

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

PRINTED: 03/01/2016
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 346167	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED C 02/18/2016
NAME OF PROVIDER OR SUPPLIER YADKIN NURSING CARE CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 903 W MAIN STREET BOX 879 YADKINVILLE, NC 27055		
(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 329 SS=D	<p>483.25(I) DRUG REGIMEN IS FREE FROM UNNECESSARY DRUGS</p> <p>Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used in excessive dose (including duplicate therapy); or for excessive duration; or without adequate monitoring; or without adequate indications for its use; or in the presence of adverse consequences which indicate the dose should be reduced or discontinued; or any combinations of the reasons above.</p> <p>Based on a comprehensive assessment of a resident, the facility must ensure that residents who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record; and residents who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.</p> <p>This REQUIREMENT is not met as evidenced by: Based on record review and staff, Pharmacist, Physician and Nurse Practitioner interview the facility failed to monitor the serum valproic acid level for 1 of 1 residents (Resident #3) with a seizure disorder that received Depakote/Divalproex Sodium (an anticonvulsant medication) and Invanz/Ertapenem (a carbapenem antibiotic) concurrently. These two medications have a potential drug interaction than</p>	F 329	<p>F 329</p> <p>STANDARD DISCLAIMER: This Plan of Correction is prepared as a necessary requirement for continued participation in the Medicare and Medicaid programs and does not, in any manner, constitute an admission to the validity of the alleged deficient practice(s).</p> <p>Resident # 3 expired on February 5, 2016</p> <p>For those residents having the potential to be affected by the same alleged deficient practice, a consulting pharmacist, other than the facility's assigned consulting pharmacist, has reviewed each resident's drug regimen to ensure residents are free from an unnecessary drug regimen. This review was completed on March 15, 2016. In addition to evaluating each resident's drug regimen to ensure the regimen was free from unnecessary drugs, the review also included an evaluation of whether or not a resident's drug regimen contained medications for which on-going monitoring was necessary. In cases where the resident's drug regimen included potentially unnecessary drugs, a consulting pharmacist, other than the facility's assigned consulting pharmacist, provided the facility with pharmacy recommendations which were communicated to the resident's attending/consulting physician with a request that the attending/consulting physician clarify the order, consider changing the dosage, and/or discontinue the medication.</p>		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

Nolan B. Brown

TITLE

Adm

(X5) DATE

3-15-16

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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F 329	Continued From page 1 can lower serum valproic acid levels, which can then result in a loss of seizure control for people with a seizure disorder. The findings included: Review of the Manufacturer ' s (Merck and Company Incorporated), Highlights of Prescribing Information for Invanz (Ertapenem); copyright 2011, revealed: " co-administration of carbapenems, including ertapenem (Invanz), to patients receiving valproic acid or divalproex sodium (Depakote) results in a reduction in valproic acid concentrations. The valproic acid concentrations may drop below the therapeutic range as a result of this interaction, therefore increasing the risk of breakthrough seizures. Increasing the dose of valproic acid or divalproex sodium may not be sufficient to overcome the interaction. The concomitant use of ertapenem and valproic acid/divalproex sodium is generally not recommended. " " If treatment with INVANZ is necessary a supplemental anti-convulsant therapy should be considered. " Review of Labeling Changes for Depakote (Divalproex Sodium) Sprinkle Capsules, approved by the Food and Drug Administration Center for Drug Administration and Research, and dated March 2008 revealed: " Interaction with Carbapenem Antibiotics: Carbapenem antibiotics (ertapenem [Invanz], imipenem, meropenem) may reduce serum valproic acid concentrations to subtherapeutic levels, resulting in loss of seizure control. Serum valproic acid concentrations should be monitored frequently after initiating carbapenem therapy. Alternative antibacterial or anticonvulsant therapy should be considered if serum valproic acid levels drop significantly or seizure control deteriorates. " Resident #3 was admitted on 1/10/07 and had cumulative diagnoses including epilepsy (a seizure disorder), congestive heart failure,	F 329	F 329 Cont'd In cases where on-going monitoring (e.g. laboratory testing to determine therapeutic efficacy) was indicated, the consulting pharmacist, other than the facility's assigned consulting pharmacist, verified that such monitoring had occurred (e.g. appropriate laboratory testing, monitoring of any required or indicated laboratory values, et.al.). In cases where indicated monitoring had not occurred, the consulting pharmacist, other than the facility's assigned consulting pharmacist, advised the facility to request 1) an order from the resident's attending/consulting physician clarifying the medication regimen, which may include a risk-benefit analysis by the clinician (e.g. nurse practitioner and/or physician) and/or 2) an order from the resident's attending/consulting physician/nurse practitioner to initiate pharmacologically appropriate monitoring to validate the necessity and efficacy of the medication regimen. Any such notifications and requests will be submitted to the attending/consulting physician for each affected resident on or before March 16, 2016 and documented in each affected resident's medical records. Routine review of each resident's drug regimen by a consulting pharmacist shall be ongoing to ensure that a resident's drug regimen remains free from unnecessary medications. In the event an oversight review determines that either appropriate drug monitoring has not occurred and/or the determination that a resident's drug regimen is not free from unnecessary medications, the consulting pharmacist shall provide a written report of such determination(s) to the facility's Director of Nursing and copies of such reports shall be provided to the facility's		

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F 329	<p>Continued From page 2</p> <p>non-Alzheimer ' s dementia and chronic kidney disease.</p> <p>The Quarterly Minimum Data Set (MDS) dated 11/6/15 revealed Resident #3 was cognitively impaired.</p> <p>Review of the Physician Orders summary for 1/1/16 - 1/31/16 revealed Resident #3 had orders for the following anti-seizure medications: Depakote 125 mg (milligrams) Sprinkle (Divalproex Sodium delayed release capsules), take two capsules (250 mg) by mouth twice a day at 8:00 AM and 8:00 PM. Depakote 125 mg Sprinkle (Divalproex Sodium delayed release capsules), take one capsule by mouth daily at noon. Keppra (Levetiracetam) 100 mg/ml (milliliter) give 5 ml (500 mg) by mouth twice a day at 9:00 AM and 5:00 PM.</p> <p>Review of the Physicians Order sheet dated 1/21/16 revealed an order for Invanz 1 gm (gram) IM (intramuscularly) for 5 days.</p> <p>Review of the Medication Administration Record for January 2016 revealed Resident #3 received Invanz as ordered on January 22, 23, 24, 25, and 26.</p> <p>Further review of the Physicians Orders for the month of January,2016 revealed no orders for monitoring the Resident #3 ' s Valproic Acid Blood Levels (a test to determine whether the blood concentration is within the therapeutic range) prior to, during or at the end of the antibiotic therapy treatment with Invanz.</p> <p>On 2/17/15 at 2:40 PM telephone interview with the Pharmacy Consultant revealed she was not aware of a drug interaction between Depakote and Invanz that would require a notification from the pharmacy to the facility but that she would look into it.</p> <p>On 2/17/16 at 3:02 PM interview with Nurse #1,</p>	F 329	<p>F 329 Cont'd</p> <p>Quality Assurance Committee pursuant to the oversight schedule outlined herein.</p> <p>Evidentiary documentation that a pharmacy consultant, other than the facility's assigned consulting pharmacist, reviewed each resident's drug regimen, along with any associated recommendations will be provided to the facility's Director of Nursing on March 15, 2016. The facility's licensed and registered nurses will receive inservice education (provided by Jerry Evans, PharmD, Pharmacy Clinical Services Director for the facility's pharmacy services provider) on March 16, 2016 that is specific to the appropriate handling and management of pharmacy recommendations, including the importance of notifying and/or soliciting a response from the resident's attending/consulting physician related to the relevant recommendation.</p> <p>All facility licensed and registered nursing staff will receive inservice education related to the pharmacy services provider's procedures for communicating and responding to potential drug interactions. The education will be provided by Jerry Evans, PharmD, Pharmacy Clinical Services Director for the facility's pharmacy services provider, on March 16, 2016. No licensed or registered nurses shall be permitted to work until they have completed the required education. Such education shall be incorporated into the facility's orientation for new nurses. Similarly, the manager of the pharmacy services provider conducted education related to the aforementioned procedures with its pharmacy staff on March 15, 2016.</p>	

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F 329	Continued From page 3 who administered the first dose of Invanz to Resident #3 on 1/22/16 stated she was not aware of a drug interaction between Depakote and Invanz at the time of administering the Invanz and had not been informed or one. She further indicated she remained unaware of any reason to monitor serum valproic acid levels if the two medications were given together. On 2/17/16 at 4:28 PM telephone interview with the Pharmacy Consultant revealed that she found there was an interaction between Depakote and Invanz, but according to the Pharmacy Software used by the Pharmacy Provider, the interaction was a Level 2 interaction. The Pharmacy Consultant stated that with a Level 2 interaction it was considered "an observance" and the medication would still be sent to the facility. On 2/18/16 at 10:45 AM telephone interview with the Attending Physician revealed he was not aware of a clinically significant drug interaction between Depakote and Invanz. He also stated that he did not recall the pharmacy notifying him of a drug interaction between Depakote and Invanz and did not recall receiving a memo from the pharmacy regarding the interaction. On 2/18/16 at 11:59 AM telephone interview with the Nurse Practitioner, who ordered the Invanz, revealed she had not been aware of a drug interaction between Depakote and Invanz and that she had not received notification from the pharmacy regarding a potential interaction that could cause serum valproic acid levels to decline. She stated that had she been made aware of the interaction Invanz would still have been the right antibiotic to treat Resident #3's Urinary Tract Infection, due to the results of the culture and sensitivity and because it was a better choice for someone with poor renal function. However, she added that she would likely have ordered a serum	F 329	F 329 Cont'd Resident attending physicians and nurse practitioners will receive inservice education (provided by Jerry Evans, PharmD, Pharmacy Clinical Services Director for the facility's pharmacy services provider) on March 16, 2016 that is specific to the appropriate handling and management of pharmacy recommendations, including the importance of notifying and/or soliciting a response from the resident's attending/consulting physician related to the relevant recommendation. As is the current practice, the facility's licensed and registered nurses shall carry out any orders given by the resident's attending physician specific to changes in the resident's drug regimen. Evidentiary documentation of recommendations made by the pharmacy services provider (including recommendations made by the consulting pharmacist) and the facility's response thereto shall be provided to the Director of Nursing every 30 days for 90 days, and quarterly thereafter for at least 1 year. Copies of such reports and related documentation shall be presented to the facility's Quality Assurance Committee pursuant to the schedule outlined herein.	3/17/2016	

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F 329	Continued From page 4 valproic acid level in conjunction with the antibiotic order. On 2/18/16 telephone interview with the Pharmacy Provider Pharmacist revealed that since the software system in the Pharmacy categorized the interaction between Depakote and Invez as a Level 2 or Class 2 interaction, it was up to the Pharmacy staff member who was processing the order to determine if the facility (a nurse) and or the physician should be notified. She stated the warning appeared as a pop up screen but when the interaction was Class 2 the staff member could bypass it without adding a reason why. She stated there would be no documentation of the rationale. The Pharmacist also said that the warning that was generated when Invez and Depakote were both ordered said that Invez could result in a drop in valproic acid level. On 2/18/16 at 4:00 PM interview with the Director of Nursing (DON) revealed that the facility relied on the Pharmacy staff to let them know about drug interactions that required consideration of medication changes or monitoring. She added that she had confidence in the Pharmacy staff 's knowledge and expertise in determining when to share a Level 2 drug interaction. The DON added that she did not expect her staff to go behind prescribers and pharmacists to look up drug interactions prior to administering newly ordered medications, but added that for more common interactions nursing staff would be more familiar with the interaction through their nursing practice. The DON indicated that while a prescriber might review drug interactions prior to ordering a medication; there had been no concerns with these medications in the past. She indicated that she expected that the prescriber would have relied on her own knowledge and	F 329			

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F 329	Continued From page 5 experience as well as on pharmacy to identify anything that was significant.	F 329			
F 425 SS=D	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 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 record review and staff, Pharmacist, Physician and Nurse Practitioner interview the facility failed to receive notification from the Pharmacy Provider regarding a drug interaction between Depakote/Divalproex Sodium (an anticonvulsant medication) and Invanz/Ertapenem (a carbapenem antibiotic) for 1 of 1 residents that received both medications and had a seizure disorder (Resident #3). The	F 425	F 425 STANDARD DISCLAIMER: This Plan of Correction is prepared as a necessary requirement for continued participation in the Medicare and Medicaid programs and does not, in any manner, constitute an admission to the validity of the alleged deficient practice(s). Resident # 3 expired on February 5, 2016 The drug regimen of all current residents in the facility has been reviewed by a consulting pharmacist, who is not the facility's assigned consulting pharmacist, for the purposes of determining the presence of unnecessary drugs and to determine the therapeutic, pharmacological efficacy for the resident's drug regimen. This review was completed on March 15, 2016 and documented in a written report to the facility's Director of Nursing. For those residents having the potential to be affected by the same alleged deficient practice, the facility's pharmacy services provider has initiated the following procedures:		

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F 425	Continued From page 6 findings included: Review of the Manufacturer ' s (Merck and Company Incorporated), Highlights of Prescribing Information for Invanz (Ertapenem); copyright 2011, revealed: " co-administration of carbapenems, including ertapenem (Invanz), to patients receiving valproic acid or divalproex sodium (Depakote) results in a reduction in valproic acid concentrations. The valproic acid concentrations may drop below the therapeutic range as a result of this interaction, therefore increasing the risk of breakthrough seizures. Increasing the dose of valproic acid or divalproex sodium may not be sufficient to overcome the interaction. The concomitant use of ertapenem and valproic acid/divalproex sodium is generally not recommended. " " If treatment with INVANZ is necessary a supplemental anti-convulsant therapy should be considered. " Review of Labeling Changes for Depakote (Divalproex Sodium) Sprinkle Capsules, approved by the Food and Drug Administration Center for Drug Administration and Research, and dated March 2008 revealed: " Interaction with Carbapenem Antibiotics: Carbapenem antibiotics (ertapenem [Invanz], imipenem, meropenem) may reduce serum valproic acid concentrations to subtherapeutic levels, resulting in loss of seizure control. Serum valproic acid concentrations should be monitored frequently after initiating carbapenem therapy. Alternative antibacterial or anticonvulsant therapy should be considered if serum valproic acid levels drop significantly or seizure control deteriorates. " Resident #3 was admitted on 1/10/07 and had cumulative diagnoses including epilepsy (a seizure disorder), congestive heart failure, non-Alzheimer ' s dementia and chronic kidney disease.	F 425	F 425 Cont'd 1. Any potential Level 1 or Level 2 drug interactions shall be communicated from the pharmacy to the facility's nursing staff (Director of Nursing when present and the Charge Nurse at other times) by phone call, fax and/or secure email. The pharmacy shall instruct/advise the facility's nursing staff (Director of Nursing when present and the Charge Nurse at other times) to obtain any needed order clarification(s) specific to the potential interaction from the resident's attending/consulting physician/nurse practitioner. Notices and instructions/advice communicated by phone call (Note: phone calls will only be used in emergency situations i.e. when the fax or email systems are not working) shall be documented in writing and signed by the pharmacy staff member making the phone call (date, time, name of person talked to at facility). Medications with potential Level 1 interactions will not be dispensed by the pharmacy services provider. At the discretion of the pharmacy services provider, drug combinations with a potential Level 2 interaction may be dispensed with an identifying notice attached to the medicine container advising a licensed or registered nurse to clarify the orders. Notifications to the facility's nursing staff (Director of Nursing when present and the Charge Nurse at other times) regarding potential Level 2 drug interactions shall occur in advance of dispensing the medication.		

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F 425	<p>Continued From page 7</p> <p>The Quarterly Minimum Data Set (MDS) dated 11/6/15 revealed Resident #3 was cognitively impaired.</p> <p>Review of the Physician Orders summary for 1/1/16 - 1/31/16 revealed Resident #3 had orders for the following anti-seizure medications: Depakote 125 mg (milligrams) Sprinkle (Divalproex Sodium delayed release capsules), take two capsules (250 mg) by mouth twice a day at 8:00 AM and 8:00 PM. Depakote 125 mg Sprinkle (Divalproex Sodium delayed release capsules), take one capsule by mouth daily at noon. Keppra (Levetiracetam) 100 mg/ml (milliliter) give 5 ml (500 mg) by mouth twice a day at 9:00 AM and 5:00 PM.</p> <p>Review of the Physicians Order sheet dated 1/21/16 revealed an order for Invez 1 gm (gram) IM (intramuscularly) for 5 days.</p> <p>Review of the Medication Administration Record for January 2016 revealed Resident #3 received Invez as ordered on January 22, 23, 24, 25, and 26.</p> <p>Further review of the Physicians Orders for the month of January, 2016 revealed no orders for monitoring the Resident #3's Valproic Acid Blood Levels (a test to determine whether the blood concentration is within the therapeutic range) prior to, during or at the end of the antibiotic therapy treatment with Invez.</p> <p>On 2/17/15 at 2:40 PM telephone interview with the Pharmacy Consultant revealed she was not aware of a drug interaction between Depakote and Invez that would require a notification from the pharmacy to the facility but that she would look into it. She also confirmed that the Monthly Drug Regimen Review for Resident #3 had not been due until the first week of February 2016.</p> <p>On 2/17/16 at 3:02 PM interview with Nurse #1,</p>	F 425	F 425 Contd		
			<p>2. If a licensed or registered nurse does not respond to the pharmacy services provider's request within 24-hours, the pharmacy services provider shall again notify the facility's Director of Nursing and/or the Charge Nurse, if the notification is during off-hours or weekends, of any potential Level 1 or Level 2 drug interaction(s) for which the pharmacy services provider has not received a response or clarification from the prescriber.</p> <p>All facility licensed and registered nursing staff will receive inservice education related to the pharmacy services provider's procedures for communicating and responding to potential drug interactions. The education will be provided by Jerry Evans, PharmD, Pharmacy Clinical Services Director for the facility's pharmacy services provider, on March 16, 2016. No licensed or registered nurses shall be permitted to work until they have completed the required education. Such education shall be incorporated into the facility's orientation for new nurses. Similarly, the manager of the pharmacy services provider conducted education related to the aforementioned procedures with its pharmacy staff on March 15, 2016.</p>		

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NAME OF PROVIDER OR SUPPLIER YADKIN NURSING CARE CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 903 W MAIN STREET BOX 879 YADKINVILLE, NC 27055		
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F 425	Continued From page 8 who administered the first dose of Invezon to Resident #3 on 1/22/16 stated she was not aware of a drug interaction between Depakote and Invezon at the time of administering the Invezon and had not been informed or one. On 2/17/16 at 4:28 PM telephone interview with the Pharmacy Consultant revealed that she found there was an interaction between Depakote and Invezon, but according to the Pharmacy Software used by the Pharmacy Provider, the interaction was a Level 2 interaction. She explained that if it was a Level 1 interaction the Pharmacy would have stopped the Invezon from going to the facility and contacted the nurse or the physician to communicate the warning so alternatives could be explored. The Pharmacy Consultant stated that with a Level 2 interaction it was considered "an observance" and the medication would still be sent to the facility. She added that the pharmacy staff may or may not contact a nurse or the physician to pass on the information about a Level 2 interaction, depending on what the interaction was. The Pharmacy Consultant did not know why the facility had not been contacted regarding a potential interaction but indicated that she thought the interaction was a rare occurrence and that Resident #3 was on the Invezon for a short time (5 days). On 2/18/16 at 10:45 AM telephone interview with the Attending Physician revealed he was not aware of a clinically significant drug interaction between Depakote and Invezon. He also stated that he did not recall the pharmacy notifying him of a drug interaction between Depakote and Invezon and did not recall receiving a memo from the pharmacy regarding the interaction. The Physician added that Resident #3 was on another anticonvulsant medication, in addition to the Depakote, and that the second anticonvulsant	F 425	F 425 Cont'd The pharmacy services provider shall provide the facility's Director or Nursing and/or her/his designee with a weekly notification of each potential Level 1 or Level 2 drug interaction(s) and whether or not the facility nursing staff responded within the required 24-hour period of time. In instances where the facility nursing staff did not respond in the prescribed period of time, the Director of Nursing shall re-educate and/or discipline any nursing staff for failing to respond timely to the pharmacy services provider's notice and request. Such notification(s) from the pharmacy services provider to the Director of Nursing shall occur weekly for 1 month, monthly for 3 months and quarterly for 1 year. Such information shall also be presented to the facility's Quality Assurance Committee for review weekly for 1 month, monthly for 3 months and quarterly for 1 year.	3/17/2016	