic changes made to ensure that the practice does not occur:

A policy was developed by the Director of Nursing which specifically speaks to the dating and discarding of medications which can expire prior to the manufacturer's printed expiration date. This policy has been placed at the front of each MAR book by the Director of Nursing as an additional, user friendly, reminder to licensed staff.

This new policy will also be included in the Nurse Orientation packet and thoroughly reviewed with new nurses by the Assistant Director of Nursing during orientation.

The following initiative has been put in
### SUMMARY STATEMENT OF DEFICIENCIES

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

<table>
<thead>
<tr>
<th>ID</th>
<th>PREFIX</th>
<th>TAG</th>
</tr>
</thead>
<tbody>
<tr>
<td>F 431</td>
<td>Continued From page 3</td>
<td></td>
</tr>
</tbody>
</table>

- **Continued From page 3**
  - Interview on 11/5/14 at 11:08 am with Nurse #4 in the presence of Nurse #5 revealed when medication packages must be dated once opened.
  - Interview on 11/5/14 at 3:40 with the director of nurses revealed her expectation included dating medication packages when opened.

- **F 431**
  - open should be dated.

- **F 431**
  - place to ensure that the correction is achieved and maintained and that it is implemented and the corrective action evaluated for its effectiveness:

  One time weekly for six weeks, the Director of Nursing or designee will check each medication cart to ensure all medications are dated as appropriate based on the manufacturer's recommendations and the new policy to ensure safe medication storage and administration. The DON will document her findings on an audit tool. Once the initial six week is complete, if the corrective action has been sustained, the DON or designee will audit each medication cart monthly to ensure no medications including nebulizer medications are expired, all medications are labeled and dated based on manufacturer's and pharmacy guidelines, and no medications belonging to discharged residents are on the medication cart. Findings will be documented on the established audit tool. If negative findings occur within the first six weeks, inservices will again be held and the audit will continue until no negative findings have occurred. The Pharmacy Technician will also monitor this on a monthly basis during the routine pharmacy cart audits. These audits will become part of the Quality Assurance Program. Findings will be presented at the monthly QAPI meeting and the corrective action plan (PIP) will be revised as needed by the committee.