STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	345202	A. BUILDING _____ B. WING _____	C 09/18/2019

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CAPITAL NURSING AND REHABILITATION CENTER	**3000 HOLSTON LANE RALEIGH, NC 27610**

(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 000	INITIAL COMMENTS The surveyor entered the facility on 9/3/19 to conduct a complaint investigation survey and exited on 9/4/19. Additional information was obtained through 9/18/19. Therefore, the exit date was changed to 9/18/19. One of nine allegations were substantiated during the complaint investigation	F 000		
F 757 SS=D	Drug Regimen is Free from Unnecessary Drugs CFR(s): 483.45(d)(1)-(6) §483.45(d) Unnecessary Drugs-General. Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used- §483.45(d)(1) In excessive dose (including duplicate drug therapy); or §483.45(d)(2) For excessive duration; or §483.45(d)(3) Without adequate monitoring; or §483.45(d)(4) Without adequate indications for its use; or §483.45(d)(5) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or §483.45(d)(6) Any combinations of the reasons stated in paragraphs (d)(1) through (5) of this section. This REQUIREMENT is not met as evidenced by: Based on resident interview, record review, staff interview, physician interview, pharmacist	F 757	The statements made on this plan of correction are not an admission to and do	10/5/19

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

Electronically Signed | 09/30/2019

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F 757	Continued From page 1 interview, and family interview the facility failed to assure one (Resident # 1) of one sampled resident, did not receive an unnecessary drug. Resident # 1 was transferred from the facility to the hospital due to a hypoglycemic emergency (the resident's blood sugar was low). During the hospitalization Resident # 1 was found to have a diabetic medication in her blood stream for which she had no order or diagnosis to support its use. The findings included: Resident # 1 was admitted to the facility on 7/5/19 following surgery for a right femur fracture. The resident's facility cumulative diagnoses list included: end stage renal disease, anemia, hypotension, atrial fibrillation, hyperlipidemia, gastro-esophageal reflux disease (GERD), glaucoma, polyneuropathy. The resident's diagnosis list did not include diabetes. The resident's facility admission orders dated 07/05/19, revealed the resident was ordered to undergo dialysis treatment on Monday, Wednesday, and Friday. The resident did not have a physician's order to receive any diabetic medications. The resident's five-day admission MDS (Minimum Data Set) assessment, completed 7/12/19, revealed the resident was cognitively intact with no visual problems. The resident's physician orders and the July 2019 Medication Administration Record (MAR) revealed the following oral medications were ordered and scheduled to be given on 7/13/19 prior to the resident's transfer to the hospital on 7/13/19 at 5:35 PM:	F 757	not constitute an agreement with the alleged deficiencies. 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. F757 The plan of correcting the specific deficiency. The plan should address the processes that lead to the deficiency cited: The facility failed to assure one (Resident # 1) of one sampled resident, did not receive an unnecessary drug. 1. Corrective action for resident(s) affected by the alleged deficient practice: On 7/14/19 the Director of Nurses audited resident #1 medications to assure no diabetic medications were in the ordered medications on the medication cart or in the med room for this resident. Results: No diabetic medications or medications that had not been ordered by the physician were found in the resident's medications on the med cart or in the med room. On 7/14/2019, the Director of Nurses and Administrator investigated the resident's claim that she received two pink pills. The results of that investigation did show that the resident did in fact receive two pink pills, Prilosec and Synthroid, which were both scheduled. Additionally through interviews with the nurses the Administrator and Director of Nurses were able to determine that the resident had	

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F 757	Continued From page 2 Prilosec over the counter tablet Delayed Release 20 mg (milligrams) one time per day (used for gastro-esophageal reflux disease); initially ordered on 7/12/19; scheduled on MAR for 6:30 AM; signed as administered by Nurse # 1 on 7/13/19 at 6:30 AM Synthroid 25 mcg (micrograms) one time per day (used for hypothyroidism); Initially ordered on 7/11/19 after an abnormal thyroid stimulating hormone level result of 5.4 on 7/9/19 (normal TSH is 0.27 to 4.20); Synthroid scheduled to be given at 6:30 AM; signed as administered by Nurse # 1 on 7/13/19 at 6:30 AM Acetaminophen 500 mg every six hours as needed for pain and give two tablets by mouth in the morning for pain for 10 days; initially ordered on 7/11/19; daily dose scheduled on MAR for 9:00 AM; signed as administered by Nurse # 2 on 7/13/19 at 9:00 AM Multivitamin one tablet every day; initially ordered on 7/5/19; scheduled on MAR for 9:00 AM; signed by Nurse # 2 as administered on 7/13/19 at 9:00 AM Omega-3 Fatty Acids Capsule 1200 mg one capsule one time a day; initially ordered on 7/5/19; scheduled on MAR for 9:00 AM; signed as administered by Nurse # 2 on 7/13/19 at 9:00 AM Senna-Docusate Sodium tablet 8.6-50 mg give two tablets one time per day for constipation; initially ordered on 7/5/19; scheduled on MAR for 9:00 AM; signed as administered by Nurse # 2 on 7/13/19 at 9:00 AM Vitamin C tablet 500 mg two times per day; initially ordered on 7/8/19; scheduled on MAR for 9:00 AM; signed as administered on 7/13/19 by Nurse # 2 at 9:00 AM Oxycodone 5 mg three times per day for pain-hold for lethargy; initially ordered 7/11/19; scheduled on MAR for 9:00 AM, 2:00 PM, and	F 757	not received any injectable insulin. On 9/10/2019 the Pharmacy Manager audited for any dispensing of Glypizide for resident #1 with no Glypizide found dispensed to resident #1. 2. Corrective action for residents with the potential to be affected by the alleged deficient practice. On 9/03/19 the Director of Nurses reviewed all resident medication orders on the 100 hall medication cart for the presence of Glipizide orders. Results: No residents were found to have Glipizide ordered for the period that resident #1 was present in the facility. On 9/3/19 the Director of Nurses reviewed the 100 hall cart and medication room for the presence of any Glipizide. Results: None found on medication cart or in the medication room. On 9/03/19 McNeill's Pharmacy completed an audit of the med dispense unit with the findings that no Glipizide had been dispensed from 7/01/19 through 9/03/19. On 9/10/2019 the pharmacy audited pharmacy dispensing of Glypizide to residents from 7/01/2019 through 9/10/2019. Results: No Glypizide was ordered or dispensed to any residents during this time period. On 9/30/19 Glypizide was moved to a segregated section of the pharmacy that contains look alike, sound alike drugs. 3. Measures /Systemic changes to prevent reoccurrence of alleged deficient practice: On 9/23/19 the Director of Nurses/Assistant Director of Nurse began education of all nurses and agency nurses	

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F 757	Continued From page 3 9:00 PM; signed as administered by Nurse # 2 at 9:00 AM and 2:00 PM on 7/13/19 According to physician orders, other medications which the resident was ordered to receive but were not administered prior to her emergency transport on 7/13/19, included the following: Coumadin 3 mg Monday, Tuesday, Thursday, Friday, Saturday and 5 mg on Wednesday; ordered on 7/10/19; scheduled on MAR for 5:00 PM and noted by Nurse # 3 as "R" which signified the resident refused on 7/13/19 Gabapentin 100 mg at bedtime for neuropathy; initially ordered on 7/5/19; scheduled on MAR for 9:00 PM; noted by Nurse # 3 not to be administered on 7/13/19 because the resident was away The nursing notes revealed the following entries prior to the resident's transfer to the hospital on 07/13/19. On 7/13/19 Nurse # 1 entered a note at 7:36 AM noting the resident's vital signs at 5:34 AM had registered: blood pressure 122/48; temperature 97; pulse 63; respirations 19. The nurse did not note the resident had voiced any concerns or complaints. On 7/13/19 Nurse # 2 entered a note at 1:03 PM. The nurse wrote, "Pt. (patient) is alert and oriented to person, situation and place, ate 50 % of breakfast and 100% of lunch. Noted watching TV and resting through out shift. The pt. voiced concerns about the medications that she received on 3rd shift, focusing on 2 pink pills. This writer reviewed Resident's medications and showed the pink pills to the pt. and her daughter and they agreed that she takes both meds, but the pt.	F 757	full time, part time and PRN on: the six rights of medication administration, the three checks of med administration and policy on addressing any medication that is unfamiliar, appears different in color, shape, size or does not match the order and or label on the ordered medication and nurse hand off of medications when resident rooms are changed that include a change in med carts. The in-services will be completed by 10/5/19 at which time the above must be in-serviced prior to working. On 9/30/19 the Pharmacy Manager conducted an in-service to review the workflow process with all staff pharmacists and technicians with emphasis placed on the components of the workflow process designed to prevent dispensing errors. 4. Monitoring Procedure to ensure that the plan of correction is effective and that specific deficiency cited remains corrected and/or in compliance with regulatory requirements. The Director of Nurses/Pharmacy Consultant will monitor compliance for the presence of unnecessary medications utilizing the Medication Quality Assurance Tool weekly x 2 and monthly x 3. Monitoring will include observation of nurse med pass of three residents on two different med carts to include the six rights and three checks of medication administration and accurateness of medications as packaged and monitoring of two residents who have had a room change that resulted in medication carts being changed for the storage of their	

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F 757	Continued From page 4 states they are different colors at home. The pt. voiced no further concerns or questions about her medications after reviewing her pills. Resident denies pain and discomfort." Following the nursing entry made at 1:03 PM on 7/13/19, the next nursing entry was made at 3:03 PM by Nurse # 3. Nurse # 3 wrote, "On walking rounds at (3:00 PM) patient is in bed with head up and awake and alert has no c/o (complaints) pain or discomfort to nurse at this time." On 7/13/19 at 5:28 PM, Nurse # 3 made an entry noting, "entered into patient's room at (5:15 PM) to give her afternoon medications and she is lying in bed with cool skin and her head is laying to the left side with saliva drooling out of the corner of her mouth patient not responding to verbal stimuli patient is breathing and has a bounding pulse called code blue and called 911 to activate emergency response. (Responsible party) notified and states she is in driveway at present and on her way inside." On 7/13/19 at 6:00 PM, Nurse # 4 wrote a note specifying she entered the resident's room after the code blue was called to find the resident not responding. Nurse # 4 noted the resident's blood sugar was 57 and she was given glucagon. The nurse noted the resident never quit breathing, and Emergency Medical Services (EMS) arrived. The physician was contacted, and orders were given to transport the resident to the hospital. Review of EMS (Emergency Medical Service) records, dated 7/13/19 revealed the following. EMS arrived on the scene on 7/13/19 at 5:24 PM. The staff reported they had given Glucagon to the resident prior to their arrival. At 5:25 PM the	F 757	medications. The Staff Pharmacist will monitor compliance with accuracy of dispensing of medications utilizing the Medication Dispensing Process Quality Assurance Tool weekly x 2 and then monthly x 3. Monitoring will include observation of 10 blister packs filled manually and monitoring of 10 blister packs filled by the automated dispensing system process. Reports will be presented to the monthly Quality Assurance committee by the Director of Nurses and Pharmacy Manager to ensure corrective action is initiated as appropriate. Compliance will be monitored and the ongoing auditing program reviewed at the monthly Quality Assurance Meeting. The monthly Quality Assurance Meeting is attended by the Administrator, Director of Nursing, MDS Coordinator, Therapy Manager, Health Information Manager, and the Dietary Manager.	

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resident's blood sugar was 32. At 5:26 PM, EMS obtained IV (intravenous access). At 5:27 PM EMS administered 15 grams of 10 % dextrose via IV. The resident responded. At 5:51 PM her blood sugar was 178, and she was transferred to the hospital at 6:09 PM.

Review of hospital records revealed Resident # 1 was hospitalized from 7/13/19 to 7/19/19. Review of the admitting physician's note, dated 7/14/19, revealed the following documentation. "Patient reports she was feeling well when she woke this morning. She remembers being given 2 pink pills that she did not recognize by one of the staff members at the skilled nursing facility and started feeling poorly shortly after that. She endorses fatigue, somnolence. She reports that her appetite was not as good as usual, but she was able to eat breakfast and most of lunch. She then remembers going to sleep and waking up with many people surrounding her and not being able to communicate. She was found to have a blood glucose in the field (outside of the hospital) of 32 and she received glucagon at the skilled nursing facility prior to arrival. Patient is not a diabetic and is not on any insulin or sulfonylureas (diabetic medications)."

Review of Resident # 1's hospital discharge summary, dated 7/19/19, revealed the following documentation regarding her hospital course:

"Upon arrive to the ED (Emergency Department) she was normotensive, afebrile, and bradycardic. Despite administration of several D50 injections and continuation on D5-1/2NS (Dextrose and Normal Saline) maintenance fluid at 100 ml/hr., patient's glucose remained in the 30s and below. She was transitioned to D10 at 75 ml/hr. (75

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milliliters per hour). She was placed on every 2 point of care glucose checks (the testing was done near to the patient's care area). Hypoglycemia panel was ordered. Endocrinology was consulted. Both insulin and Peptide levels were found to be elevated. It is likely that patient received sulfonylureas unintentionally at SNF (skilled nursing facility). Blood glucose levels returned to normal and remained stable for the duration of admission. Hypoglycemia panel pending on discharge."

Review of Endocrinology consult notes, dated 7/16/19, revealed Resident # 1's blood sugar had been stable for the past 24 hours by the date of 7/16/19 without dextrose administration. On 7/17/19 endocrinology notes revealed the consulting endocrinology team were signing off on the resident's care, and they would call the resident and family with the results of the hypoglycemic panel after the resident's discharge.

According to the discharge summary, dated 7/19/19, the resident was discharged to another facility.

Further review of the hospital records revealed the oral hypoglycemic agent panel had been collected on 7/14/19 at 11:48 AM and sent to the Mayo Clinic Laboratory. The results were filed on 7/23/19 after the resident was discharged from the hospital. The result showed Resident # 1's blood had been positive for the oral diabetic medication of Glipizide.

Resident # 1 was interviewed on 9/17/19 at 8:00 PM via phone. Resident # 1 reported the following. The resident stated she was not a

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diabetic. She also stated the only pills she had ever taken while residing at the nursing facility were from the nurses at the facility. She recalled the events of her last day at the facility as saying it seemed to be in the night when a short nurse gave her two pink pills. She tried to explain to the nurse she did not take any medication at that time and she did not think they were her pills. The nurse had told her the pills were hers, and she took them. After taking the pills she "did not feel good." She called multiple family members on her phone to tell them she did not feel good. The next thing she recalled from that day was seeming to be in the dark with someone calling her name and rubbing her hand. She awakened and saw a lot of people around her bed. They sent her to the hospital. The resident stated after her hospitalization she had gone to another nursing home and then home.

Resident # 1's responsible party (RP) was interviewed on 9/3/19 at 2:28 PM and again on 9/5/19 at 9:35 AM. The Responsible Party reported the following information. Resident # 1 had called her home on the morning of 7/13/19 and told her that she "did not feel right." The RP went to the facility around 8:00 AM. The resident described the night shift nurse (Nurse # 1) and stated Nurse # 1 had given her two pills she did not recognize. The resident informed her (the RP) that she (Resident # 1) had tried to explain to the nurse the pills were not hers, but the nurse had administered them anyway. The RP located a nurse on the hall and questioned the nurse about the resident's medications. The hall nurse stated she would come to the room. The hall nurse (Nurse # 2) thereafter entered Resident # 1's room carrying two medications and informed the Responsible Party that the medications were the

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ones given on night shift. The nurse (Nurse # 2) named them as being a thyroid medication and an antacid. The Responsible Party stated she nor the resident really looked at the color of the medications and validated the issue was resolved before the nurse walked out of the room. The resident had initially been upset when she (the RP) had arrived because of the resident's belief that she had gotten the wrong pills, but as the morning progressed, the resident appeared tired and calmed down. At approximately 11:00 AM, the Responsible Party stated she left because the resident seemed to be resting. She returned that evening. At the same time of her return, she was receiving a phone call from a facility nurse telling her Resident # 1 was to be transferred to the hospital. She entered the facility and talked to the EMS workers. The EMS workers asked about the resident's blood sugars, and the RP informed them Resident # 1 did not have diabetes. The EMS workers informed her the resident's blood sugar was low. The RP stated it was found by the hospital staff that Resident # 1 had been given Glipizide. The RP stated Resident # 1 had never been a diabetic, never taken diabetic medication, and never had blood sugar problems before or after the incident of low blood sugar on 7/13/19.

Nurse # 1 had cared for Resident # 1 from 11:00 PM on 7/12/19 to 7:00 AM on 7/13/19. Nurse # 1 was interviewed on 9/3/19 at 1:45 PM via phone and reported the following. She recalled she gave Resident # 1 her medications as scheduled around 6:00 AM. Nurse # 1 stated she recalled one of the pills was her Synthroid and the other was the medication which was due on the MAR to be administered. She had not given any Insulin or diabetic medication to the resident. The resident routinely asked what her medications were when

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they were administered. The resident had done so the morning of 7/13/19 and the nurse had informed her what type of medications the pills were. The resident had not voiced to the nurse she thought they were the wrong pills.

According to the July 2019 MAR, the other pill due and administered by Nurse # 1 at 6:30 AM on 7/13/19 had been Prilosec. According to an interview with the Administrator and Director Of Nursing on 7/14/19 at 1:30 PM, the Prilosec was a stock medication and not individually filled for a specific resident. The DON stated both the Prilosec and Synthroid had been a pinkish color and were not white. On 9/4/19 at 12 noon, the facility's stock of Prilosec was observed to be a pinkish-orange color.

Nurse # 2 had cared for Resident # 1 from 7:00 AM to 3:00 PM on 7/13/19. Nurse # 2 was interviewed on 9/3/19 at 3:00 PM and reported the following information. At the beginning of the shift, Resident # 1 was on the phone to one of her family members. Nurse # 2 stated Resident # 1 was upset because she thought she had gotten medication she was not supposed to have received. She described the night nurse and said the night nurse had given her the wrong pills. The resident described the pills she had been given as "not white." The nurse recalled the resident saying one was more of a purplish color and one more of a pinkish color. She found the two medications in the medication cart which were supposed to have been administered by Nurse # 1 and she took them along with the MAR to the room. A family member was in the room at the time. She showed the medications to the family member and the resident. The pills were colored pills and were not white. The nurse explained the

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pills might be different from the ones she had gotten at home. The nurse thought the issue was resolved, and the resident was not concerned any longer. That day when Nurse # 2 gave the resident medication, she called the name of everything she administered. The resident appeared fine the whole day and had no complaints of which she was aware. The nurse stated she did not give Resident # 1 any diabetic medication.

Nurse # 3 had cared for Resident # 1 on 7/13/19 from 3:00 PM until her time of discharge. Nurse # 3 was interviewed on 9/4/19 at 11:20 AM and reported the following information. The date of 7/13/19 was the first time she had been assigned to the resident. She had made rounds with Nurse # 2 at 3:00 PM. Nurse # 2 did not report there had been a problem nor did the resident. The resident had no complaints at 3:00 PM. Around 5:00 PM when the resident's medication was due, she entered the room to administer medication and found the resident very lethargic and barely responsive. She immediately called a code. The resident's blood sugar was low, and she was given Glucagon and transported to the emergency room. The nurse had never administered any medication to the resident.

Nurse # 4 was interviewed on 9/3/19 at 3:40 PM. Nurse # 4 had been one of the supervisors on 7/13/19 and had responded to Resident # 1's emergency. When she entered the room, the resident was still breathing. Her blood sugar was checked, and it was very low. Per a standing emergency protocol, they administered an intramuscular injection of Glucagon. The resident started to respond, and EMS arrived to take over.

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The facility Administrator and Director of Nursing (DON) were interviewed on 9/3/19 at 1:30 PM. The administrator reported they first became aware of the situation on 7/14/19 at 8:15 AM. The facility admission coordinator had checked on Resident # 1 following her hospital transfer and found there had been a question of the resident possibly erroneously receiving a diabetic medication before her transport. They were aware the resident had said she had been given two pink pills which were not hers by the night shift nurse. The DON came in that morning (7/14/19) and audited all the resident's medications. She had no diabetic medications ordered. The DON spoke to Nurse # 1, Nurse # 2, and Nurse # 3. All denied they had given any diabetic medication to the resident. The Synthroid and the Prilosec were not white pills, but more of a tinted color. They went through the medication cart. The Administrator stated on the date of 7/13/19 there had been no Insulin on the medication cart where Resident # 1's medications had been stored. They spoke to dialysis staff on 7/15/19 who reported they had not given any diabetic medications to Resident # 1 on 7/12/19. They talked to the facility physician about it. They did not talk to the resident or the responsible party prior to concluding their investigation. They concluded there was not enough evidence to substantiate the resident had received a diabetic medication and felt her blood sugar could have been a result of a medical issue.

On 9/11/19 at 3:38 PM the Administrator provided documentation that Resident # 1 was initially admitted to the facility's 300 hall. The resident was moved from the 300 hall to a private room on the 100 hall on the date of 7/10/19. According to the Administrator, Resident # 1 received

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medications from a cart which stored medications for Rooms 100-202 after she was moved on 7/10/19. She continued to receive medications from this cart up until her discharge.

On 9/5/19 at 9:35 AM a facility Pharmacist was interviewed. The Pharmacist stated Resident # 1's medications had been returned to them following her facility discharge and the medications had been destroyed and therefore they could not examine any evidence at this point. The pharmacist stated they do not stock Glipizide in a colored pill. All their Glipizide pills are white. The only new medication they had recently filled for the resident prior to her 7/13/19 discharge was the Synthroid, and the medication had been checked three times prior to dispensing it to the facility. The pharmacist stated the peak action of Glipizide is 1 to 3 hours (the time the drug is working most in a person's system).

On 9/11/19 at 1:03 PM the pharmacist provided a list of resident's names for whom they had dispensed Glipizide from 7/5/19 to 7/13/19. A review of the list revealed Resident # 1's name was not on the list. According to the list, Glipizide was not dispensed to any resident who would have received medications from the same medication cart as Resident # 1 when she resided in the 100 hall private room.

According to the list, the pharmacy dispensed Glipizide 5 milligrams for Resident # 8 on 6/29/19. According to the pharmacy list, Resident # 8 had resided in the same room as Resident # 1 while Resident # 1 was on the 300 hall. According to the pharmacy list, Resident # 8 was discharged on 7/10/19. The date of 7/10/19 was the date on which Resident # 1 moved to her new room.

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The physician, who served as Resident #1's physician at the time of the incident, was interviewed on 9/3/19 at 1:00 PM. The physician stated infection and other causes could contribute to low blood sugars, and that at times end stage renal disease patients could have low blood sugars. The physician stated she knew the facility had talked to their staff and investigated the matter, and they could find that no one had given any wrong medication to the resident. The physician was not sure of any definitive diagnoses found at the hospital because Resident # 1 had not returned to the facility or her care.

The facility medical director was interviewed on 9/6/19 at 4:02 PM. The Medical Director reported the following in the interview. He had just become the medical director during the week of 9/6/19 and had not been familiar with Resident # 1 at the time of her residency. He had taken time to review the resident's facility medical records. If the Mayo Clinic Lab had shown Glipizide in the resident's system, in his opinion it would have been more likely Resident # 1 had received it around 2:00 PM to result in the hypoglycemic state found at 5:15 PM. The Medical Director stated there was no documentation or facility interviews to corroborate this had occurred. The Medical Director was interviewed about the significance of the resident's elevated peptide levels found in the hospital. He stated peptides are increased when a person's pancreas makes Insulin, and Glipizide does act in this manner; it causes the pancreas to make Insulin and an individual's peptide levels are elevated when this occurs. The Medical Director pointed out that given the facility and pharmacy records showed

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no Glipizide on the medication cart where Resident # 1's medications were stored, then this would have indicated that someone would have had to have gone to another medication cart, removed the Glipizide, and taken it to Resident # 1. He pointed out that this seemed unlikely in his opinion.

On 9/12/19 at 2:32 PM a staff member from the Mayo Clinic Department of Laboratories and Pathology, responded by email communication that a department director would respond with more information regarding the oral hypoglycemic panel test reliability factor. On 9/18/19 the Director of the Mayo Clinic Laboratories and pathology Lab specified by email that she was oversees and unable to call at the time. She specified the following information in her email regarding the oral hypoglycemic panel. "This assay although mass spectroscopy based is still considered a screening method and therefore not considered definitive. And although during method validation we look for common interferences it is impossible to identify everything that could. As always with a screening method we recommend that it be followed up with a definitive method if medically/clinically indicated."

The Endocrinologist, who saw Resident # 1 in consultation during her hospitalization of 7/13/19, was interviewed on 9/13/19 at 2:30 PM. The Endocrinologist reported the following information in her interview. Normally an individual would have a reaction to Glipizide within 1 to 3 hours, and it would be eliminated from their system in 12 to 24 hours. Resident #1 had end stage renal disease, and therefore with end stage renal disease, Glipizide could stay in the system for a week. She stated it was plausible that Resident #

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1's hypoglycemic status on the evening of 7/13/19 could have resulted from the resident receiving the Glipizide on the morning of 7/13/19. The resident's renal disease caused the Glipizide to have a more severe impact. There was a check list they went through to rule out all other diagnoses which could have caused the hypoglycemic episode of 7/13/19. The Endocrinologist stated multiple tests were done, and no other cause was found except for the Glipizide being in Resident # 1's system. The Endocrinologist also stated she felt the Mayo Lab was reliable, and the resident's thyroid problem would not have caused any of the problems with her low blood sugar of 7/13/19. She was not aware of any medications or supplements which would have affected the result of the panel and led to a false positive.

A staff member from Resident # 1's dialysis clinic was interviewed on 9/16/19 at 1:10 PM. The staff member stated the dialysis center never gave oral medications to Resident # 1 during her dialysis days. According to the dialysis staff member, oral medications were never part of her treatment at the dialysis center.

On 9/18/19 at 10:00 AM the Administrator was interviewed and reported the following. In doing their initial investigation, they had never been aware Glipizide was identified to have been the medication suspected of causing the hypoglycemic action. Because Resident # 1 had an offer to return to the facility following her 7/13/19 hospital transfer, the facility was able to access and view her hospital records for 30 days after her transfer on 7/13/19. They did look at the initial hospital documentation which noted the resident was saying she had received two pink

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pills or that her hypoglycemia could have been due to Insulin or a diabetic medication. They verified Resident # 1's 6:00 AM Prilosec and Synthroid were pinkish in color, and there had been no Insulin on the medication cart. Therefore, the resident's statement about the pink pills seemed to describe medication she was ordered to have received, and did not seem to substantiate to them there had been an error. They also felt the hypoglycemic episode appeared to have been an extreme reaction for an oral diabetic medication, and the timeframe in which Resident # 1 alleged she received the wrong pills to have caused such an extreme reaction, did not make sense to them. The resident decided not to come back to the facility, and therefore they quit reviewing her medical records and looking for any further cause. The family nor resident ever told them Glipizide had been found to be the reason for the hypoglycemia. When Resident # 1 was moved from the 300 hall to the 100 hall, the nurses moved her medications from one cart to another. They also placed the room change in the computer, and the facility's computer system automatically updated so that the 100 Hall nurse would see the correct MAR for Resident # 1. Resident #8's medications (the medications for Resident # 1's previous roommate which had included Glipizide), would have been sent home with Resident # 8. On 7/14/19, the date on which they became aware there was allegedly a problem, they went through the medication cart and there was no Glipizide with Resident # 1's medications. The Administrator stated if Resident # 8's Glipizide had been accidentally moved with Resident # 1 rather than sent home with Resident # 8, then they would have found it on 7/14/19, and this had not been the case.

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