

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

PRINTED: 05/14/2014
FORM APPROVED
OMB NO. 0938-0391

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|---|---|---|---|----------------------|---|
| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 345397 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED C 02/20/2014 |
| NAME OF PROVIDER OR SUPPLIER SHORELAND HLTH CARE & RETIREME | | | STREET ADDRESS, CITY, STATE, ZIP CODE 200 FLOWER-PRIDGEN DR WHITEVILLE, NC 28472 | | |
| (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=E | <p>483.60(b), (d), (e) DRUG RECORDS, LABEL/STORE DRUGS & BIOLOGICALS</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>This REQUIREMENT is not met as evidenced by: Based on observation, facility policy and</p> | F 431 | The statements made on this plan of | 3/7/14 | |

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

TITLE

(X6) DATE

Electronically Signed

03/07/2014

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 | <p>Continued From page 1</p> <p>manufacturer ' s package insert review and staff interviews, the facility failed to label medications with the date of opening and failed to refrigerate unopened insulin flexpens.</p> <p>The findings included:</p> <p>1. The manufacturer ' s package insert for Novolog Insulin Flexpen revealed that once punctured, the medication could be used for up to 28 days.</p> <p>The facility ' s undated policy titled (Name of Pharmacy ' s) Long Term Care Pharmacy Recommended Storage for Selected Items read: " The following items must have a date opened sticker attached and the date & initials of person opening medication must be written on the sticker! All Insulins (except Lantus) good for only 28 days not refrigerated. "</p> <p>An observation was made of the medication cart for the 300 Hall on 2/20/14 at 11:55 AM with Nurse #1. A Novolog Insulin Flexpen stored in a plastic container labeled with the name of Resident #20 did not have a label to convey when the medication was dispensed by the pharmacy and was not labeled with the date the medication was opened. Nurse #1 stated that the medication was good for 28 days after opening and should have been dated when opened. The Nurse stated the medication would need to be thrown away.</p> <p>An interview was conducted with the Director of Nursing (DON) and the Administrator on 2/20/14 at 2:20 PM. The DON and Administrator indicated the medication had not been stored properly and offered no additional information.</p> | F 431 | <p>correction are not an admission to and do not constitute an agreement with the alleged deficiencies.</p> <p>To remain in compliance with all federal and state regulations the facility has taken or will take the actions set forth in this plan of correction. The plan of correction constitutes the facility's allegation of compliance such that all alleged deficiencies cited have been or will be corrected by the dates indicated.</p> <p>F 431</p> <p>Corrective Action for Resident Affected No residents were adversely affected by the alleged deficient practice. On 02/20/14 the five Lantus flex pens and one Advair Diskus were discarded and reordered by 200 Hall Nurse and 300 Hall Nurse.</p> <p>Corrective Action for Resident Potentially Affected All residents are potentially affected by the alleged deficient practice. On 2/20/14, each medication cart was audited for undated flex pens and open undated multi-dose Advair Diskus dispensing systems. Any undated or expired items found were discarded and reordered. This was completed by Director of Nursing, Staff Development Coordinator.</p> <p>Systemic Changes An in-service was conducted on 3/5/14 by Staff Development Coordinator. Those who attended were all RNs, LPNs, and</p> | | |

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| F 431 | <p>Continued From page 2</p> <p>2. The manufacturer ' s package insert for Novolog Insulin Flexpen revealed that unopened, the medication was good until the expiration date if stored in a refrigerator and once opened was good for 28 days.</p> <p>The facility ' s undated policy titled (Name of Pharmacy ' s) Long Term Care Pharmacy Recommended Storage for Selected Items read: " All Insulins (except Lantus) good for 28 days not refrigerated. Unopened vials should be kept in the refrigerator. "</p> <p>An observation was made of the medication cart for the 300 Hall on 2/20/14 at 11:55 AM with Nurse #1. A plastic bag with a Novolog Insulin Flexpen was labeled with the name of Resident #98. The label on the bag revealed the medication was dispensed by the pharmacy on 1/14/14. A label on the Flexpen read: " Refrigerate until opened. " Nurse #1 stated the Flexpens were dispensed by the pharmacy in a plastic bag and once opened was stored in a plastic container with the resident ' s name on the end of the container. The Nurse stated that the Flexpen for Resident #98 had not been opened and should have been stored in the refrigerator. The Nurse stated the medication would need to be thrown away.</p> <p>An interview was conducted with the Director of Nursing (DON) and the Administrator on 2/20/14 at 2:20 PM. The DON and Administrator indicated the medication had not been stored properly and offered no additional information .</p> <p>3. The manufacturer ' s package insert for Novolog Insulin Flexpen revealed that unopened,</p> | F 431 | <p>FT, PT, and PRN. Any in-house staff member who did not receive in-service training will not be allowed to work until training has been completed. The in-service topics included:</p> <p>" Recommended Storage for Selected Items after Opening (exhibit 1)</p> <p>" Also see In-service Training Record (exhibit 2)</p> <p>This information has been integrated into the standard orientation training and in the required in-service refresher courses for all employees and will be reviewed by the Quality Assurance Process to verify that the change has been sustained.</p> <p>Quality Assurance The Staff Development Coordinator will monitor this issue using the "Survey Quality Assurance Tool for Monitoring Medication Storage". The monitoring will include verifying that all multi-dose Flexpens and Multi-dose medication dispensers or vials are dated when opened and not expired. See attached monitoring tool. This will be done weekly times four weeks then monthly times three months or until resolved by Quality Of Life/Quality Assurance Committee. Reports will be given to the weekly Quality of Life- QA committee and corrective action initiated as appropriate. The Quality of Life Committee consists of the Administrator, Director of Nursing, Staff Development Coordinator, Unit Manager, Health Information Manager, MDS Coordinator.</p> | | |

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| F 431 | <p>Continued From page 3</p> <p>the medication was good until the expiration date if stored in a refrigerator and once opened was good for 28 days.</p> <p>The facility ' s undated policy titled (Name of Pharmacy ' s) Long Term Care Pharmacy Recommended Storage for Selected Items read: " All Insulins (except Lantus) good for 28 days not refrigerated. Unopened vials should be kept in the refrigerator. "</p> <p>An observation was made of the medication cart for the 300 Hall on 2/20/14 at 11:55 AM with Nurse #1. A plastic bag with a Novolog Insulin Flexpen was labeled with the name of Resident #19. The label on the bag revealed the medication was dispensed by the pharmacy on 12/2/13. A label on the Flexpen read: " Refrigerate until opened. " Nurse #1 stated the Flexpen was dispensed by the pharmacy in a plastic bag and once opened was stored in a plastic container with the resident ' s name on the end of the container. The Nurse stated that the Flexpen for Resident #19 had not been opened and should have been stored in the refrigerator. The Nurse stated the medication would need to be thrown away.</p> <p>An interview was conducted with the Director of Nursing (DON) and the Administrator on 2/20/14 at 2:20 PM. The DON and Administrator indicated the medication had not been stored properly and offered no additional information.</p> <p>4. The manufacturer ' s package insert for Novolog Insulin Flexpen revealed that unopened, the medication was good until the expiration date if stored in a refrigerator and once opened was good for 28 days.</p> | F 431 | | | |

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| F 431 | Continued From page 4 The facility ' s undated policy titled (Name of Pharmacy ' s) Long Term Care Pharmacy Recommended Storage for Selected Items read: " All Insulins (except Lantus) good for 28 days not refrigerated. Unopened vials should be kept in the refrigerator. " An observation was made of the medication cart for the 300 Hall on 2/20/14 at 11:55 AM with Nurse #1. A plastic bag with a Novolog Insulin Flexpen was labeled with the name of Resident #79. The label on the bag revealed the medication was dispensed by the pharmacy on 1/8/14. A label on the Flexpen read: " Refrigerate until opened. " Nurse #1 stated the Flexpen was dispensed by the pharmacy in a plastic bag and once opened was stored in a plastic container with the resident ' s name on the end of the container. The Nurse stated that the Flexpen for Resident #79 had not been opened and should have been stored in the refrigerator. The Nurse stated the medication would need to be thrown away. An interview was conducted with the Director of Nursing (DON) and the Administrator on 2/20/14 at 2:20 PM. The DON and Administrator indicated the medication had not been stored properly and offered no additional information . 5. The manufacturer ' s package insert for Novolog Insulin Flexpen revealed that unopened, the medication was good until the expiration date if stored in a refrigerator and once opened was good for 28 days. The facility ' s undated policy titled (Name of Pharmacy ' s) Long Term Care Pharmacy Recommended Storage for Selected Items read: | F 431 | | | |

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| F 431 | <p>Continued From page 5</p> <p>" All Insulins (except Lantus) good for 28 days not refrigerated. Unopened vials should be kept in the refrigerator. "</p> <p>An observation was made of the medication cart for the 300 Hall on 2/20/14 at 11:55 AM with Nurse #1. A plastic bag with a Novolog Insulin Flexpen was labeled with the name of Resident #1. The label on the bag revealed the medication was dispensed by the pharmacy on 2/17/14. A label on the Flexpen read: " Refrigerate until opened. " Nurse #1 stated the Flexpen was dispensed by the pharmacy in a plastic bag and once opened was stored in a plastic container with the resident ' s name on the end of the container. The Nurse stated that the Flexpen for Resident #1 had not been opened and should have been stored in the refrigerator.</p> <p>An interview was conducted with the Director of Nursing (DON) and the Administrator on 2/20/14 at 2:20 PM. The DON and Administrator indicated the medication had not been stored properly and offered no additional information.</p> <p>6. Advair Diskus contains an inhaled medication used to treat asthma and Chronic Obstructive Pulmonary Disease. The Advair Diskus is a disposable purple device that is packaged in a moisture-protective foil pouch. The manufacturer ' s package insert revealed the device should be discarded one month after removed from the moisture-protective foil pouch.</p> <p>The facility ' s undated policy titled (Name of Pharmacy ' s) Long Term Care Pharmacy Recommended Storage for Selected Items read: " The following items must have a date opened sticker attached and the date & initials of person</p> | F 431 | | | |

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| F 431 | <p>Continued From page 6</p> <p>opening medication must be written on the sticker! Advair Diskus - Discard diskus 4 weeks after removal from foil pouch. "</p> <p>An observation was made of the medication cart for the 100 Hall on 2/20/14 at 12:48 PM with Nurse #2. A plastic bag containing an opened Advair Diskus labeled with the name of Resident #89 was observed to not be dated with the date the device was removed from the foil pouch. A label on the plastic bag revealed the device was dispensed by the pharmacy on 1/10/14. Nurse #2 stated the medication was good for 30 days after opening and confirmed there was not a date on the device to indicate when the device was removed from the foil pouch.</p> <p>An interview was conducted with the Director of Nursing (DON) and the Administrator on 2/20/14 at 2:20 PM. The DON and Administrator indicated the medication had not been stored properly and offered no additional information.</p> | F 431 | | | |