DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	345438	A. BUILDING _____ B. WING _____	R-C 01/18/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
THE LAURELS OF SUMMIT RIDGE	100 RICEVILLE ROAD ASHEVILLE, NC 28805

(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:	{F 431}	The Laurels of Summit Ridge wishes to have this submitted plan of correction stand as its allegation of compliance. Our date of alleged compliance is 2/9/2012. Preparation and/or execution of this plan of correction does not constitute admission or agreement by the provider of the truth of the facts alleged or conclusions set forth in the statement of deficiencies. The plan of correction is prepared and/or executed solely because it is required by the provisions of Federal and State law. F431 The 2 vials of Tuberculin, Purified Protein Derivative (PPD) were removed from the medication cart and destroyed on 1/18/12. All other medication carts, medication rooms and medication refrigerators in the facility where inspected by the DON and Regional QA nurse for proper medication storage and outdated medications on 1/18/12. All licensed nurses were individually inserviced by the Administrator regarding proper drug storage and disciplinary actions that will be imposed on 1/19-1/20/2012. Directed inservice on medication storage will be completed for all licensed nurses by Dean Clayton, pharmacist on 2/8/12. Inservice outline and credentials attached. The DON/designee will audit all medication carts, medication room and medication refrigerators at least daily for the next 4	2/9/12

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Jude Boyer — TITLE: Administrator — (X6) DATE: 2/3/12

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 Based on observations, record review, and staff interviews the facility failed to refrigerate two (2) vials of Tuberculin, Purified Protein Derivative (PPD) and discard one (1) vial of expired PPD in one (1) of three (3) medication carts. The findings are: Review of manufacturer's recommendations documented on the box containing the two (2) vials of PPD revealed the following: "store at temperature between 38 degrees and 46 degrees Fahrenheit and Once entered, vial should be discarded after 30 days." Observation on 1/18/2012 at 8:45 AM of one medication cart on the 200 Hall revealed two opened partially used 10 milliliters vials of PPD dated as opened on 12/13/2011 and 1/2/2012. Both vials were stored in the medication cart unrefrigerated. On 1/18/2012 at 8:47 AM Licensed Nurse (LN) #1 was interviewed. She stated the two vials of PPD solution were to be kept in the medication refrigerator and their presence in her cart meant a new admission had been given a PPD test. She revealed she did not know when they had been placed in the medication cart. LN #1 also confirmed one of the vials was expired and should have been discarded 30 days after it was opened per the facility policy. On 1/18/2012 at 1:10 PM the Director of Nurses (DON) was interviewed. She stated she expected vials of PPD to be stored in the medication refrigerator and PPD vials were to be discarded 30 days after being opened.	{F 431}	weeks. Any variances will be corrected at the time of observation and concerns will be reported to the Quality Assurance Committee for further recommendations. Continued compliance will be monitored through weekly audits of the medication carts, medication rooms and medication refrigerators and through the facility's quality assurance program. Disciplinary action and monitoring will be initiated for any identified concerns.	

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{F 431}	Continued From page 2 The facility consulting Pharmacist was interviewed on 1/18/2012 at 1:45 PM. He confirmed the PPD vials were to be stored under refrigerated conditions. He also stated that once a vial was opened it was to be discarded after 30 days as the potency was reduced.	{F 431}		

Medication Storage

F-Tag 431 Synopsis of Regulation

Storage of Drugs and Biologicals

- Provides for safe and secure storage of medications i.e., medication must be stored at proper temperatures and locked at all times (except when under direct staff supervision)
- Limit access to medications to authorized staff
- Label medications in accordance with federal and state labeling requirements and accepted standards of practice and
- Have safeguards and systems in place to control, account for, and periodically reconcile controlled medications.

Medication Cart Tips

- Keep the cart clean (this means the inside, throw away all loose drugs in sharps)
- Keep cart locked when out of direct supervision
- Keep the narcotic drawer locked at all times (all schedule II medications must be double locked)
- Date open items on top of cart i.e., Medpass, juices, applesauce, yogurt. Be sure to keep items cold.

LABELING OF MEDICATIONS & BIOLOGICALS

Labeling of medications and biologicals dispensed by the pharmacy must be consistent with applicable federal and state requirements and currently accepted pharmaceutical principles and practices. Although medication delivery systems may vary, the medication label at a minimum includes:

- Medication name (generic and/or brand)
- Medcation Strength
- Expiration Date when applicable and /or Date Opened Sticker
- Resident's Name
- Route of administration
- Appropriate instructions and precautions (such as shake well, with meals, do not crush, special storage instructions).

For medications designed for multiple administrations (e.g., inhalers, eye drops), the label is affixed in a manner to promote administration to the resident for whom it was prescribed.

When medications are prepared or compounded for intravenous infusion, the label contains:

- Name and Volume of the solution
- Resident's Name
- Infusion Rate
- Name and Quantity of each additive
- Date of preparation
- Initials of compounder
- Date and time of administration
- Initials of person administering medication if different than compounder
- Ancillary precautions as applicable
- Expiration Date

For over-the-counter (OTC) medications in bulk containers (e.g., in states that permit bulk OTC medications to be stocked in the facility), the label contains:

- Original manufacturers or pharmacy-applied label indicating the medication name, strength, quantity, accessory instructions, lot number, and expiration date when applicable.
- If supplies of bulk OTC medications are used for a specific resident, the container identifies that resident by name and must contain the original manufacturers or pharmacy-applied label.

The facility ensures that medication labeling in response to order changes is accurate and consistent with applicable state requirements.

Medications Frequently Used and Storage Tips

MEDICATIONS FREQUENTLY USED AND STORAGE TIPS			
MEDICATION	**LABEL WITH DATE OPENED STICKER**	**EXPIRATION DATE AFTER OPENED**	**STORAGE INSTRUCTIONS**
NITROGLYCERIN SUBLINGUAL	✓	12 MONTHS	
ADVAIR DISKUS	✓	1 MONTH	
FLOVENT DISKUS	✓	50MCG: 6 WEEKS 100 & 250MCG: 2 MONTHS	
XOPENEX	✓	STORED IN FOIL: 1 WEEK NOT STORED IN FOIL: 2 WEEKS	PROTECT FROM LIGHT
LANTANOPROST	✓	6 WEEKS	KEEP IN REFRIGERATOR UNTIL OPENED. MAY BE STORED AT ROOM TEMP AFTER OPENED.
APISOL (PPD)	✓	30 DAYS	REFRIGERATE
FLULAVAL (INFLUENZA)	✓	28 DAYS	REFRIGERATE

Insulins

All insulin products may be kept until expiration date if stored in the refrigerator and unopened.

28 DAY EXPIRATION
APIDRA
HUMALOG
HUMALOG 50/50
HUMALOG 75/25
HUMULIN R
HUMULIN 70/30
HUMULIN N
LANTUS
NOVOLOG
NOVOLOG 70/30

42 DAY EXPIRATION
LEVEMIR
NOVOLIN R
NOVOLIN 70/30
NOVOLIN N

PLEASE REMEMBER--- The expiration of insulin starts when it is opened or removed from the refrigerator, whichever comes first.

Commission for Certification in Geriatric Pharmacy

Certifies That

Robert D. Clayton, Jr.

has successfully fulfilled the requirements to be accredited as a Certified Geriatric Pharmacist, achieving those standards of excellence set forth by examination under the Commission's Certification Program in Geriatric Pharmacy Practice

January 1, 2011
CERTIFICATION DATE

December 31, 2015
EXPIRATION DATE

1428
CERTIFICATION NUMBER

CHAIRMAN OF THE BOARD
COMMISSION FOR CERTIFICATION
IN GERIATRIC PHARMACY