

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

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTIONS		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING	(X3) DATE SURVEY COMPLETED 02/08/2022
NAME OF PROVIDER OR SUPPLIER HELLENIC SENIOR LIVING OF MISHAWAKA		STREET ADDRESS, CITY, STATE, ZIP CODE 1540 SOUTH LOGAN STREET, MISHAWAKA, , 46544			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES...	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION...	(X5) COMPLETION DATE	
R 0000	INITIAL COMMENTS This visit was for the Investigation of Complaint IN00371680. Complaint IN00371680 - Substantiated. State deficiency related to the allegations are cited at R0301. Survey date: 02/08/2022 Facility number: 014224 Residential Census: 121 This State Residential Finding is cited in accordance with 410 IAC 16.2-5. Quality review completed on 2/15/22.	R 0000	The Plan of Correction is neither an agreement with nor an admission of wrong doing by this facility or its staff members. Rather, it is submitted for compliance purposes. This facility alleges substantial compliance with this plan of correction as of March 7, 2022.		
R 0301	Pharmaceutical Services - Deficiency 410 IAC 16.2-5-6(c)(5) (5) Labeling of prescription drugs shall include the following:	R 0301	R301 #1	03/07/2022	

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

FORM APPROVED

OMB NO. 0938-0391

(A) Resident ' s full name.

(B) Physician ' s name.

(C) Prescription number.

(D) Name and strength of the drug.

(E) Directions for use.

(F) Date of issue and expiration date (when applicable).

(G) Name and address of the pharmacy that filled the prescription.

If medication is packaged in a unit dose, reasonable variations that comply with the acceptable pharmaceutical procedures are permitted.

Based on observation, record review and interview, the facility failed to ensure insulin pens in current use and a multi-dose respiratory medication had the appropriate date documented of opening to ensure proper disposal prior to expiration of the medications for 4 of 6 residents reviewed for medication storage. (Resident B, C, D, F)

Findings include:

1. During an observation of a medication cart on Level 1 on, 02/08/2022 at 9:40 a.m., a multi-dose respiratory inhalation disc (Advair) was noted to be open. The medication box indicated the medication was

The breathing treatment for the resident identified in the survey has been labeled and dated correctly.

A review of the resident's medical record was completed for each resident that Hellenic administers multi-dose respiratory inhalation discs. There are four (4) residents to whom Hellenic administers breathing treatments (Advair Discs). While this community acknowledges that this allegation may impact all parties receiving respiratory inhalation discs, the review did not find any adverse consequences from the multi-dose respiratory inhalation discs not being dated. All are reviewed and dated as of the date of substantial compliance.

To address the deficiency, the administering nurse will visualize the breathing treatment prior to administering to ensure they are dated when opened. Hellenic nurses were provided education regarding this requirement prior to working their first shift on or before the date of substantial compliance.

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

dispensed on 01/14/2022. The medication disc had 49 of 60 doses left for administration. A sticker was noted on the box indicating the date opened and disposal after 30 days of opening. A date was not written indicating the date the medication was opened.

During an interview on, 02/08/2022 at 9:42 a.m., QMA 2 indicated he was not sure when the multi-dose package had been opened and it should have an open date written on the box.

A record review of Resident C was completed on, 02/08/2022 at 10:33 a.m., and indicated Resident C's diagnoses included, but were not limited to, chronic obstructive pulmonary disease (COPD) and hypertension. The Medication Administration Record (MAR) indicated Resident C was receiving Advair Disc 250-50mg 1 puff twice daily. The Service Plan indicated Resident C needs administration for medication by QMA (Qualified Medication Assistant)/Licensed Nurse. Nursing staff will provide Resident C with assistance at the following level task level: administer.

2. During a tour of resident's room, on 02/08/2022 at 10:03 a.m., an observation was made of insulin storage. Resident B had a Novolog 70/30 insulin pen

The Director of Nursing or designated team member will audit all residents receiving Multi-dose respiratory inhalation Discs to ensure that they are properly dated weekly for 90 days. (See attached multi-dose respiratory inhalation discs form).

R301-#2, 3 & 4

All insulin pens for the three residents in question have been dated to correct the action.

Because all resident with insulin administration by pen have the potential to be affected, a review of the resident's medical record was completed for each resident that Hellenic administers insulin. Ten (10) residents were identified that receive insulin from the nurse via pen. The review did not find any adverse consequences from the insulin pen not being dated.

To address the deficiency, the 1st shift nurse will visualize the pens when administering insulin to ensure they are dated when opened. Hellenic nurses were provided education regarding

stored in a cabinet of the kitchen area. A date was not documented on the insulin pen indicating when the pen was opened.

During an interview on, 02/08/2022 at 10:04 a.m., LPN 3 indicated the insulin pen should have a date indicating when the pen was opened.

A record review of Resident B was completed on, 02/08/2022 at 11:05 a.m., and indicated Resident B's diagnosis included, but were limited to, diabetes mellitus, macular degeneration, and osteoarthritis. The Physician's Order indicated Resident B received Novolin 70/30 inject 30 units daily and 35 units in the evening. The Service Plan indicated Resident B needs administration for medication by QMA/Licensed Nurse. Nursing staff will provide Resident B with assistance at the following level task level: administration.

3. During a tour of a diabetic resident room, on 02/08/202 at 10:05 a.m., an observation was made of insulin storage. Resident D had a Novolog and Levemir insulin pen stored in a cabinet of the kitchen area. A date was not documented on the Novolog insulin pen indicating when the pen was opened.

this requirement prior to working their first shift on or before the date of substantial compliance.

In order to monitor compliance, the Director of Nursing or designated team member will audit 100% of the [insulin pens](#) weekly for proper labelling and dating for 1 month, 50% of the MAR for insulin pens for the subsequent month and 25% of the insulin pens for one month after the first 60 days of monitoring. (See attached Insulin Pen Audit Form).

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

During an interview on, 02/08/2022 at 10:07 a.m., LPN 3 indicated the insulin pen should have a date indicating when the pen was opened.

A record review of Resident D was completed on, 02/08/2022 at 11:28 a.m., and indicated Resident D's diagnosis included, but were limited to, insulin dependent diabetes mellitus, diabetic peripheral neuropathy, and hypertension. The Physician's Order indicated Resident D received Novolog 5 units three times daily before meals and Levemir 30 units at bedtime. The Service Plan indicated Resident D needs administration for medication by QMA/Licensed Nurse.

4. During a tour of a diabetic resident room, on 02/08/2022 at 10:10 a.m., an observation was made of insulin storage. Resident F had a Toujeo insulin pen stored in a cabinet of the kitchen area. A date was not documented on the Toujeo insulin pen indicating when the pen was opened.

During an interview on, 02/08/2022 at 10:11 a.m., LPN 3 indicated the insulin pen should have a date indicating the pen looked like it had just been placed in the room and placed a date of 2/8/22 on the pen.

A record review of Resident F was completed on, 02/08/2022 at 11:48 a.m., and indicated Resident F's diagnosis included, but were limited to, insulin dependent diabetes mellitus type 2, diabetic neuropathy, and prostate cancer. The Physician's Order indicated Resident F received Toujeo 20 units daily. The Service Plan indicated Resident F needs administration for medication by QMA/Licensed Nurse. Nursing staff will provide Resident F with assistance at the following level task level: administration.

A policy was requested from the Executive Director for labeling and dating of multi-use medications on, 02/08/2022 at 2:33 p.m. A policy was not provided.

This state finding relates to Complaint IN00371680.

Based on observation, record review and interview, the facility failed to ensure insulin pens in current use and a multi-dose respiratory medication had the appropriate date documented of opening to ensure proper disposal prior to expiration of the medications for 4 of 6 residents reviewed for medication storage. (Resident B, C, D, F)

Findings include:

1. During an observation of a

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

medication cart on Level 1 on, 02/08/2022 at 9:40 a.m., a multi-dose respiratory inhalation disc (Advair) was noted to be open. The medication box indicated the medication was dispensed on 01/14/2022. The medication disc had 49 of 60 doses left for administration. A sticker was noted on the box indicating the date opened and disposal after 30 days of opening. A date was not written indicating the date the medication was opened.

During an interview on, 02/08/2022 at 9:42 a.m., QMA 2 indicated he was not sure when the multi-dose package had been opened and it should have an open date written on the box.

A record review of Resident C was completed on, 02/08/2022 at 10:33 a.m., and indicated Resident C's diagnoses included, but were not limited to, chronic obstructive pulmonary disease (COPD) and hypertension. The Medication Administration Record (MAR) indicated Resident C was receiving Advair Disc 250-50mg 1 puff twice daily. The Service Plan indicated Resident C needs administration for medication by QMA (Qualified Medication Assistant)/Licensed Nurse. Nursing staff will provide Resident C with assistance at the following level task level: administer.

2. During a tour of resident's room, on 02/08/2022 at 10:03 a.m., an observation was made of insulin storage. Resident B had a Novolog 70/30 insulin pen stored in a cabinet of the kitchen area. A date was not documented on the insulin pen indicating when the pen was opened.

During an interview on, 02/08/2022 at 10:04 a.m., LPN 3 indicated the insulin pen should have a date indicating when the pen was opened.

A record review of Resident B was completed on, 02/08/2022 at 11:05 a.m., and indicated Resident B's diagnosis included, but were limited to, diabetes

mellitus, macular degeneration, and osteoarthritis. The Physician's Order indicated Resident B received Novolin 70/30 inject 30 units daily and 35 units in the evening. The Service Plan indicated Resident B needs administration for medication by QMA/Licensed Nurse. Nursing staff will provide Resident B with assistance at the following level task level: administration.

3. During a tour of a diabetic resident room, on 02/08/202 at 10:05 a.m., an observation was made of insulin storage.

Resident D had a Novolog and Levemir insulin pen stored in a cabinet of the kitchen area. A date was not documented on the Novolog insulin pen indicating when the pen was opened.

During an interview on, 02/08/2022 at 10:07 a.m., LPN 3 indicated the insulin pen should have a date indicating when the pen was opened.

A record review of Resident D was completed on, 02/08/2022 at 11:28 a.m., and indicated Resident D's diagnosis included, but were limited to, insulin dependent diabetes mellitus, diabetic peripheral neuropathy, and hypertension. The Physician's Order indicated Resident D received Novolog 5 units three times daily before

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

meals and Levemir 30 units at bedtime. The Service Plan indicated Resident D needs administration for medication by QMA/Licensed Nurse.

4. During a tour of a diabetic resident room, on 02/08/2022 at 10:10 a.m., an observation was made of insulin storage.

Resident F had a Toujeo insulin pen stored in a cabinet of the kitchen area. A date was not documented on the Toujeo insulin pen indicating when the pen was opened.

During an interview on, 02/08/2022 at 10:11 a.m., LPN 3 indicated the insulin pen should have a date indicating the pen looked like it had just been placed in the room and placed a date of 2/8/22 on the pen.

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

A record review of Resident F was completed on, 02/08/2022 at 11:48 a.m., and indicated Resident F's diagnosis included, but were limited to, insulin dependent diabetes mellitus type 2, diabetic neuropathy, and prostate cancer. The Physician's Order indicated Resident F received Toujeo 20 units daily. The Service Plan indicated Resident F needs administration for medication by QMA/Licensed Nurse. Nursing staff will provide Resident F with assistance at the following level task level: administration.

A policy was requested from the Executive Director for labeling and dating of multi-use medications on, 02/08/2022 at 2:33 p.m. A policy was not provided.

This state finding relates to Complaint IN00371680.

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting provided it is determined that other safeguards provide sufficient protection to the patients. (See instructions.)

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
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