F 329
483.25(l) DRUG REGIMEN IS FREE FROM UNNECESSARY DRUGS

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.

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.

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

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

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.

LABORATORY DIRECTORS OR PROVIDER/SUPPLIER REPRESENTATIVE’S SIGNATURE

TITLE

(3) 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.
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,

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 pharmaco logically 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
Continued From page 2

The Quarterly Minimum Data Set (MDS) dated 11/6/15 revealed Resident #3 was cognitively impaired.

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.

Review of the Medication Administration Record for January 2016 revealed Resident #3 received Invanz as ordered on January 22, 23, 24, 25, and 26.

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.

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.

On 2/17/16 at 3:02 PM interview with Nurse #1,
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 4:29 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
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<th>ID</th>
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<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR USC IDENTIFYING INFORMATION)</th>
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<td>F 329</td>
<td>Continued From page 4</td>
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<td>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 Invanz 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 Invanz and Depakote were both ordered said that Invanz 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</td>
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<td>F 329</td>
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<td>Continued From page 5 experience as well as on pharmacy to identify anything that was significant.</td>
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<td>F 425</td>
<td>SS=D</td>
<td>483.60(a),(b) PHARMACEUTICAL SVC - ACCURATE PROCEDURES, RPH</td>
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<td>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.</td>
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<td>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.</td>
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<td>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.</td>
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</table>

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 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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**Summary Statement of Deficiencies**

- **ID**: F 425
- **PREFIX**: Continued From page 6
- **Tag**: Review of the Manufacturer’s (Merk and Company Incorporated), Highlights of Prescribing Information for Invanza (Ertapenem); copyright 2011, revealed:
  - "Co-administration of carbapenems, including ertapenem (Invanza), 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."
- **Provider's Plan of Correction**
  - (Each corrective action should be cross-referenced to the appropriate deficiency)
  - 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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**Provider's Plan of Correction**

- **ID**: F 425
- **PREFIX**: Continued From page 6
- **Tag**: Review of the Manufacturer’s (Merk and Company Incorporated), Highlights of Prescribing Information for Invanza (Ertapenem); copyright 2011, revealed:
  - "Co-administration of carbapenems, including ertapenem (Invanza), 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."
- **Provider's Plan of Correction**
  - (Each corrective action should be cross-referenced to the appropriate deficiency)
  - 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.
Continued From page 7

The Quarterly Minimum Data Set (MDS) dated 11/16/15 revealed Resident #3 was cognitively impaired.

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 (Divalprox 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 (Divalprox 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.

Review of the Physicians Order sheet dated 1/21/16 revealed an order for Invanz 1 gm (gram) IM (intramuscularly) for 5 days.

Review of the Medication Administration Record for January 2016 revealed Resident #3 received Invanz as ordered on January 22, 23, 24, 25, and 26.

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.

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. She also confirmed that the Monthly Drug Regimen Review for Resident #3 had not been due until the first week of February 2016.

On 2/17/16 at 3:02 PM interview with Nurse #1, 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.

All facility licensed and registered nursing staff will receive in-service 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.
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.
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. She explained that if it
was a Level 1 interaction the pharmacy would
have stopped the Invanz 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 Invanz 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 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. The
Physician added that Resident #3 was on another
anticonvulsant medication, in addition to the
Depakote, and that the second anticonvulsant

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.