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	345561	A. BUILDING _____ B. WING _____	C 05/15/2015

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UNIVERSAL HEALTH CARE/FUQUAY-VARINA	**410 S JUDD PARKWAY SE FUQUAY VARINA, NC 27526**

(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 367 SS=D	483.35(e) THERAPEUTIC DIET PRESCRIBED BY PHYSICIAN Therapeutic diets must be prescribed by the attending physician. This REQUIREMENT is not met as evidenced by: Based on observation, record review and staff interviews the facility failed to provide an ordered nutritional supplement for 1 of 4 residents (Resident #143) whose nutrition status was reviewed. Findings included: Resident #143 was admitted to the facility on 04/01/15 with cumulative diagnoses of peripheral vascular disease, cerebrovascular accident and difficulty walking. Resident #143's Admission Minimum Data Set dated 04/08/15 revealed that Resident #143 had no swallowing disorders and weighed 134 pounds. Review of the Dietician General Notes dated 04/14/15 at 11:42 AM showed Resident #143's current body weight (CBW) was 128 pounds. Resident #143 had elevated protein and calorie needs related to a recent limb amputation, low body weight and a low albumin level (a test that measures the amount of protein in blood plasma). The Registered Dietician recommended a nutritional supplement which contained extra nutrition, extra protein and extra calories be provided at lunch for 60 days. Review of the Physician's Telephone Orders dated 04/14/15 revealed a change in Resident #143's diet from a No Added Salt Low Fat diet to a regular diet and the addition of a (name brand) nutritional supplement one carton with lunch for 60 days. Review of the white Diet Order Form dated	F 367	1. On 5/15/15 the menu label for resident #143 was updated to include a shake supplement on his tray at lunch daily by the dietary manager. The shake has been served each day since then. 2. Physician orders have been audited by the registered dietitian on 6/4/15 to identify residents with orders for nutrition supplements. Menu labels and/or MARs were also audited to assure the current orders for supplements are present. No other resident was affected by the deficient practice. 3. Nursing and Food Service staff will be in serviced by DON/ADON/RD about the process to follow when nutritional supplements are ordered by a physician, by 6/5/15. The training will include: a. Licensed nurse will obtain from MD an order for nutritional supplements, and will be made aware of the products used at the facility. b. Dietary communication form from nursing to dietary will be completed by a licensed nurse. c. Food service director will add shake or frozen supplements to menu label so it is served from the kitchen. Other nutrition supplements given by nursing (such as Pro-Stat, Bene Protein, or Med Pass) will be listed on the MAR for charge nurse to	6/8/15

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

Electronically Signed | 06/05/2015

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F 367	Continued From page 1 04/14/15 for Resident #143 showed a diet change to a regular diet and a (brand name) nutritional supplement one carton with lunch for 60 days was written. The form instructed the white copy go to Nursing, the yellow copy to Dietary, and the pink copy to Pharmacy. Review of the Dietician General Notes dated 05/13/15 at 3:14 PM showed Resident #143's CBW was 125 pounds which indicated a weight trend down, but stable for two weeks. The note showed Resident #143 received the ordered nutritional supplement daily. The current nutritional regime was recommended to be continued. In an observation on 05/14/15 at 12:55 PM Resident #143 did not receive the ordered nutritional supplement on the meal tray. The meal card did not show that a supplement was to be added to the meal tray but did list the diet as regular. In an observation on 05/15/15 at 12:25 PM Resident #143 did not receive the ordered nutritional supplement on the meal tray. The meal card did not show that a supplement was to be added to the meal tray but did show a regular diet was ordered. In an interview on 05/15/15 at 12:30 PM Nursing Assistant (NA) #1 stated any supplements that needed to be served to a resident were listed on the meal card. She indicated Resident #143's meal card did not list a supplement. In an interview on 05/15/15 at 12:32 PM Nursing Manager #1 indicated changing a resident ' s diet consisted of several steps. An order for a diet change was received and then a diet order form was filled out and hand walked to the kitchen and handed to someone on the dietary staff. She stated supplements that were ordered for residents to be served with meals were provided	F 367	administer. d. Notification of central supply by a nurse when a non-food nutritional supplement is ordered. Central supply will order as needed. e. Administration of supplements (oral and with med administration) will be monitored at random during rounds by the DON, RD, and/or dietary manager. A list of orders for supplements delivered by dietary will be maintained by the dietary manager. Audits (to include all 3 meals and med pass) will be done by the DON,RD, or dietary manager to assure supplements are served as ordered. Audits will be done as follows: Audit 5 supplements daily x 1 week; 5 supplements 3 times weekly for one month; and 5 supplements 1 time weekly for one month. 4. Results will be shared at the monthly QA meeting monthly by the DON for 3 months, where the need for further audits will be determined.	

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F 367	Continued From page 2 by the dietary staff on meal trays. She indicated nursing staff would know if a resident received a supplement because it would be written on the resident ' s meal card. In an interview on 05/15/15 at 2:55 PM the Dietary Manager (DM) stated he could not locate the Diet Order Form which showed Resident #143 had a supplement ordered or a change to a regular diet. He indicated he had never received the order and that was why Resident #143 did not receive the ordered supplement. In a telephone interview on 05/15/15 at 3:15 PM the Registered Dietician (RD) stated she did not follow-up to make sure Resident #143 received the ordered supplement. She indicated when an order was written for a resident to receive a supplement she expected the order to be followed. In an interview on 05/15/15 at 4:10 PM the Director of Nursing (DON) indicated it was her expectation that orders for supplements be sent to the kitchen if applicable and that the kitchen supply it on the resident's meal trays.	F 367		
F 425 SS=E	483.60(a),(b) PHARMACEUTICAL SVC - ACCURATE PROCEDURES, RPH The facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in §483.75(h) of this part. The facility may permit unlicensed personnel to administer drugs if State law permits, but only under the general supervision of a licensed nurse. A facility must provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet	F 425		6/8/15

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F 425	Continued From page 3 the needs of each resident. The facility must employ or obtain the services of a licensed pharmacist who provides consultation on all aspects of the provision of pharmacy services in the facility. This REQUIREMENT is not met as evidenced by: Based on observation, record review and Pharmacist and staff interviews the contracted pharmacy failed to notify the Director of Nursing when a concern was raised regarding ice crystals in a vial of insulin and failed to monitor the medication refrigerator temperature logs that were posted on the door of the refrigerator for temperatures that were out of range for medications stored in the refrigerator. Findings included: Review of the undated Pharmacy Consulting Services contract revealed under Requirements: "(name of pharmacy) will provide pharmacy consulting services in conjunction with Facility's duties under applicable law. Such duties may include, as applicable, monthly inspections of each of the Facility's nursing stations, the drug storage area, and medical records to monitor compliance with pharmacy policies and procedures and state and federal regulations; the provision of a written report regarding the inspections and on the results of the drug regimen review, noting any irregularities or other areas of concern. Operator agrees to cause the Director of Nursing and attending physician to act upon the consultant reports by indicating acceptance or rejection of the reports pursuant to	F 425	1. On 5/14/15 all refrigerated medications in both medication rooms were discarded by the DON, and replaced that evening by the contracted pharmacy. 2. Both refrigerators were defrosted by maintenance on 5/14/15 and thermostats set to maintain temperature range of 35-46 degrees. Temperatures have been within this range since that day. 3. A. Nursing staff will be trained regarding storage of medications/biologicals, by the DON or ADON by 6/5/15. Training will include: 1. Appropriate temperature range(35-46 degrees) of refrigerators 2. Documentation of the temperature daily by a licensed nurse. 3. Procedure for licensed nurse to follow if temperature is found to be out of range (discard contents of refrigerator, notify maintenance director and DON immediately, and re-order medications). 4. Procedure for licensed nurse to notify DON if pharmacy has been called regarding medication storage issues or questionable altered integrity of medications.	

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F 425	Continued From page 4 applicable legal requirements." Review of the Pharmacy Policies and Procedures Manual dated 07/08/13 under Storage of Medications lists Policy: "Medications and biologicals are stored safely, securely, and properly, following manufacturer's recommendations or those of the supplier."Procedures k. shows, "Medications requiring "refrigeration" or "temperatures between 2 degrees C (36 degrees F) and 8 degrees C (46 degrees F)" are kept in a refrigerator with a thermometer to allow temperature monitoring." Procedures m. shows, "Outdated, contaminated, or deteriorated medications and those in containers that are cracked, soiled, or without secure closures are immediately removed from stock, disposed of according to procedures for medication disposal and reordered from the pharmacy if a current order exists." Review of the Med Room Inspection Nursing Station Inspection Report provided by the facility pharmacy dated 04/20/15 showed a refrigerator temperature of 38 degrees for the Station one Medication Room. The report showed the refrigerator temperature for Nursing Station two was 40 degrees. Review of the Refrigeration/Freezer Temperature Record for April 2015 for Medication Room one showed only two recorded refrigerator temperatures between 04/01/15 and 04/20/15 when the pharmacy representative inspected the Medication Room. On 04/07/15 the temperature was 28 degrees. This temperature was below the 35-46 degrees required for medication storage. The temperature on 04/16/15 was listed as 37 degrees. Review of the Refrigeration/Freezer Temperature Record for April 2015 for Medication Room two showed two recorded refrigeration temperatures	F 425	B. Completion of temperature logs will be monitored by the DON or a designated nurse manager on daily rounds, 7 days per week. Audit of the temperature logs and appropriate response will be monitored by the DON or a nurse manager daily during rounds. Audit of the temperature logs and appropriate response will be completed by the DON/ADON daily times 2 weeks; 3 times weekly for 1 month; and once weekly for 1 month. DON or ADON will communicate with the pharmacy weekly concerning conversations held by the facility nurses with pharmacists. DON or ADON will follow up to assure that questions or concerns voiced to pharmacy have been addressed. 4. Results of the audits will be shared at the monthly QA meeting for 3 months by the DON, where the need for further audits will be determined	

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F 425	Continued From page 5 between 04/01/15 and 04/20/15 when the pharmacy representative inspected the Medication Room were not recorded. The recorded temperatures were not below 35 degrees or higher than 46 degrees. Review of the Refrigeration/Freezer Temperature Record for May 2015 for Medication Room one showed 10 recorded temperatures for 05/01/15-05/11/15. Seven of these recorded temperatures ranged between 20 and 32 degrees. These temperatures were considered out of range for medication storage. There was one blank where no temperature was recorded and three temperature recordings between 36 and 42 degrees. Review of the Refrigeration/Freezer Temperature Record for May 2015 for Medication Room two showed 13 recorded temperatures from 05/01/15-05/13/15. Seven of these temperatures were below 35 degrees and ranged from 24 degrees to 32 degrees. In an observation of Medication Room two on 05/14/15 at 1:15 PM the refrigerator logs were posted on the front of the medication refrigerator in a plastic sleeve. In an observation of Medication Room one on 05/14/15 at 3:15 PM the refrigerator logs were posted on the front of the medication refrigerator in a plastic sleeve. In an interview on 05/14/15 at 3:36 PM Pharmacist #1 stated any temperature that was 32 degrees or below would be considered freezing. She indicated medications that were in the refrigerator during the times the temperature was 32 degrees or below should have been discarded. She indicated nurses could also visually check the medications to see if they were frozen. In an interview on 05/14/15 at 5:25 PM	F 425		

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F 425	Continued From page 6 Pharmacist #2 stated she had received a telephone call from a nurse at the facility on 05/12/15. She indicated the nurse inquired if she was able to use insulin which had ice crystals in the vial. Pharmacist #2 indicated she informed the nurse she would be unable to use the insulin and to discard the vial. She also informed the nurse to adjust the refrigerator temperature. She did not notify the Director of Nursing. In an interview on 05/15/15 at 9:10 AM the Director of Nursing (DON) stated it was her expectation that the pharmacy notify her and provide a report when there were issues with medications or medication storage. She indicated she had not received a report or a telephone call from the pharmacy that there were problems with refrigerator temperatures or ice crystals in insulin.	F 425		
F 431 SS=E	483.60(b), (d), (e) DRUG RECORDS, LABEL/STORE DRUGS & BIOLOGICALS The facility must employ or obtain the services of a licensed pharmacist who establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled. 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. In accordance with State and Federal laws, the facility must store all drugs and biologicals in	F 431		6/8/15

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F 431	Continued From page 7 locked compartments under proper temperature controls, and permit only authorized personnel to have access to the keys. 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 observation, record review and staff interviews the facility failed to store medications at recommended temperatures for 2 of 2 medication refrigerators and failed to dispose of expired medication stored in 1 of 2 medication refrigerators. Findings included: Review of the Refrigeration/Freezer Temperature Record for April 2015 for Medication Room one showed only five recorded refrigerator temperatures between 04/01/15 and 04/30/15. On 04/07/15 the recorded temperature was 28 degrees. The recorded temperature on 04/16/15 was listed as 37 degrees. The recorded temperature on 04/25/15 was 38 degrees. The recorded temperature on 04/26/15 was 36 degrees and the recorded temperature on 04/28/15 was 34 degrees. Review of the Refrigeration/Freezer Temperature Record for April 2015 for Medication Room two showed four missing recorded refrigeration temperatures. There were no recorded	F 431	1. All refrigerated medications located in medication rooms were discarded by the DON, and replaced by the contracted pharmacy on 5/15/15. 2. All insulins in the E-kit were discarded by the DON and a new E-kit ordered and received from the pharmacy on 5/14/15. Both refrigerators were defrosted by maintenance and thermostats set to appropriate level to maintain temperature range of 35-46 degrees on 5/14/15. Temperatures have been within this range since that day. 3. A. Nursing staff will be trained regarding storage of medications/biologicals by the DON or ADON by 6/5/15. Training will include: a. Appropriate temperature ranges of refrigerators. b. Documentation of the temperature daily by a licensed nurse as well as	

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F 431	Continued From page 8 temperatures below 36 degrees. Review of the Refrigeration/Freezer Temperature Record for May 2015 for Medication Room one showed 10 recorded temperatures for 05/01/15-05/11/15. Seven of these recorded temperatures ranged between 20 and 32 degrees. There was one blank where no temperature was recorded and three temperature recordings between 36 and 42 degrees. Review of the Refrigeration/Freezer Temperature Record for May 2015 for Medication Room two showed 13 recorded temperatures from 05/01/15-05/13/15. Seven of these temperatures were below 35 degrees and ranged from 24 degrees to 32 degrees. Review of the Tuberculin Purified Protein Derivative (PPD) manufacturer instructions included with the medication revealed under Storage: "Store at 2 degrees to 8 degrees C (Celsius) (35 degrees to 46 degrees F (Farenheit). Do not freeze (bold letters). Discard product if exposed to freezing." Review of the United States Food and Drug Administration literature revealed, "According to the product labels from all three U.S. insulin manufacturers, it is recommended that insulin be stored in a refrigerator at approximately 36°F to 46°F. Avoid freezing the insulin. Do not use insulin that has been frozen." An observation of the medication refrigerator in Medication Room two on 05/14/15 at 1:15 PM revealed the refrigerator contained multiple vials and flex pens containing different insulins. There was also one unopened vial of PPD. The temperature log was posted on the front of the refrigerator in a plastic sleeve. An observation of the medication refrigerator in Medication Room one on 05/14/15 at 3:15 PM revealed the refrigerator contained multiple vials	F 431	whether the contents of the E-kit are in proper date range. c. Procedure for licensed nurse to follow if temperature is found to be out of range (discard contents of refrigerator, notify maintenance director and DON immediately, and re-order medications). d. Need for licensed nurse to check expiration dates daily of insulins, tuberculin, and other perishable biologicals. Document results daily. Discard any that are out of date and reorder, 7 days per week. e. Need for licensed nurse to assure that the insulin E-Kit is exchanged nightly for a new kit from the pharmacy. f. Audit of the temperature logs and appropriate response will be monitored daily by the DON or nurse manager daily during rounds. g. Nurse will contact pharmacy with any questions related to medications, such as questionable integrity, expired medications, etc. Report calls/conversation to the DON or nurse manager on duty. h. DON will communicate with the pharmacy weekly about any concerns or questions that the nurses may have contacted them about. At that time, the DON will follow up the information appropriately. B. Completion of temperature logs will be monitored by the DON or nurse manager on daily rounds, 7 days per week. Audit of the temperature logs and appropriate response will be monitored by the DON or a nurse manager daily during	

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F 431	Continued From page 9 and flex pens containing different insulins. There were also one unopened vial of PPD and 4 unopened vials. The temperature log was posted on the front of the refrigerator in a plastic sleeve. The Director of Nursing (DON) came to the medication room and stated the refrigerator temperature was too low and would be adjusted. In an interview on 05/14/15 at 3:20 PM Nurse #1 stated it was a problem if the refrigerator was too cold for medication storage. She indicated the Maintenance Manager should have been called to check the refrigerator and the nurses should have followed up on it. She stated the medications should have been removed from the refrigerator until the temperature was fixed. In an interview on 05/14/15 at 3:36 PM Pharmacist #1 stated any temperature 32 degrees or below would be considered freezing. She indicated when the nurses saw the temperature was below 33 degrees they should have discarded the medications. She indicated that simply recording what temperature the thermometer read was not enough. Pharmacist #1 stated the nurses should have acted on the reading and recorded what interventions had been done. In an observation on 05/14/15 at 4:20 PM the medications had been removed from the Medication Room one refrigerator and placed in the Medication Room two refrigerator. On examination of the unsealed insulin E-kit in the Medication Room two refrigerator an open multi-dose vial of insulin was found with a handwritten initial use date of 02/18/15 and a handwritten expiration date of 03/17/15. In an interview on 05/14/15 at 4:50 PM the DON stated it was her plan to remove and replace all refrigerated medications that needed to be kept at 36 degrees to 46 degrees.	F 431	rounds. Audit of the temperature logs and E-kit exchange, and appropriate response, will be completed by the DON/ADON daily times 2 weeks; 3 times weekly for 1 month; and once weekly for 1 month. DON or ADON will communicate with the pharmacy weekly concerning conversations held by the facility nurses with pharmacists. DON or ADON will follow up to assure that questions or concerns voiced to pharmacy have been addressed. 4. Results will be shared at the QA meeting monthly by the DON for 3 months, where the need for further audits will be determined.	

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F 431	Continued From page 10 In an interview on 05/14/15 at 5:25 PM Pharmacist #2 stated a nurse (she could not recall the nurse's name) had called and spoken to her on 05/12/15 regarding finding ice crystals in insulin. Pharmacist #2 informed the nurse to discard the insulin as it could not be used if it had been frozen. She indicated she informed the nurse that the refrigerator temperature also needed adjustment. She indicated the target range of the refrigerator temperatures should be posted as well as what interventions should be taken if the temperatures were out of range. In an interview on 05/14/15 at 5:10 PM Certified Pharmacy Technician #1 stated the insulin E-kit was exchanged every night. She indicated if there was an expired insulin in the kit it was due to a facility staff member placing it there. She stated a nurse may have found it on a medication cart and placed it in the E-kit to be replaced as the nurses were aware the insulin E-kit was exchanged every night. In an interview on 05/15/15 at 7:50 AM Nurse #2, who had recorded refrigerator temperatures of 20 degrees on 05/09/15 and 25 degrees on 05/10/15, stated refrigerator temperatures were recorded on the 7 PM to 7 AM shift. She indicated if the refrigerator temperature was not in range the pharmacy should be notified. She stated all the nurses were aware of what they would need to do. Nurse #2 stated each time she wrote down a temperature it was in range or she would have notified the pharmacy. She stated she had never had to notify the pharmacy regarding temperatures not being in an acceptable range. In an interview on 05/15/15 at 7:54 AM the DON stated she did not know why the temperature logs were not completed but that they should have been. She indicated it was her expectation the medication refrigerator logs be completed daily.	F 431		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	345561	A. BUILDING _____ B. WING _____	C 05/15/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNIVERSAL HEALTH CARE/FUQUAY-VARINA	**410 S JUDD PARKWAY SE FUQUAY VARINA, NC 27526**

(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 431	Continued From page 11 In an interview on 05/15/15 at 9:10 AM the DON stated she had spoken to the Pharmacy Manager and been told the insulin E-kit was exchanged every night. She indicated the pharmacist did not notify her by telephone or in writing that there was a problem with the medication refrigerator temperatures. She indicated it was her expectation that the pharmacist would have notified her when a nurse from the facility had called regarding finding ice crystals in the insulin. It was also her expectation that the nurses would have notified her and filled out a maintenance slip when there were issues with refrigerator temperatures. She indicated she expected the nurses to discard the medications or return the medications to the pharmacy for replacement. She indicated these things were not done. In a telephone interview on 05/15/15 at 10:02 AM Nurse #3, who recorded a refrigerator temperature of 28 degrees on 05/04/15 and a temperature of 30 degrees on 05/05/15, stated she wrote down the refrigerator temperatures as part of her assignment. She indicated she was not aware that she was supposed to do anything other than record the temperatures. She stated she knew medications needed to be stored at certain temperatures depending on what was written on the box. She indicated she did not check what those temperatures were. She also did not notify anyone, adjust the refrigerator temperature or remove the medications from the refrigerator to place them in the other medication refrigerator.	F 431		