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Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	HAL051048	A. BUILDING: _____ B. WING _____	02/29/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
GABRIEL MANOR ASSISTED LIVING CENTER	84 JOHNSON ESTATE RD CLAYTON, NC 27520

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D 000	Initial Comments The Adult Care Licensure Section conducted an annual survey from 02/28/24 to 02/29/24.	D 000	Response to the cited deficiencies do not constitute an admission of agreement by the facility of the facts alleged or conclusions set forth in the statement of deficiencies. The plan of correction is prepared solely as a matter of compliance with the law.	
D 358	10A NCAC 13F .1004(a) Medication Administration 10A NCAC 13F .1004 Medication Administration (a) An adult care home shall assure that the preparation and administration of medications, prescription and non-prescription, and treatments by staff are in accordance with: (1) orders by a licensed prescribing practitioner which are maintained in the resident's record; and (2) rules in this Section and the facility's policies and procedures. This Rule is not met as evidenced by: Based on observations, interviews, and record reviews, the facility failed to ensure medications were administered as ordered for 3 of 6 residents (#6, #7, #8) observed during the medication passes including errors with two eye drops for severe dry eye disease (#7) and a topical gel for pain and inflammation (#6, #8). The findings are: The medication error rate was 15% as evidenced by 4 errors out of 26 opportunities during the 7:00am/8:00am and 10:00am medication passes on 02/29/24. a. Review of Resident #7's current FL-2 dated 06/07/23 revealed: -Diagnoses included depression, anxiety disorder, hyperlipidemia, osteoarthritis, and acid reflux. -There was an order for Serum Tears place 1 drop into both eyes 4 times a day. (Serum Tears	D 358	The facility has completed an audit and all medications requiring a dosing card now have dosing cards rubber banded to the medication. The facility is working with the lab who will be creating the labels needed for the eye drop and will call facility when they are ready for pick up. The lab will make sure all future eye drops are labeled before sending to the facility. The facility will complete a Medication Administration Refresher training for all current Medication Aides to address the identified errors. The facilty will complete Resident Rights training with an emphasis on the six rights of medication administration for all current Medication Aides. The SCC,RCC or designee will complete weekly medication cart audits to ensure all dosing cards are in place and all medication is properly labeled. The SCC, RCC or designee will complete weekly medication administration pass observations to ensure compliance with rule area 10A NCAC 13F.1004 Medication Administration The Executive Director will meet with the SCC, RCC or designee to discuss audits and medication administration observations weekly for six weeks and monthly there after to ensure compliance with rule area 10A NCAC 13F .1004 Medication Administration.	3/27/24 3/20/24 3/20/24 3/25/24 3/25/24 3/25/24

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Angela Anderson, TITLE: Executive Director, (X6) DATE: 3-28-24

Reviewed and Acknowledged Marisa A Sugol 04/08/24

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D 358	Continued From page 1 is a blood-derived eye drop used to treat dry eye syndrome.) Review of Resident #7's February 2024 electronic medication administration record (eMAR) revealed: -There was an entry for Serum Tears place 1 drop into both eyes 4 times daily in the morning, noon, dinner, and bedtime; wait 5 minutes between drops. -Serum Tears was scheduled for administration at 7:00am, 12:00pm, 5:30pm, and 8:00pm. -Serum Tears was documented as administered from 02/01/24 - 02/29/24 (7:00am). Observation of the 7:00am/8:00am medication pass on 02/29/24 revealed: -The medication aide (MA) went into Resident #7's room and retrieved an eye drop bottle with a blue and white lid in a plastic ziploc bag from the resident's refrigerator. -There was no labeling on the ziploc bag or the eye drop bottle. -The eye drop bottle was about half full of a viscous light-yellow liquid. -The MA administered one drop of the liquid from the unlabeled eye drop bottle in each of Resident #7's eyes at 7:42am. -Without labeling, it could not be determined the name or strength of the eye drop administered or the expiration date of the eye drops. Interview with Resident #7 on 02/29/24 at 10:26am revealed: -She had macular degeneration and she used eye drops for dry eye symptoms. -The Serum Tears were made at a local laboratory using 8 vials of her own blood to make a blood serum. -She usually received 12 bottles at each visit to	D 358		

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D 358	Continued From page 2 the laboratory and she thought one bottle usually lasted about 1 week. -She did not receive any paperwork with the Serum Tears eye drop bottles and they were not labeled. -They were packaged in a mailing package with just her name labeled on the outside of the package. -She was told by the staff at the laboratory to store the eye drop bottles in the freezer and once opened, put the opened bottle in the refrigerator. -She did not know if the eye drops expired after a certain period of time once opened. -She did not know if the current bottle of Serum Tears that she received that morning, 02/29/24, had expired. Observation of Resident #7's medications in her room on 02/29/24 at 10:32am revealed: -There was a silver mailing package in the resident's freezer with the resident's name handwritten on the outside of the package. -There was a styrofoam tray inside the package with 9 eye drop bottles with a blue and white lid and a viscous light-yellow liquid inside of each bottle. -There were 3 areas of the styrofoam tray with no eye drop bottles. -None of the 9 eye drop bottles remaining were labeled with any information, including the name of the resident, the name or strength of the eye drops, instructions, date dispensed, or expiration information. Interview with the MA on 02/29/24 at 10:43am revealed: -Resident #7 had been receiving Serum Tears eye drops at least since the end of 2023. -The Serum Tears eye drop bottles had never been labeled.	D 358		

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D 358	Continued From page 3 -She had called the resident's ophthalmology provider in the past when the resident first got the eye drops to get them to label the eye drops. -The ophthalmology provider could not label the eye drops because they did not provide the eye drops to the resident. -The family got the eye drops from somewhere (not sure where) so she was not sure who should be labeling the eye drops. -She did not know if or when the Serum Tears eye drops expired. Interview with the Memory Care Coordinator (MCC) on 02/29/24 at 11:10am revealed: -Resident #7's Serum Tears eye drops were not labeled. -She had no idea about the Serum Tears eye drops because the resident and her family handled getting the eye drops. -She did not know if the Serum Tears expired after a certain period of time. -The resident said the MAs could administer the Serum Tears until they were gone. Interview with the Administrator on 02/29/24 at 11:28am revealed: -The facility had tried to get labels for Resident #7's Serum Tears eye drops through the facility's contracted pharmacy provider. -The facility's contracted pharmacy provider was unable to label Resident #7's Serum Tears eye drops because they did not dispense the eye drops. -The resident's Serum Tears eye drops were made somewhere (not sure where) and the resident's family member was involved with helping the resident get the eye drops. -She did not know why the provider who dispensed the eye drops did not label them. -She did not know if the eye drops had an	D 358		

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D 358	Continued From page 4 expiration date. Telephone interview with triage staff at Resident #7's ophthalmology provider on 02/29/24 at 11:52am revealed: -The ophthalmologist was unavailable for interview. -Resident #7 had been ordered Serum Tears since May 2023. -The Serum Tears were made and dispensed by a local laboratory company. -She was not sure of the ingredients in the Serum Tears. -The resident's supply of Serum Tears were supposed to be kept frozen until ready to use. -The actively used bottle of Serum Tears was supposed to be refrigerated. -She did not know why there was no labeling on the Serum Tears because they did not provide the Serum Tears to the resident. -She did not know when the Serum Tears expired. -Resident #7 was ordered to receive Serum Tears because the resident had severe, dry eyes. Telephone interview with a phlebotomist at Resident #7's laboratory provider on 02/29/24 at 12:20pm revealed: -The laboratory's Clinical Director was unavailable for interview. -The laboratory used a kit from another company to help make the Serum Tears eye drops so she was not sure of all of the ingredients in the eye drops. -They usually gave the resident a 6-month supply and all had to be kept in the freezer except one bottle currently being used, which should be refrigerated. -They usually gave the resident an instruction sheet with this storage information.	D 358		

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D 358	Continued From page 5 -There was no expiration information in the instructions and she did not know when the Serum Tears expired. -She did not know why the laboratory did not label the Serum Tears eye drop bottles. Review of Resident #7's order and instruction sheet faxed by the laboratory on 02/29/24 revealed: -The resident's order was for Serum Tears 30% with eye drop applications 4 times per day. -The instructions included the resident would receive (12 each) 5ml preservative free bottles of Serum Tears. -60ml of Serum Tears was an approximate 6-month supply at 4 drops per eye per day. -After arriving home, freeze all but one bottle of Serum Tears. -Keep unfrozen bottle well refrigerated during period of use. -Thaw each bottle as needed keeping those not in use frozen. -Use as directed per physician. -There was no information regarding expiration of the eye drops. Telephone interview with Resident #7's family member on 03/01/24 at 9:45am revealed: -Resident #7 had macular degeneration and dry eyes, causing her eyes to be very sensitive to light. -The resident's Serum Tears were made using the resident's blood plasma which was used to make an eye serum. -The Serum Tears eye drop bottles were never labeled by the laboratory provider. -She did not know if the Serum Tears eye drops expired after a certain period of time. b. Review of Resident #7's current FL-2 dated	D 358		

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D 358	Continued From page 6 06/07/23 revealed an order for Xiidra 5% eye drops, place 1 drop into each eye twice daily. (Xiidra eye drops are used to treat dry eye disease.) Review of Resident #7's February 2024 electronic medication administration record (eMAR) revealed: -There was an entry for Xiidra 5% eye drops, place 1 drop into each eye twice daily; wait 5 minutes between drops. -Xiidra was scheduled for administration at 8:00am and 8:00pm. -Xiidra was documented as administered from 02/01/24 - 02/29/24 (8:00am). Observation of the 7:00am/8:00am medication pass on 02/29/24 revealed: -The medication aide (MA) prepared and administered Resident #7's scheduled morning medications from 7:43am - 7:56am. -The MA did not offer or attempt to administer Resident #7's Xiidra 5% eye drops when she received her other morning medications. -Resident #7's Xiidra was not administered as ordered. Interview with Resident #7 on 02/29/24 at 10:26am revealed: -She had macular degeneration and she used eye drops for dry eye symptoms. -She had not received Xiidra eye drops yet that morning, 02/29/24, because the MA never came back to administer them. -The MA did not offer the Xiidra eye drops that morning, 02/29/24, and she had not refused them. Observation of Resident #7's medications on hand on 02/29/24 at 10:48am revealed:	D 358		

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D 358	Continued From page 7 -There was a supply of Xiidra 5% eye drops dispensed on 11/20/23. -There were instructions to instill 1 drop into both eyes twice daily approximately 12 hours apart. Interview with the MA on 02/29/24 at 10:43am revealed: -She forgot to administer Resident #7's Xiidra eye drops that morning, 02/29/24, when she administered the resident's other morning medications because she usually waited at least 5 minutes between different eye drops. -Sometime after the medication pass (could not recall time), she went back to Resident #7 to administer the Xiidra eye drops but the resident did not want them. -She planned to administer the Xiidra eye drops at 11:00am when Resident #7 was supposed to get another eye drop. -She documented Xiidra eye drops were administered at 8:00am on the eMAR in error. Interview with the Memory Care Coordinator (MCC) on 02/29/24 at 11:10am revealed: -Resident #7 received multiple eye drops and the MAs were supposed to wait 5 minutes between the different eye drops. -Resident #7's Xiidra eye drops should have been administered within the one-hour time frame of when it was scheduled. Interview with the Administrator on 02/29/24 at 11:28am revealed: -Resident #7's Xiidra eye drops should have been administered within one hour of the scheduled time of 8:00am. -The MA should not have documented Resident #7's Xiidra eye drops were administered at 8:00am on 02/29/24 if they were not administered.	D 358		

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D 358	Continued From page 8 Telephone interview with triage staff from Resident #7's ophthalmology provider on 02/29/24 at 11:52am revealed: -The ophthalmologist was unavailable for interview. -Resident #7 was ordered to receive Xiidra eye drops because the resident had severe, dry eyes. -If Resident #7 did not receive Xiidra as ordered, the resident's eyes could become red and inflamed. c. Review of Resident #8's current FL-2 dated 03/14/23 revealed: -Diagnoses included arthritis, depression, aphasia, hypertension, prosthetic heart valve, cerebrovascular accident, and gastroesophageal reflux disease. -There was an order for Diclofenac Sodium Gel 1%, apply 4 grams to left knee as needed for pain. (Diclofenac Sodium Gel is a topical ointment used to treat pain and inflammation. Diclofenac Sodium Gel is supplied with a plastic dosing card with markings for 2 grams and 4 grams that should be used to measure the proper dose.) Review of Resident #8's physician's order dated 02/12/24 revealed an order for Diclofenac Gel 1% Apply 2 grams topically to left knee daily, **use dosing card**. Review of Resident #8's February 2024 electronic medication administration record (eMAR) revealed: -There was an entry for Diclofenac Gel 1%, apply 2 grams topically to left knee daily, **use dosing card**. - Diclofenac Gel 1% was scheduled for administration at 10:00am.	D 358		

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D 358	Continued From page 9 - Diclofenac Gel 1% was documented as administered daily at 10:00am from 02/01/24 - 02/29/24, except on 02/13/24, 02/17/24, and 02/18/24 when it was documented as refused. Observation of the 10:00am medication pass on 02/29/24 revealed: -The medication aide (MA) squeezed a quarter-sized amount of Diclofenac Gel 1% onto her gloved hand and applied the unmeasured Diclofenac Gel to the resident's left knee at 9:58am. -The MA did not use a dosing card to measure 2 grams of Diclofenac Gel 1% as ordered. Observation of Resident #8's medications on hand on 02/29/24 at 9:58am revealed: -There was a tube of Diclofenac Gel 1% with instructions to apply 2 grams topically to left knee daily **use dosing card**. -There was no plastic dosing card in the box with Resident #8's tube of Diclofenac Gel. Interview with Resident #8 on 02/29/24 at 10:40am revealed: -The MAs usually applied Diclofenac Gel to her left knee every day. -The MAs usually squeezed the Diclofenac Gel onto their gloved hand and then rubbed it on her left knee. -The Diclofenac Gel helped with her knee pain. Interview with the MA on 02/29/24 at 10:51am revealed: -She usually used a plastic dosing card that came in the package with Resident #8's Diclofenac Gel. -She did not see the plastic dosing card in the box that morning, 02/29/24, so she squeezed some of the Diclofenac Gel onto her gloved finger without using a dosing card to measure it.	D 358		

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D 358	Continued From page 10 -Sometimes the dosing card was in the box and sometimes it was not. -When the dosing card was not in the box, she would administer the Diclofenac Gel without measuring the amount. -The Diclofenac Gel usually helped the resident and the resident had not complained of knee pain to her. Interview with the Memory Care Coordinator (MCC) on 02/29/24 at 11:10am revealed: -Diclofenac Gel 1% came with a plastic dosing card and should be used by the MAs to measure the correct dosage. -If the MAs were unable to locate the dosing card that came with the Diclofenac Gel, the MAs should contact the pharmacy to get a new dosing card. Interview with the Administrator on 02/29/24 at 11:28am revealed: -The MAs should use the plastic dosing card to measure the correct dosage of Diclofenac Gel. -The MAs should call the pharmacy if there was no plastic dosing card on hand for the resident's Diclofenac Gel. Interview with Resident #8's primary care provider (PCP) on 02/29/24 at 1:52pm revealed: -Resident #8 should be administered the ordered dosage of 2 grams of Diclofenac Gel. -If the Diclofenac Gel was not measured and less than 2 grams was applied, it would not be as effective in treating the resident's pain. d. Review of Resident #6's current FL-2 dated 01/12/24 revealed: -Diagnoses included dementia, insomnia, conductive hearing loss, and cognitive communication deficit.	D 358		

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D 358	Continued From page 11 -There was an order for Diclofenac Sodium 1% Gel, apply 2 grams topically to right knee twice daily. (Diclofenac Sodium 1% Gel is a medication used to treat arthritis pain). Observation of the Special Care Unit (SCU) on 02/29/24 from 8:50am to 8:55am revealed the Memory Care Coordinator (MCC) was working as the medication aide (MA) for the first shift. Observation of the 10:00am medication pass on 02/29/24 from 9:08am to 9:25am revealed: -The MCC measured 2 grams of Diclofenac 1% Gel on the dosing card and applied the gel topically to Resident #6's right knee. -The MCC measured 2 grams of Diclofenac 1% Gel on the dosing card and applied the gel topically to Resident #6's left knee. Review of Resident #6's February 2024 electronic medication administration record (eMAR) revealed: -There was an entry for Diclofenac 1% Gel, apply 2 grams topically to right knee twice daily. -Use dosing card. -Diclofenac 1% Gel was documented as administered at 10:00am on 02/29/24. [illegible] complained of knee pain in both knees before her primary care provider (PCP) prescribed Diclofenac 1% Gel. -She had always applied Diclofenac 1% Gel to both of Resident #6's knees. -She applied Diclofenac 1% Gel to both knees so Resident #6 would not have pain because the Resident walked in the hallways frequently throughout the day -She thought the order was for Diclofenac 1% Gel	D 358		