Summary Statement of Deficiencies

Label/Store Drugs and Biologicals

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10/8/18

§483.45(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.

§483.45(h) Storage of Drugs and Biologicals

§483.45(h)(1) 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.

§483.45(h)(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, record review, and staff interviews the facility failed to date an opened bottle of Latanoprost 0.005% eye drops in 1 of 2 medication carts checked for medication storage in the facility.

Findings included:

Per facility's expired medication removal policy that was last updated on 03/15/18, pharmacy

Lab Director's or Provider/Supplier Representative's Signature

Electronically Signed

10/04/2018

Eckerd Living Center, LLC’s response to this report of survey does not denote agreement with the statement of deficiencies; nor does it constitute an admission that any stated deficiency is accurate. We are filing the POC because it is required by law.

The process that lead to the deficiency cited.
products should not be kept in stock beyond the expiration date shown on the label and no contaminated or deteriorated drugs should be available for use.

Per manufacturer's package insert for the storage of Latanoprost eye drops: "Protect from light. Store unopened bottle(s) under refrigeration at 36 to 46 degree Fahrenheit. Once bottle is opened for use, it may be stored at room temperature up to 77 degree Fahrenheit for 6 weeks".

Resident #15 was admitted to the facility on 04/19/17 with diagnoses included glaucoma. Resident #15 was prescribed Latanoprost 0.005% eye drops. This particular bottle of eye drops was opened on 7/31/18 and was due to expire on 9/11/2018. The bottle was labeled with the open date, however the bottle was not labeled with an expiration date. The eye drops were still being used on 9/25/2018, 14 days past the manufacturer’s recommended expiration date after opening. This was observed by the nurse and surveyor during the medication cart review.

The procedure for implementing the acceptable plan of correction. All multi dose medications will be labeled with an open date and an expiration date. All medications will come labeled from pharmacy prior to being placed on medication carts. Medications currently in use have been relabeled with stickers noting the date opened and the appropriate expiration date. The pharmacy has added that this specific eye drop, Latanoprost, is set to expire 42 days after being opened to the monthly “Medication Cart Review” checklist. The nurses that review the medication cart will initial that these drops are labeled and in date. All Nurses have received instruction on the importance of properly labeling medications when opened and checking the expiration date on the medications that they are dispensing during their shift. The monitoring procedure to ensure that the plan of correction is effective and that the sited deficiency remains corrected.
and free of expired medication. The nurses were instructed to check each medication before administration. Each month, the consultant pharmacist would send her a list of medication that needed to be checked in respective medication carts. The DON would order the third shift nurses to check all the medication carts thoroughly at least once monthly. It was her expectation for all the nurses to follow manufacturer's guidelines with respect to expiration date for opened medications to ensure the facility was free of expired medication.

On 09/27/18 at 01:55 PM an interview was conducted with the Administrator. She expected the nurses to write the opening date and expiration date clearly on the label in order to minimize confusions. It was her expectation for the facility to remain free of expired medication.

Interventions to prevent expired medications from remaining on medication carts have been successful as there have been no other expired medications in use on the medication carts.

Every week the Director of Nursing, or their designee, will complete a medication cart review of 10 random multi-dose medications. The DON, or their designee, will ensure that there is an open date and an expiration date on all multi-dose medications. The DON will monitor that the medications are within the manufacturer’s recommended expiration date after opening. Such cart review will continue until 3 consecutive months have shown no expired multi-dose medications at which time the reviews will be reduced from weekly to monthly. The QAPI team is responsible for reviewing any trends or reoccurring issues monthly. The QAPI team will perform a root cause analysis of any deficits in technology, education, or process that contributes to expired medications remaining on the medication cart and implement procedural changes to ensure that compliance is achieved and maintained.