

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

PRINTED: 09/01/2023
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 345420	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED C 07/06/2023
NAME OF PROVIDER OR SUPPLIER ALAMANCE HEALTH CARE CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 1987 HILTON ROAD BURLINGTON, NC 27217		
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F 000	<p>INITIAL COMMENTS</p> <p>The survey team entered the facility on 6/21/23 to conduct a complaint investigation and exited on 6/21/23. Additional information was obtained on 6/22/23, 6/23/23 and 6/26/23. The survey team reentered the facility on 7/5/23 and exited on 7/6/23 to conduct a partial extended survey and investigate another complaint. Therefore, the survey exit date was changed to 7/6/23.</p> <p>The following intakes were investigated NC00202039, NC00202609, NC00202603, NC00203868, and NC00204313. Intake NC00203868 resulted in immediate jeopardy.</p> <p>One of the six complaint allegations resulted in deficiency.</p> <p>Immediate Jeopardy was identified at:</p> <p>CFR 483.25 at tag F684 at a scope and severity J CFR 483.45 at tag F757 at a scope and severity J</p> <p>The tags F684 and F757 constituted Substandard Quality of Care.</p> <p>For tag F 684 immediate jeopardy began on 6-15-23 and was removed on 7-3-23. For tag F 757 immediate jeopardy began on 5-15-23 and was removed on 7-3-23.</p>	F 000			
F 607 SS=D	<p>Develop/Implement Abuse/Neglect Policies CFR(s): 483.12(b)(1)-(5)(ii)(iii)</p> <p>§483.12(b) The facility must develop and implement written policies and procedures that:</p> <p>§483.12(b)(1) Prohibit and prevent abuse, neglect, and exploitation of residents and</p>	F 607		7/31/23	

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

TITLE

(X6) DATE

Electronically Signed

07/25/2023

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 607	<p>Continued From page 1</p> <p>misappropriation of resident property,</p> <p>§483.12(b)(2) Establish policies and procedures to investigate any such allegations, and</p> <p>§483.12(b)(3) Include training as required at paragraph §483.95,</p> <p>§483.12(b)(4) Establish coordination with the QAPI program required under §483.75.</p> <p>§483.12(b)(5) Ensure reporting of crimes occurring in federally-funded long-term care facilities in accordance with section 1150B of the Act. The policies and procedures must include but are not limited to the following elements.</p> <p>§483.12(b)(5)(ii) Posting a conspicuous notice of employee rights, as defined at section 1150B(d)(3) of the Act.</p> <p>§483.12(b)(5)(iii) Prohibiting and preventing retaliation, as defined at section 1150B(d)(1) and (2) of the Act.</p> <p>This REQUIREMENT is not met as evidenced by: Based on record review, staff interview, pharmacist interview, and physician interview the facility failed to implement their abuse policy and investigate and report to the state agency an allegation that a resident had been given an illegal drug (Ecstasy) while residing at their facility. The facility also failed to assure the Administrator was immediately notified of the allegation. This was for one (Resident # 1) of four residents sampled for abuse. The findings included:</p> <p>Review of the facility's policy for "Abuse/ Neglect/</p>	F 607	<p>The facility sets forth the following plan of correction to remain in compliance with all federal and state regulations. The facility has taken or will take the actions set forth in the plan of correction. The following plan of correction constitutes the facility's allegation of compliance. All alleged deficiencies cited have been or will be corrected by the date or dates indicated.</p> <p>F607-Develop/Implement Abuse/Neglect Policies 1. Resident #1 was no longer a resident</p>		

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F 607	<p>Continued From page 2</p> <p>Misappropriation/ Crime Reporting Requirements/ Investigations," dated 1/23/20, revealed the following instructions. Immediately upon notification of an abuse allegation the administrator was to report to the state agency the allegation. The Administrator was to also thoroughly investigate and file a complete written report of the investigation to the State Agency within five working days. The policy also directed, "Notify the Adult Protective Services agency, the local Ombudsman, and the appropriate local law enforcement authorities (police, sheriff's office, and or/medical examiner as deemed appropriate) for any incident of patient abuse, mistreatment, neglect, or misappropriation of personal property or other reasonable suspicion of a crime."</p> <p>Resident # 1 was initially admitted to the facility on 3/31/23 after being hospitalized for general debility and a thoracic compression fracture. Additionally, the resident had diagnoses of hypertension, congestive heart failure, atrial fibrillation, diabetes, Addison's disease (an endocrine disorder), gastroesophageal reflux disease, urinary retention, and panic attacks.</p> <p>The resident was discharged from the facility to the hospital on 4/18/23 upon her request when she complained of not feeling well.</p> <p>Review of hospital records for Resident # 1 revealed that on 4/18/23 a urine drug screen was done in the hospital Emergency Department. The drug screen report was positive for MDMA (Ecstasy). (Ecstasy is an illegal stimulant drug). Further review of hospital records revealed Resident # 1 remained hospitalized until 4/28/23. On Resident # 1's 4/28/23 hospital discharge summary, no mention was made of the positive</p>	F 607	<p>of the facility.</p> <p>2. All current residents have the potential to be affected by this same deficient practice.</p> <p>3. On 7/18/2023, 100% of all documented service concerns were reviewed by the Regional Director of Clinical Services to ensure that none met the criteria that required investigating/reporting to an outside agency for the past 30 days and to ensure that the administrator was aware of any possible incident or allegations that met investigation/reporting requirements to an outside agency. There were no negative findings noted on review.</p> <p>On 7/26/23 the Director of Nursing and nursing leadership began in servicing all staff on the facility's Abuse policy and procedure to follow when reporting and investigating abuse allegations.</p> <p>All allegations of abuse or neglect will be thoroughly investigated regardless of the resident's status of current or discharged from the facility. All allegations will be immediately reported to the facility administrator when received.</p> <p>The Director of Nursing or designee will review all service concerns daily to ensure that they do not include any allegations that meet criteria for investigation/reporting to outside agency.</p> <p>4. The Director of Nursing/designee will audit all service concerns daily x4 weeks, then bi-weekly x2, then monthly thereafter. Findings will be reported to the monthly QAPI committee. The Administrator is responsible for this plan of correction.</p>		

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F 607	<p>Continued From page 3</p> <p>Ecstasy drug test. According to the discharge summary, the resident had been treated for medical shock (when the body does not get enough blood). The physician noted he suspected an adrenal crisis had led to the resident's problem. According to hospital records, Resident # 1 was discharged on 4/28/23 to a different facility than the one she had resided in from 3/31/23 until 4/18/23.</p> <p>Resident # 1's family member was interviewed via phone on 6/21/23 at 1:45 PM and reported the following. While hospitalized on 4/18/23, Resident # 1 had tested positive for a substance that when broken down was found to be Ecstasy. A hospital Nurse Practitioner had talked to him about the report. He had in turn talked to the facility about two weeks after Resident # 1 had been discharged from the facility on 4/18/23. He had made it clear to the Social Worker and ADON (Assistant Director of Nursing) that Ecstasy had been found in Resident # 1's system when she had been discharged from their facility and not the facility, she had gone to on 4/28/23. No one ever got back to him after he made the concern known to them.</p> <p>Review of a "service concern report" form, dated 5/4/23 at 4:00 PM revealed the former ADON (Assistant Director of Nursing) and the Social Worker had received a concern from Resident # 1's family on that date regarding the Ecstasy being found in the resident's urine at the hospital. The concern form documented that Resident # 1's family reported to them that the resident had been treated for "an overdose related to methamphetamine which broke down to something similar to ecstasy."</p>	F 607	5. Date of compliance: July 31, 2023		

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F 607	<p>Continued From page 4</p> <p>Under the heading of "action taken" on the 5/4/23 concern form, there was a notation that read, "obtained records from hospital. She was currently at (another facility). DON (Director of Nursing) and consultant called with no answer from (family member)." There was no further notation on the form about further follow up.</p> <p>The facility's Social Worker was interviewed on 6/21/23 at 2:20 PM and reported the following. When Resident # 1's family member came to them with the 5/4/23 concern, Resident # 1 had already been at another facility. The family member was reporting that there had been a substance found at the hospital in her body that broke down to Ecstasy. They dug into some hospital records and found the timeframe of what the resident's family was saying did not seem to match the time when the facility had cared for Resident # 1.</p> <p>The former ADON was interviewed via phone on 6/21/23 at 2:30 PM and reported the following. Resident # 1's family member reported the incident to them while the resident was in the hospital. He told her that the hospital had done a drug panel and found there was an ingredient that was ecstasy when broken down. She was not clear on what hospitalization he was referring to but thought it was the hospitalization after Resident # 1 had resided at their facility. She had made a concern form out and notified the Director of Nursing.</p> <p>Interview with the Administrator on 6/21/23 at 1:00 PM revealed he had not been made aware of the allegation that Resident # 1 had Ecstasy in her system when she was transferred to the hospital from the facility.</p>	F 607			

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F 607	<p>Continued From page 5</p> <p>The Director of Nursing (DON) and Nurse Consultant were interviewed on 6/21/23 at 1:15 PM and reported the following. The former ADON had told the DON about the family's concern that ecstasy was found in Resident #1's system while she was at the hospital. It was the DON's understanding that the family was referring to the resident's last hospitalization at the time the family member had been reporting it to them. They pulled her hospitalization records, and the resident was last hospitalized on 5/2/23 from another facility. They looked at the 5-2-23 hospital records and saw no records of illegal drugs in the resident's system. They thought the family member had confused them with another facility. Therefore, they had not been aware that the resident had tested positive for Ecstasy on 4/18/23, and they had not investigated how this could have occurred or reported the allegation to the state agency or other agency per their policy since they thought the family was confused.</p> <p>Interview with the facility's Consultant Pharmacist on 6/21/23 at 5:08 PM revealed the following information. The high blood pressure medication, Metoprolol, can cause a false positive result for amphetamines/ecstasy. According to the record, Resident # 1 was receiving Metoprolol for high blood pressure while at the facility.</p> <p>The facility's Medical Director was interviewed on 6/21/23 at 5:30 PM and reported the following. A lot of medications can cross react to form a positive drug screen and Metoprolol was one of them. It was his medical opinion that the urine drug test yielded a false positive result. Ecstasy usually gives a high to individuals. He had seen the resident on the day before her 4/18/23 facility</p>	F 607			

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F 607	Continued From page 6 discharge and she did not present with symptoms of illicit drug use.	F 607			
F 684 SS=J	Quality of Care CFR(s): 483.25 § 483.25 Quality of care Quality of care is a fundamental principle that applies to all treatment and care provided to facility residents. Based on the comprehensive assessment of a resident, the facility must ensure that residents receive treatment and care in accordance with professional standards of practice, the comprehensive person-centered care plan, and the residents' choices. This REQUIREMENT is not met as evidenced by: Based on record review, staff interview, Pharmacist interview, Nurse Practitioners' interview, and Physician interview the facility failed to coordinate care for a resident with a seizure disorder. The resident's valproic acid medication dosage was decreased by a Psychiatric Nurse Practitioner who believed it only to be used for mood stabilization and who was unaware the medication was being using for seizure control. There was no communication with the medical provider before the change. The resident seized, was hospitalized, and intubated following the dosage decrease. Prior to transport to the hospital, Resident # 10's seizure was documented to not respond to intramuscular Ativan medication and lasted approximately 28 minutes before emergency medical services arrived for care and transport. This was for one (Resident # 10) of three sampled residents reviewed for seizure medications. Immediate Jeopardy began on 6/15/23 when	F 684	F684-Quality of Care 1. Resident #10 was in the hospital and at time of the survey and not a current resident in the facility. 2. All residents on antiseizure medications are at risk of being affected by this deficient practice. All other residents receiving Valproic Acid and being followed by the Psychiatric NP were audited on 6/23/23 by the regional director of clinical services, to determine if there were other such discrepancies noted, such as change of indication for use or diagnosis. Any discrepancy found was reported to the attending physician and/or medical NP for immediate follow-up. The regional director of clinical services and/or DON will review all residents by 6/30/23 at the direction of the medical director/attending physician (the same individual) to assure the appropriate levels	7/31/23	

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F 684	<p>Continued From page 7</p> <p>Resident #10's valproic acid dosage was decreased by a Psychiatric Nurse Practitioner without consulting with the health care providers. Immediate Jeopardy was removed on 7/3/23 when the facility provided an acceptable credible allegation for immediate jeopardy removal. The facility will remain out of compliance at a scope and severity level of D (not actual harm with the potential for more than minimal harm that is not immediate jeopardy) for the facility to complete staff training and to assure monitoring systems put in place are effective.</p> <p>The findings included:</p> <p>Record review revealed Resident # 10 was initially admitted to the facility on 3/21/21. The resident's diagnoses included in part traumatic brain injury and complex partial epilepsy (seizure disorder,) depression, and anxiety.</p> <p>Resident #10's quarterly Minimum Data Set assessment, dated 3/16/23, coded the resident as severely cognitively impaired. He was also assessed to need total assistance with his activities of daily living, have no behaviors during the assessment period, and to have a seizure disorder.</p> <p>Record review revealed Resident # 10 received both lacosamide and valproic acid for seizures. The last order for lacosamide was dated 5/12/23 and directed that the resident receive 10 ml (milliliters) 10 mg (milligrams)/ml two times per day. This remained as an active order up until his date of discharge.</p> <p>Orders and lab results related to Resident # 10's valproic acid medication were as follows:</p>	F 684	<p>for anti-seizure medications are being monitored via lab including the medications Valproic Acid (Depakote), Carbamazepine (Tegretol), Phenytoin (Dilantin), Levetiracetam (Keppra), to assure there are no medications not being monitored appropriately, no delayed lab results, and no failures of the provider or center to monitor other residents on these anti-seizure medications.</p> <p>As of 6/28/23, the Chief Nursing Officer, the Medical Director/attending physician, the consulting pharmacy group, and the DON met to determine, agree upon and implement the following process for all current residents that receive Valproic Acid (Depakote), Carbamazepine (Tegretol), Phenytoin (Dilantin), Levetiracetam (Keppra) and other seizure medications will have labs to monitor these drug levels. "</p> <p>All of those receiving these medications will be subject to the following:</p> <p>" Lab monitoring once every three months for two months.</p> <p>" Lab monitoring once every six months thereafter.</p> <p>" Baseline lab will occur for new admissions, then at the notated schedule above</p> <p>The consultant pharmacist will be involved at admission and monthly thereafter to identify anti-seizure medications and to determine if they are being monitored appropriately via the recommended labs at the recommended intervals noted above. The Chief Nursing Officer communicated with the pharmacy</p>		

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F 684	<p>Continued From page 8</p> <p>From 5/2/23 until 5/10/23, Resident # 10 was ordered to receive 11 ml (250 mg/5ml) valproic acid three times per day. (This would equate to 550 mg three times per day)</p> <p>On 5/10/23 a valproic acid level was done and registered 108. (A therapeutic medication level is when the blood level of the medication is in a range to be helpful but not dangerous. The facility's lab report noted therapeutic range for valproic acid to be 50 to 100 for seizures.)</p> <p>On 5/10/23 at 2:38 PM Nurse # 2 noted in a nursing note that she had received a critical lab value regarding a valproic acid level of 108 and called it into Medical Nurse Practitioner (NP) # 1.</p> <p>On 5/10/23 an order was given to decrease the valproic acid dosage to 10 ml (250 mg/ 5 ml) three times per day.(This would equate to 500 mg three times per day.) This order stayed in effect until 6/15/23. The order specifically noted the valproic acid was for seizures.</p> <p>On 5/11/23 the Physician ordered Resident # 10's valproic acid level be rechecked on the date of 5/15/23. The order was electronically signed by the Physician on 5/12/23. This order remained as an active order up until the resident's discharge date of 6/19/23 with no revision of the order. There was no valproic acid level drawn on 5/15/23 or a notation in the record why it was not done.</p> <p>On 6/15/23 Resident # 10 was seen by the Psychiatric Nurse Practitioner (NP) related to behaviors. The psychiatric NP noted that Resident # 10's valproic acid was prescribed for mood stabilization, and she was going to start a</p>	F 684	<p>consultant about this expectation on 6/28/23.</p> <p>3. After the meeting of the Chief Nursing Officer, Medical Director/attending physician, consulting pharmacy group, and DON, the nurse administrative team will be educated by the DON or regional director of clinical services on this process by 6/30/23, to ensure all expected labs have been ordered on admission and ongoing. This will be tracked via the lab tracking policy outlined below and monitored for implementation ongoing via the process outlined below in the daily clinical meeting. The Chief Nursing Officer communicated with the pharmacy consultant about this expectation on 6/28/23.</p> <p>The Psychiatric NP was educated on 6/27/23 by the Medical Director on his expectations for comprehensive medical record review, specifically review for indications of use and diagnosis for anti-seizure medications and/or for gradual dose reductions for psychotropic medications which can also be used for seizures (ie. Valproic Acid) before making recommendations for changes. Any concerns on the medical impact, related and unrelated to mood and behavior, should be discussed and coordinated with the provider (attending physician and/or medical NP) before changes are recommended. Additionally, any medication such as Valproic Acid, which can also be indicated for mood stabilization should be reviewed closer to determine actual indication for usage, and to monitor lab values prior to</p>		

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F 684	<p>Continued From page 9</p> <p>gradual dose reduction because his level had been high.</p> <p>On 6/15/23 Nurse # 5 entered an order into the computer for the Psychiatric NP for a lower dosage of the valproic acid. The order was for 5 ml (250 mg/ 5ml) three times per day. (This would equate to 250 mg three times per day.) The order was specifically written that the valproic acid was being used for behaviors. It did not mention that it was used for seizure control.</p> <p>On 6/15/23 Nurse # 5 noted in a nursing note that she had informed Resident # 10's responsible party that the valproic acid dosage had been dropped from 10 ml to 5 ml. Nurse # 5 noted this was done following a visit from the psychiatric NP and the valproic acid was given for behaviors. There was no notation that the medical physician or medical Nurse Practitioner were consulted.</p> <p>On 6/19/23 at 12:48 PM Nurse # 4 noted in a nursing note that Resident # 10 had a grand mal seizure (a seizure where there is loss of consciousness and violent muscle contractions), facility staff and the Medical NP responded, the resident was given IM (intramuscular) Ativan without any positive results. Nurse # 4 further noted the seizure became more intense and EMS (Emergency Medical Services) was called to transfer the resident to the hospital.</p> <p>On 6/19/23 Medical Nurse Practitioner # 2 entered a note in Resident # 10's record noting the resident's seizure had worsened although he had been given the Ativan. She noted he had seized for about 28 minutes when EMS arrived.</p> <p>According to hospital records Resident # 10 was</p>	F 684	<p>recommending a decrease in dosage.</p> <p>The Medical Director is the attending physician for all residents at the facility. Moving forward and related to this event, he will educate any current advanced care practitioners (current NPs medical and other consulting NPs), any future attending physicians, advanced care practitioners and internal consulting entities on comprehensive medical review and interdisciplinary provider discussion when consulting providers desire to make changes, and/or when the Medical NP is making changes to an anti-seizure medication. The expectation is that levels will be drawn, and a comprehensive review done before dosages are being changed for all providers involved. The center DON knows who all current providers are; she will be made aware by the Administrator and/or Medical Director when new providers and consultant providers begin practicing at the facility. She has ensured all current providers have been educated by the Medical Director as of 6/29/23 and will ensure the new providers are communicated to the Medical Director for the need to education, tracked to completion, and maintain documentation of it onsite moving forward.</p> <p>The consultant pharmacist will be involved at admission and monthly thereafter to identify antiseizure mediations and to determine if they are being monitored appropriately via the recommended labs. Education began for nursing staff to include licensed nurses and nursing assistants on</p>		

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F 684	<p>Continued From page 10</p> <p>evaluated in the emergency department on 6/19/23 and was intubated. The resident's valproic acid level was determined to be subtherapeutic at 39 and he was loaded (given an initial large dose of medication to obtain a quick response) with intravenous valproic acid. The Emergency Department physician also noted Resident # 10 had arrived in the Emergency Department in a postictal state (a period of recovery after a seizure) and within two hours started to have leftward eye deviation that was concerning for possible seizure activity. According to hospital records, the Emergency Department physician determined Resident #10 required a higher level of care. A larger hospital was contacted, and a transfer acceptance was obtained that same day (6/19/23) to their Intensive Care Unit for LTM EEG (long term electroencephalographic monitoring, which is the capability of recording electrical brain activity over long periods of time).</p> <p>Resident # 10 remained hospitalized as of 6/26/23.</p> <p>Following Resident # 10's discharge from the facility, the facility received from their lab the first valproic acid level that had been drawn since the order for the 5/15/23 level. The lab report showed the valproic acid level had been drawn on 6/17/23. The lab report noted it was received on 6/21/23 and reported to the facility on 6/22/23. The valproic acid level registered 21, which indicated the resident's level was subtherapeutic prior to his 6/19/23 seizure.</p> <p>The facility's pharmacy consultant was interviewed on 6/26/23 at 12:22 PM and reported the following. A therapeutic valproic acid level for</p>	F 684	<p>6/27/23 by the Director of Nursing (DON), Regional Director of Clinical Services, or a member of nursing administration. Education included Nursing policy 2303, "Report of Consultation."</p> <p>Education included:</p> <p>" The physician may order a consultation with another physician or healthcare provider.</p> <p>" Nurse (DON, supervisor, unit manager, charge nurse or designee) should review the report of consultation or physician progress notes as applicable. These reports are provided to center nursing staff by the contracted provider at the time of the consultation.</p> <p>" The nurse will report findings to attending physician, Physician Assistant (PA) or Nurse Practitioner (NP). This will be reported verbally onsite or via phone call if the provider is not available onsite, at the time of the review, as indicated for order implementation, changes to current orders or rejection of orders if not approved by the provider.</p> <p>" Implement orders as indicated and/or approved by the attending physician, PA or NP after review after review verbally. If the order was rejected, the nurse will communicate to the consulting entity and follow-up as needed with the provider.</p>		

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F 684	<p>Continued From page 11</p> <p>seizure control would be 50 to 100. The lab had flagged the value of 108 on 5/10/23 because it was higher than the upper therapeutic range. Toxic levels (levels when serious adverse effects are brought about due to excessive medication in a person's system) would be considered 175 or greater. She had last reviewed Resident # 10's record on 5/26/23 and noted that his dosage had been changed following the lab value on 5/10/23. Resident # 10 had a history of his levels going up and down. It would have been her recommendation that no changes be made in the dosage until a repeat level be done given his history, but the dosage had been already changed before she did her review. The valproic acid dosage which had been ordered on 6/15/23 by the Psychiatric NP was "historically" a very low dose for Resident # 10, but she had not reviewed him again following 5/26/23 to have reported this. According to the facility pharmacy consultant the facility had been doing monthly valproic acid levels and she thought that was appropriate, and therefore she did not have any recommendation on 5/26/23.</p> <p>Medical Nurse Practitioner # 1 was interviewed on 6/26/23 at 4:10 PM and reported the following. She was the on- call provider when a facility nurse called her on 5/10/23 with the valproic acid level of 108 on 5/10/23. She had asked about any seizure activity the resident had, and the nurse had told her that he had none. She had decreased his dosage by 1 ml during the three times per day it was given. She had instructed the nurse to have the level repeated in a month. It would have been the nurse's responsibility to have put the order in. No one had told her that his level had been going up and down. If this had been shared with her, then she would have</p>	F 684	<p>Any nursing staff member that did not receive education on 6/27/23 will receive education by the beginning of their next shift by the DON or designee. The Staff Development Coordinator will be responsible for tracking staff that still require education. Any staff that has not received education will not be allowed to work until education is received. All newly hired licensed staff will be educated by the Staff Development Coordinator, DON, or a member of nursing administration on this policy.</p> <p>This education will be added to the orientation process. Staff Development was notified of this responsibility on 6/27/23.</p> <p>All consultation visits and associated orders will be tracked by the DON or Regional Director of Clinical Services to ensure that the policy/process was followed as outlined above.</p> <p>All reports of consultation from the previous day and all new orders related to consultations will be brought to and tracked in the daily clinical meeting (M-F) and the weekend supervisor will review reports of consultation on Saturday/Sunday to ensure the process has been followed. This process will begin on 6/29/23.</p> <p>4. The Director of Nursing or Regional Director of Clinical Services will audit all</p>		

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F 684	<p>Continued From page 12</p> <p>instructed the facility nurse to consult with the regular provider the next day and let them decide.</p> <p>Medical NP # 2, who generally covered the facility's residents, was interviewed on 6/23/23 at 11:38 AM and reported the following. She was not aware of any changes to the order that had been given to draw the valproic acid level on 5/15/23. She was also not aware Resident # 10's valproic acid level had been decreased on the date of 6/15/23. She found this out on 6/19/23 after he had the seizure.</p> <p>The facility's Psychiatric NP was interviewed on 6/23/23 at 1:25 PM and reported the following. She did not think the valproic acid was being used for seizure control. She thought it was only used for mood stabilization and behaviors. She was seeing him on 6/15/23 because of his increased behaviors. He had recently bitten a staff member. When she saw Resident # 10 on 6/15/23 she saw that his last valproic acid level had been critically high and she ordered that the dosage be decreased. She had talked to the facility nurses about this but not with the medical physician or the medical NP.</p> <p>Nurse # 5 was interviewed on 6/23/23 at 12:30 PM and reported the following. She had entered in the order on 6/15/23 for the decrease in the valproic acid level after the Psychiatric Nurse Practitioner wrote the order but did not talk to the medical physician or the medical Nurse Practitioner. She thought the Psychiatric NP had talked to the Medical NP about the dose change.</p> <p>During an interview with the DON on 6/23/23 at 1:40 PM, the DON reported the valproic acid was being used for seizure control and was also</p>	F 684	<p>consults daily x4 weeks, then 2x/week x4, then weekly x4. All findings will be reported to the monthly QAPI committee.</p> <p>The administrator is responsible for this plan of correction.</p> <p>5. Date of completion: July 31, 2023</p>		

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F 684	<p>Continued From page 13 helping with some of the resident's behaviors.</p> <p>The facility's Medical Director was interviewed on 6/23/23 at 5:15 PM and reported the following. He felt the Nurse Practitioners could have collaborated better about the medication changes for Resident # 10. Resident # 10 had a history of having seizures regardless of seizure medications. He could not say that the lower dose of valproic acid and subtherapeutic level did not contribute to his seizure on 6/19/23.</p> <p>The Administrator was interviewed on 6/23/23 at 6:00 PM with the Director of Nursing. According to the Administrator and the Director of Nursing, the facility had identified that Resident # 10's seizure medication dosage had been changed by the Psychiatric Nurse Practitioner without checking with the medical provider and they had initiated but not completed a plan of correction.</p> <p>The Administrator was informed of Immediate jeopardy on 6/26/23 at 7:19 PM. The Administrator presented the following Immediate Jeopardy removal plan.</p> <p>Identify those recipients who have suffered, or are likely to suffer, a serious adverse outcome as a result of the noncompliance.</p> <p>Resident #10 was on Valproic Acid, as indicated for seizures. On 6/15/23 a consulting Psychiatric Nurse Practitioner (NP) decreased the dosage from Valproic Acid Oral Solution 250 MG/5ML, Give 10 ml three times a day to Valproic Acid Oral Solution 250 MG/5ML, Give 5 ml three times a day, related to a medication review regarding behaviors. However, as noted previously in the resident's medical record, its diagnosis and</p>	F 684			

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F 684	<p>Continued From page 14</p> <p>indication for use was for seizures. The Psychiatric NP was not aware the medication was used for seizure control because she did not conduct a thorough review of the medical record. The medical physician and/or facility medical staff (Nurse practitioner) were not consulted, and orders were not reviewed with the attending physician and/or his NP before the change in dosage. The resident seized and was hospitalized and intubated on 6/19/23 and remains there as of this date.</p> <p>The center staff did not follow professional standards in assuring that Nursing Policy 2303, entitled "Report of Consultation," related to physician consults was followed. Previously, this internal contracted provider (in this case the Psychiatric NP) was functioning independently with no medical reviews conducted by the attending physician or medical NP, to approve, deny or change recommended orders prior to implementation. The psychiatric NP was being supervised by her contract provider, a Psychiatrist.</p> <p>All other residents receiving Valproic Acid and being followed by the Psychiatric NP were audited on 6/23/23 by the regional director of clinical services, to determine if there were other such discrepancies noted, such as change of indication for use or diagnosis. Any discrepancy found was reported to the attending physician and/or medical NP for immediate follow-up.</p> <p>The regional director of clinical services and/or DON will review all residents by 6/30/23 at the direction of the medical director/attending physician (the same individual) to assure the appropriate levels for anti-seizure medications</p>	F 684			

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F 684	<p>Continued From page 15</p> <p>are being monitored via lab including the mediations Valproic Acid (Depakote), Carbamazepine (Tegretol), Phenytoin (Dilantin), Levetiracetam (Keppra), to assure there are no medications not being monitored appropriately, no delayed lab results, and no failures of the provider or center to monitor other residents on these anti-seizure medications.</p> <p>As of 6/28/23, the Chief Nursing Officer, the Medical Director/attending physician, the consulting pharmacy group, and the DON met to determine, agree upon and implement the following process for all current residents that receive Valproic Acid (Depakote), Carbamazepine (Tegretol), Phenytoin (Dilantin), Levetiracetam (Keppra) and other seizure medications will have labs to monitor these drug levels</p> <p>" All of those receiving these medications will be subject to the following:</p> <ul style="list-style-type: none"> o Lab monitoring once every three months for two months. o Lab monitoring once every six months thereafter. o Baseline lab will occur for new admissions, then at the notated schedule above <p>" The consultant pharmacist will be involved at admission and monthly thereafter to identify anti-seizure medications and to determine if they are being monitored appropriately via the recommended labs at the recommended intervals noted above. The Chief Nursing Officer communicated with the pharmacy consultant about this expectation on 6/28/23.</p> <p>After the meeting of the Chief Nursing Officer, Medical Director/attending physician, consulting pharmacy group, and DON, the nurse administrative team will be educated by the DON</p>	F 684			

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F 684	<p>Continued From page 16</p> <p>or regional director of clinical services on this process by 6/30/23, to ensure all expected labs have been ordered on admission and ongoing. This will be tracked via the lab tracking policy outlined below, and monitored for implementation ongoing via the process outlined below in the daily clinical meeting. The Chief Nursing Officer communicated with the pharmacy consultant about this expectation on 6/28/23.</p> <p>Specify the action the entity will take to alter the process or system failure to prevent a serious adverse outcome from occurring or recurring, and when the action will be completed.</p> <p>The Psychiatric NP was educated on 6/27/23 by the Medical Director on his expectations for comprehensive medical record review, specifically review for indications of use and diagnosis for anti-seizure medications and/or for gradual dose reductions for psychotropic medications which can also be used for seizures (ie. Valproic Acid) before making recommendations for changes. Any concerns on the medical impact, related and unrelated to mood and behavior, should be discussed and coordinated with the provider (attending physician and/or medical NP) before changes are recommended. Additionally, any medication such as Valproic Acid, which can also be indicated for mood stabilization should be reviewed closer to determine actual indication for usage, and to monitor lab values prior to recommending a decrease in dosage.</p> <p>The Medical Director is the attending physician for all residents at the facility. Moving forward and related to this event, he will educate any current advanced care practitioners (current NPs</p>	F 684			

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F 684	<p>Continued From page 17</p> <p>medical and other consulting NPs), any future attending physicians, advanced care practitioners and internal consulting entities on comprehensive medical review and interdisciplinary provider discussion when consulting providers desire to make changes, and/or when the Medical NP is making changes to an anti-seizure medication. The expectation is that levels will be drawn and a comprehensive review done before dosages are being changed for all providers involved. The center DON knows who all current providers are; she will be made aware by the Administrator and/or Medical Director when new providers and consultant providers begin practicing at the facility. She has ensured all current providers have been educated by the Medical Director as of 6/29/23, and will ensure the new providers are communicated to the Medical Director for the need to education, tracked to completion, and maintain documentation of it onsite moving forward.</p> <p>The consultant pharmacist will be involved at admission and monthly thereafter to identify anti-seizure mediations and to determine if they are being monitored appropriately via the recommended labs.</p> <p>Education began for nursing staff to include licensed nurses and nursing assistants on 6/27/23 by the Director of Nursing (DON), regional director of clinical services, or a member of nursing administration. Education included Nursing policy 2303, "Report of Consultation." Education included: " The physician may order a consultation with another physician or healthcare provider " Nurse (DON, supervisor, unit manager, charge nurse or designee) should review the</p>	F 684			

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F 684	<p>Continued From page 18</p> <p>report of consultation or physician progress notes as applicable. These reports are provided to center nursing staff by the contracted provider at the time of the consultation.</p> <p>" The nurse will report findings to attending physician, Physician Assistant (PA) or Nurse Practitioner (NP). This will be reported verbally onsite or via phone call if the provider is not available onsite, at the time of the review, as indicated for order implementation, changes to current orders or rejection of orders if not approved by the provider.</p> <p>" Implement orders as indicated and/or approved by the attending physician, PA or NP after review after review verbally. If the order was rejected, the nurse will communicate to the consulting entity and follow-up as needed with the provider.</p> <p>Any nursing staff member that did not receive education on 6/27/23 will receive education by the beginning of their next shift by the DON or designee. The Staff Development Coordinator will be responsible for tracking staff that still require education. Any staff that has not received education will not be allowed to work until education is received. All new hire licensed staff will be educated by the Staff Development Coordinator, DON or a member of nursing administration on this policy. This education will be added to the orientation process. Staff Development was notified of this responsibility on 6/27/23.</p> <p>All consultation visits and associated orders will be tracked by the DON or regional director of clinical services to ensure that the policy/process was followed as outlined above. All reports of consultation from the previous day and all new</p>	F 684			

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F 684	<p>Continued From page 19</p> <p>orders related to consultations will be brought to and tracked in the daily clinical meeting (M-F) and the weekend supervisor will review reports of consultation on Saturday/Sunday to ensure the process has been followed. This process will begin on 6/29/23.</p> <p>Date of immediate jeopardy removal is 7/3/23. Person responsible for implementation the plan is the Administrator.</p> <p>The facility's credible allegation of Immediate Jeopardy removal was validated on 7/5/23 and 7/6/23.</p> <p>The validation was evidenced by record reviews and interviews to verify all residents receiving anti-seizure medications (including valproic acid, carbamazepine, phenytoin, and levetiracetam) had lab work completed to ensure their blood levels of the medications were monitored appropriately.</p> <p>An interview with the facility's consultant pharmacist confirmed she would recommend newly admitted residents receiving such medications would have a baseline drug level obtained and the level monitored appropriately.</p> <p>Multiple interviews were conducted with licensed nurses to ensure the necessary in-service education was provided prior to working their shift. The nurses consistently reported they received in-service education, which included the process for reporting consultation findings to the facility's medical team (Medical NPs or MD) and verifying any new orders with one of these providers prior to initiating the orders.</p>	F 684			

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F 684	Continued From page 20 An interview conducted with the Psychiatric NP confirmed she was counseled on the need to complete a comprehensive medical review prior to recommending a change in medication. Interviews with the facility's medical team (Medical NPs and MD) indicated they would be responsible for reviewing and verifying all orders recommended by a consulting provider prior to the implementation of these orders.	F 684			
F 756 SS=D	On 7/6/23 it was confirmed that Immediate Jeopardy was removed on 7/3/23. Drug Regimen Review, Report Irregular, Act On CFR(s): 483.45(c)(1)(2)(4)(5) §483.45(c) Drug Regimen Review. §483.45(c)(1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist. §483.45(c)(2) This review must include a review of the resident's medical chart. §483.45(c)(4) The pharmacist must report any irregularities to the attending physician and the facility's medical director and director of nursing, and these reports must be acted upon. (i) Irregularities include, but are not limited to, any drug that meets the criteria set forth in paragraph (d) of this section for an unnecessary drug. (ii) Any irregularities noted by the pharmacist during this review must be documented on a separate, written report that is sent to the attending physician and the facility's medical director and director of nursing and lists, at a minimum, the resident's name, the relevant drug, and the irregularity the pharmacist identified. (iii) The attending physician must document in the	F 756		7/31/23	

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F 756	<p>Continued From page 21</p> <p>resident's medical record that the identified irregularity has been reviewed and what, if any, action has been taken to address it. If there is to be no change in the medication, the attending physician should document his or her rationale in the resident's medical record.</p> <p>§483.45(c)(5) The facility must develop and maintain policies and procedures for the monthly drug regimen review that include, but are not limited to, time frames for the different steps in the process and steps the pharmacist must take when he or she identifies an irregularity that requires urgent action to protect the resident. This REQUIREMENT is not met as evidenced by:</p> <p>Based on record review and pharmacy consultant interview the facility pharmacy consultant failed to report to the medical physician that 1) a resident's valproic acid level had not been done as ordered at the time she did her monthly review and 2) that her recommendation was that no further dosage changes be made without a level being checked. This was for 1 of 3 residents reviewed related to their seizure medication (Resident # 10). The findings included.</p> <p>Record review revealed Resident # 10 was initially admitted to the facility on 3/21/21. He was discharged to the hospital on 6/19/23. The resident's diagnoses included in part traumatic brain injury and complex partial epilepsy (neurological disorder that causes seizures), depression, and anxiety.</p> <p>Record review revealed Resident # 10 received both lacosamide and valproic acid for seizures. The last order for lacosamide was dated 5/12/23</p>	F 756	<p>F756-Drug Regimen is Free from Unnecessary Drugs</p> <ol style="list-style-type: none"> 1. Resident #10 was in hospital at time of this review. 2. All residents are within the facility are at risk of being potentially affected. 3. The pharmacy manager will in-service the consulting pharmacist of the expectations and regulations regarding completion of Drug Regimen Reviews and related regulatory requirements. This Inservice will be completed by 7/28/2023. The consultant pharmacist will be involved at admission and monthly thereafter to identify antiseizure medications to determine if they are being monitored appropriately via recommended labs. When needed the consultant pharmacist will make the needed recommendations and communicate them the medical provider via the monthly pharmacist consultant report. The DON/designee will review all 		

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F 756	<p>Continued From page 22</p> <p>and directed that the resident receive 10 ml (milliliters) 10 mg (milligrams)/ml two times per day. This remained as an active order up until his date of discharge.</p> <p>Orders and lab results related to Resident # 10's valproic acid medication were as follows:</p> <p>From 5/2/23 until 5/10/23, Resident # 10 was ordered to receive 11 ml (250 mg/5ml) valproic acid three times per day. (This would equate to 550 mg three times per day).</p> <p>On 5/10/23 a valproic acid level was done and registered 108. (Therapeutic range is 50 to 100 for seizures).</p> <p>On 5/10/23 at 2:38 PM Nurse # 2 noted in the record that she had received a critical lab value regarding a valproic acid level of 108 and called it into Medical Nurse Practitioner (NP) # 1.</p> <p>On 5/10/23 an order was given to decrease the valproic acid dosage to 10 ml (250 mg/ 5 ml) three times per day. (This would equate to 500 mg three times per day.) This order stayed in effect until 6/15/23. The order specifically noted the valproic acid was for seizures.</p> <p>On 5/11/23 the physician ordered Resident # 10's valproic acid level be rechecked on the date of 5/15/23. The order was electronically signed by the physician on 5/12/23. This order remained as an active order up until the resident 's discharge date of 6/19/23 with no revision of the order.</p> <p>There was no valproic acid level drawn on 5/15/23 or a notation in the record why it was not done.</p>	F 756	<p>admission MRR/monthly MRR to assure that all residents current and admitted to the facility with antiseizure medications have been reviewed by the consultant pharmacist and any recommendations made have been communicated to the medical practitioner and implemented timely once approved by the medical provider.</p> <p>4. The DON/designee will review MRR summaries weekly x4 weeks, then Bi-weekly x4 for all new admission and will review all monthly MRR summaries monthly x 3 months, to assure compliance is maintained.</p> <p>The DON/designee will take results of reviews to QA by the DON and reviewed monthly at the Quality Assurance Committee Meeting for any further recommendations. The Administrator will be responsible for any follow up on any recommendation from the QA Committee and additional training as indicated.</p> <p>5. Date of completion: July 31, 2023</p>		

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

PRINTED: 09/01/2023
FORM APPROVED
OMB NO. 0938-0391

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F 756	Continued From page 23 Review of the facility's pharmacy consultant report, dated 5/27/23, revealed Resident # 10's name was on the list of residents she had reviewed for the dates of 5/1/23 through 5/27/23, and for which she had no recommendations. At the time of the pharmacist's drug regiment review, Resident # 10 still had no valproic acid level drawn per the 5/11/23 order. The facility's pharmacy consultant was interviewed on 6/26/23 at 12:22 PM and reported the following. A therapeutic valproic acid level for seizure control would be 50 to 100. The lab had flagged the value of 108 on 5/10/23 because it was higher than the upper therapeutic range. Toxic levels would be considered 175 or greater. She had last reviewed Resident # 10's record on 5/26/23 and noted that his dosage had been changed following the lab value on 5/10/23. Resident # 10 had a history of his levels going up and down. It would have been her recommendation that no changes be made in the dosage until a repeat level be done given his history, but the dosage had already been changed before she did her review and therefore, she did not call it to the attention of the physician. According to the pharmacy consultant the facility had been doing monthly valproic acid levels and she thought that was appropriate, and therefore she did not have any recommendation on 5/26/23 for the physician about his valproic acid blood level checks either.	F 756			
F 757 SS=J	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	F 757		7/31/23	

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F 757	Continued From page 24 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 record review and staff, Pharmacist, Nurse Practitioner, and Physician interviews the facility failed to provide effective monitoring of medication blood levels and manage dose changes for a seizure medication (valproic acid). On 5/10/23 Resident #10's valproic acid level was 108 (therapeutic level is 50-100 mcg/mL). The laboratory results were reported to the on-call provider who ordered a decrease in the daily dosage of Resident #10's valproic acid. No orders were entered into the resident's record that day for any repeat valproic acid level to be drawn. On 5/12/23 Resident #10's Physician electronically signed an order to repeat the valproic acid level on 5/15/23. This order was not received by the laboratory and remained active up until the resident's hospitalization on 6/19/23. On 6/15/23 Resident #10 was seen by the Psychiatric Nurse	F 757	F757-Drug Regiment is Free from Unnecessary Drugs 1. The Regional Director of Clinical Services and/or DON will review all residents by 6/30/23 at the direction of the medical director/attending physician (the same individual) to assure the appropriate levels for anti-seizure medications are being monitored via lab including the mediations Valproic Acid (Depakote), Carbamazepine (Tegretol), Phenytoin (Dilantin), Levetiracetam (Keppra), to assure there are no medications not being monitored appropriately, no delayed lab results, and no failures of the provider or center to monitor other residents on these anti-seizure medications. As of 6/28/23, the Chief Nursing Officer,		

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F 757	<p>Continued From page 25</p> <p>Practitioner (NP) related to behaviors. The Psychiatric NP noted incorrectly that Resident # 10's valproic acid was prescribed for mood stabilization and ordered a further reduction of the valproic acid daily dosage. No monitoring of the resident's valproic acid level was ordered at the time of the visit. The lab successfully drew a valproic acid level on 6/17/23, and the result revealed the level was subtherapeutic. The subtherapeutic level was not reported to the facility until 6/22/23, and there was no documentation in the record the facility tried to obtain the result prior to 6/22/23. On 6/19/23 Resident # 10 had a grand mal seizure (a seizure where there is loss of consciousness and violent muscle contractions), which was documented not to respond to intramuscular Ativan medication and lasted approximately 28 minutes before emergency medical services arrived for care and transport. Resident #10 was transported to the local hospital emergency department and intubated (a tube was inserted into the trachea for ventilation). Upon Emergency Department evaluation, Resident # 10's valproic acid level was 39, which was subtherapeutic. The Emergency Department physician determined Resident #10 required LTM EEG (long term electroencephalographic monitoring, which is the capability of recording electrical brain activity over long periods of time) and Resident #10 was transferred to the Intensive Care Unit at a larger hospital that same day. This was for 1 of 3 sampled residents reviewed for seizure medications (Resident #10).</p> <p>Immediate Jeopardy began on 5/15/23 when the facility did not obtain the physician ordered valproic acid level for Resident #10. The immediate jeopardy was removed on 7/03/23</p>	F 757	<p>the Medical Director/attending physician, the consulting pharmacy group, and the DON met to determine, agree upon and implement the following process for all current residents that receive Valproic Acid (Depakote), Carbamazepine (Tegretol), Phenytoin (Dilantin), Levetiracetam (Keppra) and other seizure medications will have labs to monitor these drug levels.</p> <p>All of those receiving these medications will be subject to the following:</p> <ul style="list-style-type: none"> " Lab monitoring once every three months for two months. " Lab monitoring once every six months thereafter. " Baseline lab will occur for new admissions, then at the notated schedule above " The consultant pharmacist will be involved at admission and monthly thereafter to identify anti-seizure medications and to determine if they are being monitored appropriately via the recommended labs at the recommended intervals noted above. The Chief Nursing Officer communicated with the pharmacy consultant about this expectation on 6/28/23. " After the meeting of the Chief Nursing Officer, Medical Director/attending physician, consulting pharmacy group, and DON, the nurse administrative team will be educated by the DON or regional director of clinical services on this process by 6/30/23, to ensure all expected labs have been ordered on admission and ongoing. This will be tracked via the lab tracking policy outlined below and 		

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F 757	<p>Continued From page 26</p> <p>when the facility provided and implemented an acceptable credible allegation of immediate jeopardy removal. The facility remains out of compliance at a lower scope and severity level of D to ensure monitoring of systems put into place are effective and to complete staff training.</p> <p>The findings included:</p> <p>Record review revealed Resident # 10 was initially admitted to the facility on 3/21/21. The resident's diagnoses included in part traumatic brain injury and complex partial epilepsy (neurological disorder that causes seizures), depression, and anxiety.</p> <p>Resident #10's quarterly Minimum Data Set assessment, dated 3/16/23, coded the resident as severely cognitively impaired. He was also assessed to need total assistance with his activities of daily living, have no behaviors during the assessment period, and to have a seizure disorder.</p> <p>Record review revealed Resident # 10 received both lacosamide and valproic acid for seizures. The last order for lacosamide was dated 5/12/23 and directed that the resident receive 10 ml (milliliters) 10 mg (milligrams)/ml two times per day. This remained as an active order up until his date of discharge.</p> <p>From 5/2/23 until 5/10/23, Resident # 10 was ordered to receive 11 ml (250 mg/5ml) valproic acid three times per day. (This would equate to 550 mg three times per day).</p> <p>On 5/10/23 a valproic acid level was done and registered 108 mcg/mL. (A therapeutic</p>	F 757	<p>monitored for implementation ongoing via the process outlined below in the daily clinical meeting. The Chief Nursing Officer communicated with the pharmacy consultant about this expectation on 6/28/23.</p> <p>2. The Psychiatric NP will be educated by the Medical Director on his expectations for comprehensive medical record review, specifically review for indications of use and diagnosis for anti-seizure medications and/or for gradual dose reductions for psychotropic medications which can also be used for seizures (ie. Valproic Acid) before making recommendations for changes. Any concerns on the medical impact, related and unrelated to mood and behavior, should be discussed and coordinated with the provider (attending physician and/or medical NP) before changes are recommended. Additionally, any medication such as Valproic Acid, which can also be indicated for mood stabilization should be reviewed closer to determine actual indication for usage, and to monitor lab values prior to recommending a decrease in dosage. This will be done by 6/28/23.</p> <p>The Medical Director is the attending physician for all residents at the facility. Moving forward and related to this event, he will educate any current advanced care practitioners (current NPs medical and other consulting NPs), any future attending physicians, advanced care practitioners and internal consulting entities on comprehensive medical review</p>		

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F 757	<p>Continued From page 27</p> <p>medication level is when the blood level of the medication is in a range to be helpful but not dangerous. The facility's lab report noted therapeutic range for valproic acid to be 50 to 100 mcg/ml. A subtherapeutic level for valproic acid would be medication blood levels below 50 mcg/ml. A toxic level would indicate levels when serious adverse effects are brought about due to excessive medication in a person's system).</p> <p>On 5/10/23 at 2:38 PM Nurse # 2 noted in a nursing note that she had received a critical lab value regarding a valproic acid level of 108 and called it into Medical Nurse Practitioner (NP) # 1.</p> <p>On 5/10/23 a phone order was given by Medical NP # 1 to decrease the valproic acid dosage to 10 ml (250 mg/ 5 ml) three times per day. (This would equate to 500 mg three times per day.) This order stayed in effect until 6/15/23. The order specifically noted the valproic acid was for seizures.</p> <p>On 5/11/23 the Physician ordered Resident # 10's valproic acid level be rechecked on the date of 5/15/23. The order was electronically signed by the physician on 5/12/23. This order remained as an active order up until the resident's discharge date of 6/19/23 with no revision of the order. There was no valproic acid level drawn on 5/15/23 or a notation in the record why it was not done.</p> <p>On 5/27/23 the facility Pharmacy Consultant completed a Medication Regimen Review and noted she had no recommendations related to Resident # 10's medications.</p> <p>On 6/15/23 Resident # 10 was seen by the</p>	F 757	<p>and interdisciplinary provider discussion when consulting providers desire to make changes and/or when the Medical NP is making changes to an anti-seizure medication. The expectation is that levels will be drawn, and a comprehensive review done before dosages are being changed for all providers involved. The center DON knows who all current providers are; she will be made aware by the Administrator and/or Medical Director when new providers and consultant providers begin practicing at the facility. She has ensured all current providers have been educated by the Medical Director as of 6/29/23 and will ensure the new providers are communicated to the Medical Director for the need to education, tracked to completion, and maintain documentation of it onsite moving forward.</p> <p>Education began for nursing staff to include licensed nurses and nursing assistants on 6/27/23 by the Director of Nursing (DON) or designee. In the case of this deficient practice, the lab tracking process, from order/requisition to a timely final result was not in place and was in violation of our Laboratory Tracking Policy 1702.</p> <p>Education included the policy and protocols listed: -</p> <p>A licensed nurse will monitor and track all physician or physician extender ordered laboratory tests and will ensure that lab tests are drawn as ordered and communicate results to the physician in a timely manner.</p> <p>A. The Center will obtain lab services to</p>		

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F 757	<p>Continued From page 28</p> <p>Psychiatric Nurse Practitioner (NP) related to behaviors. The Psychiatric NP noted that Resident # 10's valproic acid was prescribed for mood stabilization, and she was going to start a gradual dose reduction because his level had been high.</p> <p>On 6/15/23 Nurse # 5 entered the order from the Psychiatric NP into the computer for a lower dosage of the valproic acid. The order was for 5 ml (250 mg/ 5ml) three times per day. (This would equate to 250 mg three times per day.) The order was specifically written that the valproic acid was being used for behaviors. It did not mention that it was used for seizure control.</p> <p>On 6/15/23 Nurse # 5 noted in the record that she had informed Resident # 10's responsible party that the valproic acid dosage had been dropped from 10 ml to 5 ml in addition of increasing another medication for behaviors the resident had. Nurse # 5 noted this was done following a visit from the Psychiatric NP and the valproic acid was given for behaviors. There was no notation that the Medical Physician or Medical Nurse Practitioner were consulted.</p> <p>Nurse # 5 was interviewed on 6/23/23 at 12:30 PM and reported the following. She had entered the order written by the Psychiatric NP on 6/15/23 for the decrease in the valproic acid but did not talk to the Medical Physician or the Medical Nurse Practitioner. She thought the Psychiatric NP had talked to the Medical NP about the dose change.</p> <p>On 6/16/23 at 9:42 AM Nurse # 6 noted in a nursing noted the following. The phlebotomist said she was unable to draw the resident's lab due to the resident moving his arm. The</p>	F 757	<p>meet the needs of its patients. Education occurred to nurses, specifically related to the need for blood levels drawn for residents on seizure medications, such as Dilantin, Valproic Acid and Keppra.</p> <p>B. Lab services will be provided only when ordered by the physician or physician extender and the physician or extender will be notified of lab results in a timely manner.</p> <p>C. When an order for a lab test is received, for the current month, a licensed nurse receiving the order will complete a lab requisition form from the lab vendor. The information will include:</p> <ol style="list-style-type: none"> patient name and room number. Test ordered. Date lab test is to be drawn. Medicare/Medicaid numbers. Other insurance information. Name of the ordering physician Date of birth. Diagnosis related to the test ordered. <ol style="list-style-type: none"> Any special instructions. <p>D. A licensed nurse receiving the order will document the information on the appropriate current month's lab tracking log located in the lab notebook. Routine labs will be recorded on the lab tracking log.</p> <p>The DON, Unit Manager or Nursing Administration monitors the lab tracking log, to assure from order, to requisition, to result, to communication to the provider is timely. The expectation is that all routine/normal labs should be back in 24 hours. Labs results not back in 24 hours should be reviewed and monitored for</p>		

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F 757	<p>Continued From page 29</p> <p>phlebotomist recommended that the resident be given a medication to help him not move so the blood draw could be completed. Nurse # 6 further noted the Medical NP was made aware. According to a lab report, a valproic acid level was drawn on 6/17/23.</p> <p>On 6/19/23 at 12:48 PM Nurse # 4 noted in a nursing note that Resident # 10 had a grand mal seizure, facility staff and the Medical NP # 2 responded, the resident was given IM (intramuscular) Ativan without any positive results. Nurse # 4 further noted the seizure became more intense and EMS was called to transfer the resident to the hospital.</p> <p>On 6/19/23 Medical Nurse Practitioner # 2 entered a note in Resident # 10's record noting the resident's seizure had worsened although he had been given the Ativan. She noted he had seized for about 28 minutes when EMS arrived.</p> <p>According to hospital records Resident # 10 was evaluated in the emergency department on 6/19/23 and was intubated. The resident's valproic acid level was determined to be subtherapeutic at 39 and he was loaded (given an initial large dose of medication to obtain a quick response) with intravenous valproic acid. The Emergency Department physician also noted Resident # 10 had arrived in the Emergency Department in a postictal state (a period of recovery after a seizure) and within two hours started to have leftward eye deviation that was concerning for possible seizure activity. According to hospital records, the Emergency Department physician determined Resident #10 required a higher level of care. A larger hospital was contacted, and a transfer acceptance was</p>	F 757	<p>timeliness in the case that they are not expected to take more than 24 hours.</p> <p>E. If the routine lab test order is not due in the current month, the licensed nurse will document the appropriate information onto the Lab Tracking Log indicating the type of lab test ordered and date to be completed. The 11-7 shift licensed nurse or supervisor will check the Lab Tracking Form and the Culture & Sensitivity Lab Tracking Form nightly for lab work to be drawn in the morning. The appropriate requisition will be pulled from the lab book (or completed if necessary) and placed in the Center designated location for the lab technician.</p> <p>F. Upon completion of the lab draw, a licensed nurse will document the date the specimen was drawn on the appropriate Lab Tracking Log. If the lab is unable to be drawn, the information will be communicated to the attending physician, NP or PA for new orders, approval to move the lab or any follow-up as needed depending on the need of the resident.</p> <p>G. Upon receipt of lab results, a licensed nurse will document the date the results were received on the appropriate Lab Tracking form. All routine lab results, such as Valproic acid, Dilantin and Keppra level should be back in 24 hours. All lab values that are not back in 24 hours where the expectation was 24 hours, should be investigated for timeliness, follow-up to the lab and report to physician for any further actions or orders needed.</p> <p>H. Critical results will be called to the physician or extender and documented as indicated. The lab reports critical findings</p>		

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F 757	<p>Continued From page 30</p> <p>obtained that same day (6/19/23) to their Intensive Care Unit for LTM EEG (long term electroencephalographic monitoring, which is the capability of recording electrical brain activity over long periods of time).</p> <p>Resident # 10 remained hospitalized as of 6/26/23.</p> <p>Following Resident # 10's discharge from the facility, the facility received from their lab the first valproic acid level that had been drawn since the order for the 5/15/23 level. The lab report showed the valproic acid level had been drawn on 6/17/23. The lab report noted it was received on 6/21/23 and reported to the facility on 6/22/23. The valproic acid level registered 21, which indicated the resident's level was subtherapeutic prior to his 6/19/23 seizure.</p> <p>The facility's Pharmacy Consultant was interviewed on 6/26/23 at 12:22 PM and reported the following. A therapeutic valproic acid level for seizure control would be 50 to 100. The lab had flagged the value of 108 on 5/10/23 because it was higher than the upper therapeutic range. Toxic levels would be considered 175 or greater. She had last reviewed Resident # 10's record on 5/26/23 and noted that his dosage had been changed following the lab value on 5/10/23. Resident # 10 had a history of his levels going up and down. It would have been her recommendation that no changes be made in the dosage until a repeat level be done given his history, but the dosage had already been changed before she did her review. According to the facility Pharmacy Consultant the facility had been doing monthly valproic acid levels and she thought that was appropriate, and therefore she</p>	F 757	<p>via phone to the charge nurse, and the charge nurse will report this verbally in person or via phone to the provider as soon as possible for follow-up, but not later than two hours after receiving the lab notification.</p> <p>I. Once the physician or extender has been notified of lab results, the nurse will document the date of notification and the method of notification in the appropriate space(s) on the appropriate Lab Tracking Log and place his/her initials in the nurse initial column on the form.</p> <p>J. A licensed nurse will document any necessary information for follow up on the 24- hour shift report.</p> <p>3. Any nursing staff member that did not receive education on 6/27/23 will receive education by the beginning of the next shift by the DON or designee. The Staff Development Coordinator will be responsible for tracking staff that still require education. Any staff that has not received education will not be allowed to work until education is received. All new hire licensed staff will be educated by the Staff Development Coordinator or designee on this policy. This education will be added to the orientation process. Staff Development was notified of this responsibility on 6/27/23.</p> <p>4. All lab orders will be tracked by the DON or designee to ensure that they are requisitioned, tracked for timely results, reviewed by the attending physician, NP or PA daily and follow up as indicated. Each day (M-F) the lab tracking log along with the previous day's new lab orders will be brought to the clinical meeting by</p>		

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F 757	<p>Continued From page 31</p> <p>did not have any recommendation on 5/26/23. She further reported the decreased daily dosage of valproic acid which had been ordered on 6/15/23 by the Psychiatric NP was "historically" a very low dose for Resident # 10, but she had not reviewed him again following 5/26/23 to have reported this.</p> <p>Medical Nurse Practitioner # 1 was interviewed on 6/26/23 at 4:10 PM and reported the following. She was the on- call provider when a facility nurse called her on 5/10/23 with the valproic acid level of 108 on 5/10/23. She had asked about any seizure activity the resident had, and the nurse had told her that he had none. She had decreased his dosage by 1 ml three times per day and she had instructed the nurse to have the level repeated in a month. It would have been the nurse's responsibility to have put the order in. No one had told her that his level had been going up and down. If this had been shared with her, then she would have instructed the facility nurse to consult with the regular provider the next day and let them decide.</p> <p>The facility's Psychiatric NP was interviewed on 6/23/23 at 1:25 PM and reported the following. She did not think Resident #10 was prescribed the valproic acid for seizure control. She thought it was only used for mood stabilization and behaviors. When she saw Resident # 10 on 6/15/23 she saw that his last valproic acid level had been critically high, and she ordered that the dosage be decreased. She had talked to the facility nurses about this but not with the Physician or the Medical NP.</p> <p>The Medical NP #2, who generally covered the facility's residents, was interviewed on 6/23/23 at</p>	F 757	<p>nursing administration from each unit to review for this process by the DON, and on Saturday/Sunday, the weekend supervisor will complete the same process for each unit.</p> <p>The Director of Nursing will complete weekly audits all lab orders received to assure compliance. These audits will be completed weekly x8 weeks, bi-weekly x4 and monthly thereafter or until substantial compliance is achieved.</p> <p>All findings will be reported to the monthly QAPI committee.</p> <p>5.Date of completion: July 31, 2023</p>		

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F 757	<p>Continued From page 32</p> <p>11:38 AM and reported the following. She was not aware of any changes to the order that had been given to draw Resident #10's valproic acid level on 5/15/23. She was also not aware Resident # 10's valproic acid dosage had been decreased on 6/15/23. On 6/19/23 after Resident # 10 had a seizure, she found the valproic acid dosage had been decreased.</p> <p>The Director of Nursing (DON) was interviewed on 6/23/23 at 11:00 AM and reported the following. She thought the ordered lab for valproic acid for 5/15/23 was an error in the electronic medical record system, and the order was supposed to have been drawn on 6/15/23. The DON reported it was her understanding that the lab had not obtained enough blood for the valproic acid on 6/15/23 but they had attempted to get it that day. They tried again on 6/16/23 and the resident was moving too much. The lab was obtained on 6/17/23.</p> <p>During a follow up interview with the DON on 6/23/23 at 1:40 PM, the DON reported the valproic acid was being used for seizure control and was also helping with some of the resident's behaviors.</p> <p>The facility's lab manager was interviewed on 6/23/23 at 3:35 PM and reported the following. On 6/15/23 there had been no order for a valproic acid level. The lab was trying to draw another unrelated lab which had had been ordered for Resident # 10. On 6/16/23 they had the first order from the facility to have a valproic acid level done. The lab tried to draw it on 6/16/23 along with the special-order lab, which they had been unsuccessful in obtaining the previous day. On 6/16/23 the resident moved too much, and they</p>	F 757			

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F 757	<p>Continued From page 33</p> <p>could not get the valproic acid lab or the specialty lab. On 6/17/23 they returned and drew both labs, the valproic acid lab and the specialty lab. They ran the valproic acid lab themselves that day (6/17/23) because it was a routine lab for them. They sent out the specialty lab to their cooperative lab they worked with. The results for the specialty lab usually took a few days to complete and both results (the valproic acid level and the specialty lab) were released to the facility on 6/22/23.</p> <p>The Chief Executive Officer for the facility's lab was interviewed on 6/23/23 at 4:12 PM and reported the following. They retained a scanned copy of requisitions from facilities. The first requisition for Resident # 10's valproic acid level, since the 5/10/23 level had been done was 6/16/23. It was drawn on 6/17/23 and the result was finalized on 6/17/23 at 2:15 PM that same day. They had sent the specialty lab that had been drawn along with the valproic acid level to their cooperating lab to run. Lab results automatically populate electronically when all results are completed from the lab into the facility's electronic medical record computer system. It had been several years since they had contracted to do lab services for the facility, and there had been management changes since procedures had been set up and discussed with staff. At the initiation of services, he generally went over with the facility how lab results would be delivered to them. It had been set up with the facility that labs would automatically populate to their electronic medical record. There was a way the facility staff could log directly into the lab's system and see a result, but the facility had not chosen to have access when things were set up with them.</p>	F 757			

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F 757	Continued From page 34 The resident's Physician, who also serves as the facility's Medical Director, was interviewed on 6/23/23 at 5:15 PM and reported the following. He felt the Nurse Practitioners could have collaborated better about the medication changes for Resident # 10. Resident # 10 had a history of having seizures regardless of seizure medications. The Physician reported that although Resident # 10 had a history of seizures while on medications, he could not say that the lower dose of valproic acid and subtherapeutic level did not contribute to his seizure on 6/19/23. The Administrator was interviewed on 6/23/23 at 6:00 PM with the Director of Nursing. According to the Administrator and the Director of Nursing, the facility had identified that Resident # 10's seizure medication dosage had been changed by the Psychiatric Nurse Practitioner without checking with the medical provider and they had initiated but not completed a plan of correction. The facility Administrator was informed of Immediate Jeopardy on 6/26/23 at 7:19 PM. The Administrator submitted the following Immediate Jeopardy removal plan. Identify those recipients who have suffered, or are likely to suffer, a serious adverse outcome as a result of the noncompliance. Resident #10 was ordered to receive two medications for seizure management, Lacosamide Oral Solution 10 MG/ML Give 10 ml by mouth two times a day and Valproic Acid Oral Solution 250 MG/5ML, Give 11 ml three times a day. On 5/10/23 a routine lab was drawn to measure the valproic acid level, an	F 757			

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F 757	<p>Continued From page 35</p> <p>elevated level was determined high at 108, normal range 50-100 by the lab, and the high result was called from the lab to the center charge nurse. The charge reported it to the Medical NP who was not in the center, but on-call via phone at the time, who changed the dosage from 11mls three times a day to 10ml's three times day, diagnosis epilepsy. Upon further investigation, the medical NP who answered the call related to the critical lab stated she decreased the medication, but did not give follow-up lab orders. When asked why, she stated she would have left it to the provider onsite to determine the next lab date.</p> <p>On 6/15/23, the dosage was again decreased from Valproic Acid Oral Solution 250 MG/5ML, Give 10 ml three times a day to Valproic Acid Oral Solution 250 MG/5ML, Give 5 ml three times a day by the psychiatric NP, as part of a consult related to behaviors. The psychiatric NP failed to recognize the Valproic Acid was indicated for epilepsy, and failed to determine the current valproic acid level prior to decreasing the dosage given his history of epilepsy. An interview with the pharmacist revealed she would never have recommended an additional dosage change without a repeat level because Resident #10's levels tended to go up and down. However, this change was made without any level being checked.</p> <p>Upon investigation, the psychiatric NP stated she likely verbally ordered a Valproic Acid level on 6/15/23 for the next lab day, to monitor his levels, because that is her normal practice. This order was not entered into the electronic health record, but was entered in writing onto the lab requisition log.</p>	F 757			

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F 757	Continued From page 36 The facility lab called the center on 6/16/23 shortly after midnight to state an unrelated requisitioned lab for 6/15/23 needed to be repeated. The night shift nurse added the requisitioned lab for Valproic Acid (ordered on 6/15/23 for next lab day) to the carbon copy of the unrelated lab that was scheduled to be repeated on 6/16/23. The lab called the facility on 6/16/23, to let them know they would be unable to draw the lab, due to the behaviors of the resident and suggested that he needed Ativan prior to his labwork. This was discussed with the IDT, and it was determined that an alternative non-medicinal patient-center approach could be used to attempt the draw the lab the next lab day, on 6/17/23. The lab was successfully drawn on 6/17/23 and was sub-therapeutic at that time, but the facility did not receive the results until 6/22. The facility failed to follow procedures of critical importance, related to lab tracking, monitoring of serious medication for seizures at the time of dose changes, and timely follow up on lab results. The Valproic Acid was not monitored. The resident had a seizure, was hospitalized, and intubated in the interim on 6/19/23 and remains at the hospital at this time. The regional director of clinical services and/or DON will review all residents by 6/30/23 at the direction of the medical director/attending physician (the same individual) to assure the appropriate levels for anti-seizure medications are being monitored via lab including the mediations Valproic Acid (Depakote), Carbamazepine (Tegretol), Phenytoin (Dilantin), Levetiracetam (Keppra), to assure there are no medications not being monitored appropriately,	F 757			

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F 757	<p>Continued From page 37</p> <p>no delayed lab results, and no failures of the provider or center to monitor other residents on these anti-seizure medications.</p> <p>As of 6/28/23, the Chief Nursing Officer, the Medical Director/attending physician, the consulting pharmacy group, and the DON met to determine, agree upon and implement the following process for all current residents that receive Valproic Acid (Depakote), Carbamazepine (Tegretol), Phenytoin (Dilantin), Levetiracetam (Keppra) and other seizure medications will have labs to monitor these drug levels</p> <p>" All of those receiving these medications will be subject to the following:</p> <ul style="list-style-type: none"> o Lab monitoring once every three months for two months. o Lab monitoring once every six months thereafter. o Baseline lab will occur for new admissions, then at the notated schedule above <p>" The consultant pharmacist will be involved at admission and monthly thereafter to identify anti-seizure medications and to determine if they are being monitored appropriately via the recommended labs at the recommended intervals noted above. The Chief Nursing Officer communicated with the pharmacy consultant about this expectation on 6/28/23.</p> <p>After the meeting of the Chief Nursing Officer, Medical Director/attending physician, consulting pharmacy group, and DON, the nurse administrative team will be educated by the DON or regional director of clinical services on this process by 6/30/23, to ensure all expected labs have been ordered on admission and ongoing. This will be tracked via the lab tracking policy outlined below, and monitored for implementation</p>	F 757			

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F 757	<p>Continued From page 38</p> <p>ongoing via the process outlined below in the daily clinical meeting. The Chief Nursing Officer communicated with the pharmacy consultant about this expectation on 6/28/23.</p> <p>Specify the action the entity will take to alter the process or system failure to prevent a serious adverse outcome from occurring or recurring, and when the action will be completed.</p> <p>The Psychiatric NP will be educated by the Medical Director on his expectations for comprehensive medical record review, specifically review for indications of use and diagnosis for anti-seizure medications and/or for gradual dose reductions for psychotropic medications which can also be used for seizures (ie. Valproic Acid) before making recommendations for changes. Any concerns on the medical impact, related and unrelated to mood and behavior, should be discussed and coordinated with the provider (attending physician and/or medical NP) before changes are recommended. Additionally, any medication such as Valproic Acid, which can also be indicated for mood stabilization should be reviewed closer to determine actual indication for usage, and to monitor lab values prior to recommending a decrease in dosage. This will be done by 6/28/23.</p> <p>The Medical Director is the attending physician for all residents at the facility. Moving forward and related to this event, he will educate any current advanced care practitioners (current NPs medical and other consulting NPs), any future attending physicians, advanced care practitioners and internal consulting entities on comprehensive medical review and interdisciplinary provider</p>	F 757			

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F 757	<p>Continued From page 39</p> <p>discussion when consulting providers desire to make changes, and/or when the Medical NP is making changes to an anti-seizure medication. The expectation is that levels will be drawn and a comprehensive review done before dosages are being changed for all providers involved. The center DON knows who all current providers are; she will be made aware by the Administrator and/or Medical Director when new providers and consultant providers begin practicing at the facility. She has ensured all current providers have been educated by the Medical Director as of 6/29/23, and will ensure the new providers are communicated to the Medical Director for the need to education, tracked to completion, and maintain documentation of it onsite moving forward.</p> <p>Education began for nursing staff to include licensed nurses and nursing assistants on 6/27/23 by the Director of Nursing (DON) or designee. In the case of this deficient practice, the lab tracking process, from order/requisition to a timely final result was not in place and was in violation of our Laboratory Tracking Policy 1702.</p> <p>Education included the policy and protocols listed:</p> <p>-A licensed nurse will monitor and track all physician or physician extender ordered laboratory tests and will ensure that lab tests are drawn as ordered and communicate results to the physician in a timely manner.</p> <p>1. The Center will obtain lab services to meet the needs of its patients. Education occurred to nurses, specifically related to the need for blood levels drawn for residents on seizure medications, such as Dilantin, Valproic Acid and Kepra.</p>	F 757			

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

PRINTED: 09/01/2023
FORM APPROVED
OMB NO. 0938-0391

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F 757	Continued From page 40 2. Lab services will be provided only when ordered by the physician or physician extender and the physician or extender will be notified of lab results in a timely manner. 3. When an order for a lab test is received, for the current month, a licensed nurse receiving the order will complete a lab requisition form from the lab vendor. The information will include: a. patient name and room number. b. Test ordered. c. Date lab test is to be drawn. d. Medicare/Medicaid numbers. e. Other insurance information. f. Name of the physician ordering the test. g. Date of birth. h. Diagnosis related to the test ordered. i. Any special instructions. 4. A licensed nurse receiving the order will document the information on the appropriate current month's lab tracking log located in the lab notebook. Routine labs will be recorded on the lab tracking log. The DON, Unit Manager or Nursing Administration monitors the lab tracking log, to assure from order, to requisition, to result, to communication to the provider is timely. The expectation is that all routine/normal labs should be back in 24 hours. Labs results not back in 24 hours should be reviewed and monitored for timeliness in the case that they are not expected to take more than 24 hours. 5. If the routine lab test order is not due in the current month, the licensed nurse will document the appropriate information onto the Lab Tracking Log indicating the type of lab test ordered and date to be completed. The 11-7 shift licensed nurse or supervisor will check the Lab	F 757			

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F 757	Continued From page 41 Tracking Form and the Culture & Sensitivity Lab Tracking Form nightly for lab work to be drawn in the morning. The appropriate requisition will be pulled from the lab book (or completed if necessary) and placed in the Center designated location for the lab technician. 6. Upon completion of the lab draw, a licensed nurse will document the date the specimen was drawn on the appropriate Lab Tracking Log. If the lab is unable to be drawn, the information will be communicated to the attending physician, NP or PA for new orders, approval to move the lab or any follow-up as needed depending on the need of the resident. 7. Upon receipt of lab results, a licensed nurse will document the date the results were received on the appropriate Lab Tracking form. All routine lab results, such as Valproic acid, Dilantin and Keppra level should be back in 24 hours. All lab values that are not back in 24 hours where the expectation was 24 hours, should be investigated for timeliness, follow-up to the lab and report to physician for any further actions or orders needed. 8. Critical results will be called to the physician or extender and documented as indicated. The lab reports critical findings via phone to the charge nurse, and the charge nurse will report this verbally in person or via phone to the provider as soon as possible for follow-up, but not later than 9. Once the physician or extender has been notified of lab results, the nurse will document the date of notification and the method of notification in the appropriate space(s) on the appropriate Lab Tracking Log and place his/her initials in the nurse initial column on the form. 10. A licensed nurse will document any necessary information for follow up on the 24-hour shift	F 757			

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F 757	<p>Continued From page 42 report</p> <p>Any nursing staff member that did not receive education on 6/27/23 will receive education by the beginning of the next shift by the DON or designee. The Staff Development Coordinator will be responsible for tracking staff that still require education. Any staff that has not received education will not be allowed to work until education is received. All new hire licensed staff will be educated by the Staff Development Coordinator or designee on this policy. This education will be added to the orientation process. Staff Development was notified of this responsibility on 6/27/23.</p> <p>All lab orders will be tracked by the DON or designee to ensure that they are requisitioned, tracked for timely results, reviewed by the attending physician, NP or PA daily and follow-up as indicated. Each day (M-F) the lab tracking log along with the previous day's new lab orders will be brought to the clinical meeting by nursing administration from each unit to review for this process by the DON, and on Saturday/Sunday, the weekend supervisor will complete the same process for each unit.</p> <p>Date of immediate jeopardy removal is 7/3/23. Person responsible for implementation the plan is the Administrator</p> <p>The facility's credible allegation of Immediate Jeopardy removal was validated on 7/5/23 and 7/6/23.</p> <p>The validation was evidenced by record reviews and interviews to verify all residents receiving</p>	F 757			

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F 757	Continued From page 43 anti-seizure medications (including valproic acid, carbamazepine, phenytoin, and levetiracetam) had lab work completed to ensure their blood levels of the medications were monitored appropriately. An interview with the facility's consultant pharmacist confirmed she would recommend newly admitted residents receiving such medications would have a baseline drug level obtained and the level monitored appropriately thereafter. Multiple interviews were conducted with licensed nurses to ensure the necessary in-service education was provided prior to working their shift. The nurses consistently reported they received in-service education, which included the facility's procedures for tracking, monitoring, providing follow up, and communicating the results for all lab orders utilizing a lab tracking log (located in a lab notebook at the Nursing Station). An interview conducted with the Psychiatric NP confirmed she was counseled on the need to complete a comprehensive medical review prior to recommending a change in medication. Interviews with the facility's medical team (Medical NPs and MD) indicated they would be responsible for reviewing and verifying all orders recommended by a consulting provider prior to the implementation of these orders. The facility's Immediate Jeopardy removal date of 7/3/23 was validated.	F 757			
F 760 SS=E	Residents are Free of Significant Med Errors CFR(s): 483.45(f)(2)	F 760		7/31/23	

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F 760	<p>Continued From page 44</p> <p>The facility must ensure that its- §483.45(f)(2) Residents are free of any significant medication errors.</p> <p>This REQUIREMENT is not met as evidenced by:</p> <p>Based on interviews with the facility staff, Regional Director of Clinical Services, Nurse Practitioner (NP) and Medical Doctor (MD), and record reviews, the facility failed to correctly identify the diagnosis (indication) for the use of an antiseizure medication. This medication was inadvertently discontinued when the order was corrected to indicate it was used to treat seizures, resulting in a failure to administer 6 consecutive doses of the antiseizure medication for 1 of 3 residents (Resident #11) reviewed with a history of seizures.</p> <p>The findings included:</p> <p>Resident #11 was admitted to the facility on 6/17/16 with a cumulative diagnosis which included epilepsy and bipolar disorder.</p> <p>A review of the resident's electronic medical record (EMR) indicated a 2/17/23 physician's order was written for 500 milligrams (mg) Depakote Delayed Release (DR) to be given by mouth twice daily. The order incorrectly indicated this medication was being used to treat Resident #11's bipolar disorder. Depakote is a derivative of valproic acid and is used for multiple indications, including the treatment of seizures and bipolar disorder.</p> <p>Resident #11's most recent Minimum Data Set (MDS) was an annual assessment dated 6/29/23. The MDS indicated the resident had intact cognition.</p>	F 760	<p>F760-Residents are Free of Significant Med Errors</p> <ol style="list-style-type: none"> On 7/5/23 resident #11 had a serum valproic acid level drawn and results reported on 7/5/23. The medical provider was notified, and no new orders given. All residents that reside in the facility have the potential to be affected by this practice. On 7/21/21 all orders written for anti-seizure medications since 7/1/2023 were reviewed for appropriateness and implementation in the electronic health record. On 7/5/23 the Chief Nursing Officer re-educated the Regional Director of Clinical Services on the following. <ul style="list-style-type: none"> PCC order entry- Running/Reviewing Order Re-cap report to review all discontinued and current orders. Appropriate review of Order re-cap during daily clinical meeting and following up on questionable order changes. The DON or designee will review all discontinued/edited orders for anti-seizure medications daily during the daily clinical meeting to determine reason for discontinuation or updating to assure that the action is appropriate. Any identified issues will be corrected and immediately communicated to the medical provider. Monitoring will include weekly monitoring of all antiseizure medications 		

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F 760	Continued From page 45 The resident's EMR revealed his blood level of valproic acid was drawn and reported on 6/30/23 to be 53 microgram per milliliter (ug/ml). The laboratory report indicated the therapeutic range for valproic acid used to treat seizures was 50 - 100 ug/ml. Resident #11's June 2023 and July 2023 Medication Administration Records (MARs) revealed he received Depakote DR twice daily as ordered up to 6/30/23. However, the June MAR indicated while the resident received his morning dose of Depakote DR, he was not administered an evening dose of Depakote DR. Resident #11's July 2023 MAR documented the resident failed to receive both his morning and evening doses of Depakote DR on 7/1/23 and 7/2/23. The MAR also showed Resident #11 failed to receive his morning dose of Depakote DR on 7/3/23. The resident missed a total of 6 consecutive doses of 500 mg Depakote DR before the medication was re-initiated on 7/3/23. On 7/3/23 at 1:49 PM, a physician's order was received to administer 500 mg Depakote DR to the resident by mouth twice daily for seizures. A Medication (Med) Error Report dated 7/3/23 documented a med error occurred on 7/1/23 and 7/2/23 with Resident #11's Depakote DR. Notes on the Medication Error Report indicated the error occurred when the diagnosis (indication) was changed by the Regional Director of Clinical Services on 6/30/23 and the medication was inadvertently omitted. The corrective measures taken included re-entering the medication into Resident #11's EMR and ordering a repeat valproic acid blood level be drawn on 7/6/23. The	F 760	to assure that they are still action and appropriate, monitoring will occur weekly x4, bi-weekly x2 and monthly thereafter or until substantial compliance is obtained. Findings will be reported to the monthly QAPI committee. The Administrator is responsible for this plan of correction. 5. Date of completion: July 31, 2023		

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F 760	<p>Continued From page 46</p> <p>report indicated the med error did not adversely affect the resident.</p> <p>An interview was conducted on 7/5/23 at 4:47 PM with the Regional Director of Clinical Services. During the interview, the Director reported on 6/30/23 she was working on an audit to verify the diagnosis (or indication) in Resident #11's EMR for Depakote DR. She recalled making a change in the order's diagnosis for the Depakote DR and intended to update the order. However, the Director reported she must have unintentionally discontinued the medication instead of updating the order.</p> <p>On 7/5/23 at 2:17 PM, an interview was conducted with Nurse Practitioner (NP) #2. During the interview, the NP reported she saw Resident #11 on 6/30/23 and recalled he was receiving 500 mg Depakote DR at that time. When she returned to the facility on 7/3/23, he was no longer on the Depakote DR. She reported the concern to the facility's DON and re-ordered the medication. Upon further inquiry, NP #2 acknowledged the resident did have a history of seizures and was not on any additional antiseizure medications. She reported Resident #11 could not recall when he last had a seizure. The NP stated she delayed having a repeat valproic acid level drawn until 7/6/23 because the resident did not like to have lab work done.</p> <p>An interview was conducted on 7/5/23 at 2:21 PM with the facility's Director of Nursing (DON). During the interview, the DON reported an order was received to have a valproic acid level done on this date (7/5/23) instead of 7/6/23 if Resident #11 would allow it.</p>	F 760			

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F 760	<p>Continued From page 47</p> <p>A blood sample was collected from Resident #11 on 7/5/23 at 4:45 PM with the results reported on 7/5/23 at 7:21 PM. The lab results indicated his valproic acid blood level was 54 ug/ml (within the therapeutic range).</p> <p>An interview was conducted on 7/6/23 at 2:10 PM with Resident #11. During the interview, the resident acknowledged he had a history of seizures but stated he could not remember when he last experienced one. Upon further inquiry, the resident stated his last seizure was "years ago."</p> <p>An interview was conducted on 7/5/23 at 2:30 PM with the facility's Medical Director. The Medical Director reported to his knowledge, Resident #11 had not experienced any recent seizures. He stated, "Sure, it's not good when meds are not given." However, he reported he would not start another antiseizure medication at this time or a higher dose of Depakote DR to make up for the missed doses. Instead, he felt it would be appropriate to wait a week or so to see what the resident's valproic acid level was and to make any decisions about his medication at that time.</p>	F 760			