STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	365753	A. Building B. Wing	09/16/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Royal Oak Nursing & Rehab Ctr	6973 Pearl Rd Middleburg Heights, OH 44130

For information on the nursing home's plan to correct this deficiency, please contact the nursing home or the state survey agency.

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (Each deficiency must be preceded by full regulatory or LSC identifying information)
F 0760 Level of Harm - Actual harm Residents Affected - Few	Ensure that residents are free from significant medication errors. **NOTE- TERMS IN BRACKETS HAVE BEEN EDITED TO PROTECT CONFIDENTIALITY** 34297 THE FOLLOWING DEFICIENCY REPRESENTS AN INCIDENT OF PAST NON-COMPLIANCE THAT WAS SUBSEQUENTLY CORRECTED PRIOR TO THIS SURVEY. Based on record review, manufacturer medication information, and interview the facility failed to ensure Resident #69 was free from significant medication error. Actual harm occurred on 07/29/24 when Resident #69 required evaluation and treatment in the emergency room due to a significant medication error of the resident's Topiramate (anti-epileptic/seizure medication). The resident had been administered, per the nurse practitioner, greater than three times the recommended dose of the medication (ordered 100 mg twice a day and received 625 mg twice a day) from 07/24/24 until 07/29/24 when the error was discovered. This affected one resident (#69) of five residents reviewed for medication administration. Findings include: Review of Resident #69's admission orders provided by the family per the Director of Nursing (DON) revealed a hospital After Visit Summary report dated 09/25/23. The report indicated the resident was ordered Topiramate 25 milligrams (mg)/milliliter (ml) solution, four ml by mouth two times a day for seizures (100 mg of Topiramate twice daily). Review of Resident #69's Admission Notice form dated 07/24/24 at 5:00 P.M. revealed the resident was a respite stay from home and was admitted with spastic cerebral palsy with epilepsy. Review of Resident #69's medical record revealed the resident was admitted on [DATE] and discharged on [DATE] with diagnoses including epilepsy, gastrostomy status and scoliosis. Review of Resident #69's Discharge Minimum Data Set (MDS) 3.0 assessment dated [DATE] revealed the resident was rarely/never understood. Review of Resident #69's physician orders revealed an order dated 07/24/24 (discontinued 07/29/24) for Topiramate oral solution 25 mg/ml give 25 ml via percutaneous endoscopic gastrostomy (PEG) tube (tube inserted through the abdominal wall and into the stomach for nutrition, fluids and medications to be delivered directly into the stomach) two times a day to prevent seizures (625 mg of Topiramate twice daily). (continued on next page)

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

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F 0760 Level of Harm - Actual harm Residents Affected - Few	Review of Resident #69's Physician/Nurse Practitioner (NP) Progress Note dated 07/27/24 at 12:04 P.M. authored by NP #889 revealed Resident #69 had severe developmental delay and was not alert and oriented. The resident was nonverbal and could not make his needs known. The resident appeared comfortable. The resident's past medial history (PMH) included seizures, scoliosis, PEG tube, asthma, and unspecified lack of expected normal physiological development in childhood. Review of Resident #69's medication administration records (MARS) and treatment administration records (TARS) revealed the Topiramate 25 ml via the PEG tube twice daily due at rise and bedtime were administered at bedtime on 07/24/24, rise and bedtime on 07/25/24, rise and bedtime on 07/26/24, rise and bedtime on 07/27/24, rise and bedtime on 07/28/24 and rise on 07/29/24 for a total of 10 doses. Review of Resident #69's progress note dated 07/29/24 at 5:01 P.M. authored by the DON revealed the resident was sent to the emergency department (ED) for evaluation due to a mediation error regarding the Topiramate seizure medication. Several attempts were made to contact the resident's mother with the phone going to voicemail. Review of Resident #69's After Visit Summary form dated 07/29/24 revealed the resident's reason for visit was drug overdose and the diagnosis was poisoning by mixed antiepileptics accidental initial encounter. Review of Resident #69's physician orders revealed an order dated 07/29/24 for Topiramate oral solution 25 mg/ml give four ml via PEG tube two times a day to prevent seizures (100 mg twice daily). Review of Resident #69's physician orders revealed a new order dated 07/30/24 to hold the Topiramate for four doses then resume Topiramate 25 mg/ml four ml per PEG tube twice daily. Review of Resident #69's progress noted dated 07/30/24 at 1:50 A.M. authored by Licensed Practical Nurse (LPN) #802 revealed the resident returned from the hospital via an ambulance and on a stretcher. The aunt was notified and the pharmacy stated they would send the new order for the Topiramate seizure mediation in the night's medication tote. Review of Resident #69's progress note dated 07/30/24 at 2:16 P.M. authored by LPN #838 revealed a phone call was received from the NP inquiring on the status of the resident. A new order was received to hold the Topiramate times four doses then resume at 25 mg/ml give 4 ml per PEG tube twice daily. Review of Resident #69's progress note dated 07/30/24 at 10:30 P.M. authored by Registered Nurse (RN) #833 revealed the resident was discharged (home) and a copy of the paperwork was provided to the mother per request. Interview on 09/12/24 at 8:21 A.M. with LPN #821 revealed Resident #69 was an evening admission and she accidentally mixed up the Topiramate order. When questioned, she stated Resident #69's Topiramate seizure medication was put in the electronic health record (EHR) as the wrong dose and another nurse caught the error. (continued on next page)

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F 0760 Level of Harm - Actual harm Residents Affected - Few	Interview on 09/12/24 at 9:28 A.M. with the DON confirmed the significant medication error was identified on 07/29/24. The DON stated Resident #69's physician order for the Topiramate seizure medication was put in wrong during the admission process on 07/24/24 and the error was corrected on 07/29/24. The resident was assessed immediately following discovery of the significant medication error on 07/29/24 with no adverse outcome including increased seizure activity, convulsions and a change in the resident's vital signs. The NP was notified who sent the resident to the hospital following discovery of the significant medication error and the resident's family members were notified of the significant medication error. The DON stated all other residents were then assessed for significant medication errors. LPN #821 was immediately provided education on significant medication errors and putting in orders for new admissions during the admission process. All other nurses were educated on significant medication errors and putting in orders during the admission process. The DON stated audits for new admissions were completed daily five times a week to ensure significant medication errors did not occur again. Telephone interview on 09/12/24 at 12:39 P.M. with NP #889 indicated she was made aware of Resident #69's accidental overdose of Topiramate seizure medication. She confirmed the maximum dosage of the medication was 400 mg per day and the resident received greater than three times the recommended dosage on the dates noted above. NP #889 stated she had assessed Resident #69 in person on 07/27/24 and denied the resident had a change in condition because of the overdose of the seizure medication including changes in the resident's vital signs, changes in mentation and increased seizure activity but the resident was sent to the hospital for monitoring because he had received such a high dose. The NP confirmed she ordered Topiramate 25 mg/ml four ml twice per day and the facility put in 25 mg/4 ml 25 ml twice per day in error. NP #889 stated she believed the resident tolerated the overdose because he had been on the medication for an extended length of time, but the outcome could have been different with a far more severe outcome including death. NP #889 confirmed she did not catch the inaccurate dose of Topiramate in the resident's EHR during her visit on 07/27/24 but immediately addressed the overdose on 07/29/24 when she was called by the facility staff. Review of the manufacturer directions for Topiramate dated 10/2012 revealed the medication was used for epilepsy with the recommended dose of 400 mg/day in two divided doses. Further review revealed overdoses of Topiramate had been reported. Signs and symptoms included convulsions, drowsiness, speech disturbance, blurred vision,, mentation impaired, lethargy, abnormal coordination, stupor, hypotension, abdominal pain, agitation, dizziness and depression. The clinical consequences were not severe in most cases, but deaths had been reported after poly/drug overdoses involving Topiramate. In acute Topiramate overdose, if the ingestion was recent, the stomach should be emptied immediately by lavage or by induction of emesis. Treatment should be appropriately supportive. Hemodialysis was an effective means of removing Topiramate from the body. The deficient practice was corrected on 07/30/24 when the facility implemented the following corrective actions: On 07/29/24 at approximately 3:00 P.M., Resident #69 was immediately assessed following discovery of the significant medication error and subsequent overdose of the Topiramate anti-seizure medication. On 07/29/24 at approximately 3:08 P.M., the DON notified NP #889 of Resident #69's Topiramate significant medication error. (continued on next page)

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F 0760 Level of Harm - Actual harm Residents Affected - Few	On 07/29/24 at 3:45 P.M., NP #889 and LPN #822 sent Resident #69 to the hospital for further evaluation. On 07/29/24 at approximately 5:01 P.M., the DON notified Resident #69's family members of the Topiramate significant medication error. On 07/29/24 at approximately 5:00 P.M., the DON provided education to LPN #821 regarding the Admission Order Procedure policy (revised 11/2016), Admission/Readmission Chart Review Process policy (revised 03/01/22) and Medication Errors inservice. On 07/29/24 at approximately 6:00 P.M., the DON completed a whole house audit on resident medications to determine if any other residents had medication errors. No outcomes were identified. On 07/29/24 at 6:00 P.M., the DON implemented a new 24-Hour Admission/Re-Admit Chart Review form to be completed by all nurses which states once the follow-up had been completed, the audit form would be maintained in a binder for review by the regional nurse. From 07/29/24 at 4:20 P.M. to 07/30/24 at 8:25 A.M., the DON provided inservice education to LPN #822 regarding the 24-Hour Admission/Re-Admit Chart Review form to be completed by all nurses. The DON also provided inservice education to an additional 15 LPNs including LPNs #801, #804, #812, #814, #820, #838, #844, #861, #870, #872, #873, #892, #893, #894, #895 and 3 RN's including RNs #833, #841 and #875 on on the Admission Order policy, Admission/Readmission Chart Review Process policy and Medication Errors Inservice as well as the new 24-Hour Admission/Re-Admit Chart Review form. Beginning 07/30/24, the DON initiated daily audits five times per week (Monday through Friday) of the 24-Hour Admission/Re-Admit Chart Review form to ensure accuracy of medication administration orders. This deficiency represents non-compliance investigated under Complaint Number OH00156422.