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NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
STONEVALLEY NURSING HOME	**123 MAIN STREET** **ANYWHERE, US 00000**

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F 760 SS=G	Residents are Free of Significant Med Errors CFR(s): 483.45(f)(2) The facility must ensure that its- §483.45(f)(2) Residents are free of any significant medication errors. This REQUIREMENT is not met as evidenced by: Based on staff interview, facility document review, clinical record review and complaint investigation, the facility staff failed to ensure one of three residents in the survey sample was free from a significant medication error (Resident #1). Resident #1's daily dosage of the anti-seizure medication Dilantin (Phenytoin) was increased when his Dilantin levels were already high in response to a miscommunicated lab test result. The increased dosage caused the resident's Dilantin level to exceed therapeutic levels resulting in hospitalization for treatment of Dilantin toxicity and multiple falls with injury associated with the toxic Dilantin levels (harm). The resident experienced a laceration to his left eyebrow region, ligament injury to the left pinky finger, a laceration to the right middle finger, several bruises/abrasions to his knees and swelling of his face due to repeated falls associated with toxic effects from the high Dilantin levels. The findings include: Resident #1 was admitted to the facility on 11/22/11 and was discharged to the hospital on 11/28/17. Diagnoses for Resident #1 included seizure disorder, intellectual disability, heart	F 760	Resident #1 is no longer a resident of this facility. An audit was completed by the Administrative Nurses (DON, ADON, SDC, QI nurse and/or MDS Nurse) of all resident orders received within the last 30 days for accuracy (orders vs. MAR) and to ensure ordered labs were obtained as ordered. Results of the audit were communicated to the physician. Physician was notified of any errors and orders were carried out as received. All Licensed Nurses (RN□s and LPN□s) were re-educated by Administrative Nurses (DON, ADON, SDC, QI nurse and/or MDS Nurse) on process of transcription of orders and medication error process using Receipt of Physician's orders and Notification of Physician for change in resident's condition and medication error policies. Administrative Nurses (DON, ADON, SDC, QI Nurse and/or MDS Nurse) will review during morning clinical meeting all new orders (medication and labs) and will initial the order slip, to ensure they are	2/4/18

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F 760	Continued From page 1 failure, functional quadriplegia, cognitive communication deficit, dementia, diabetes and psychosis. The minimum data set (MDS) dated 10/12/17 assessed Resident #1 with moderately impaired cognitive skills. This MDS assessed Resident #1 as always continent of bowel/bladder and to require supervision with set up help only for transfers, dressing and toileting. Resident #1's clinical record documented a physician's order dated 3/3/17 for Dilantin chew 100 mg (milligrams) to be given twice per day and an order dated 3/3/17 for Dilantin chew 50 mg to be given at 2:00 p.m. each day for treatment/prevention of seizures. The record documented a physician's order dated 11/15/17 for a Dilantin level to be obtained on 11/16/17. A lab report dated 11/18/17 documented the resident's Dilantin (free) level on 11/16/17 was high at 2.5 mg/L (milligrams per liter) as compared to the reference range of 1.0 to 2.0 mg/L. A nurse documented notification to the physician of the lab results. A telephone order was documented on 11/18/17 increasing Resident #1's Dilantin dosage to 200 mg twice per day and 100 mg at be given at 2:00 p.m. each day in response to the lab test. This order also included instructions to repeat the resident's Dilantin level on 11/24/17. A nursing note dated 11/18/17 documented, "[Physician] informed of resident Dilantin level 2.5, order given to give Dilantin 200 mg by mouth every morning and every evening and to give 100 mg by mouth at 2 pm daily. Dilantin level to be checked next week, placed in lab book to check 11/24/17."	F 760	transcribed, carried out accurately, labs obtained as ordered and results accurately reported to the physician. To maintain continued compliance the DON will share the results of the audits with the Quality Assurance Performance Improvement (QAPI) Committee on a quarterly basis. If additional issues are noted those issues will be addressed immediately and corrective action taken.	

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F 760	Continued From page 2 The order for the increased Dilantin doses was inaccurately entered on the resident's November 2017 medication administration record (MAR). The order for Dilantin 200 mg twice per day was not added to the MAR until 11/26/17. Resident #1 continued to be administered Dilantin 100 mg twice per day from 11/18/17 through 11/25/17. The resident's 2:00 p.m. dose of Dilantin was increased from 50 mg to 100 mg starting on 11/18/17 as ordered. The twice per day 100 mg doses of Dilantin were stopped on 11/25/17 and starting on 11/26/17 the resident was administered Dilantin 200 mg twice per day. The resident's total daily dose of Dilantin progressed as follows: prior to 11/18/17 received 250 mg per day; 11/18/17 through 11/25/17 was given 300 mg per day; 11/26/17 until discharge on 11/28/17 was given 500 mg per day. The clinical record documented no repeat Dilantin level on 11/24/17 as ordered by the physician. The clinical record documented increased falls for Resident #1 in November 2017 as the Dilantin doses increased. The resident had only one prior fall (on 9/9/17) from January through October of 2017. The resident experienced six falls in November 2017 prior to being sent to the emergency room on 11/28/17 following the third fall that day resulting in a laceration above his left eye. Nursing notes documented the following falls with injuries for Resident #1 during November 2017. 11/7/17 at 6:21 p.m. - "Heard a loud noise, went to check to see, found resident in floor, on knees with bedside table overturned with resident over it...Resident has minor scratch on bridge of nose with minor bleeding from left nostril...Applied	F 760		

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Band-Aid to bridge of nose..."

11/23/17 at 7:11 p.m. - "this nurse called to room by cna [certified nurses' aide] feeding residents roommate found him [Resident #1] lying on floor beside his bed with his legs over the trash can assessed no injury...assisted back to bed socks removed and skid socks applied."

11/26/17 at 1:15 p.m. - "heard noise in room....upon entering the room, observed resident lying on the right side at the foot of the bed, in front of w/c [wheelchair]. when asked resident denied falling. laceration noted to right middle finger, cleaned and dressed. no other injuries noted at this time...bruise noted to left hand. able to move wrist and all digits. some edema noted to left hand..."

11/28/17 at 1:42 p.m. - "Was called to residents room and was advised that resident was in floor in the bathroom...resident was sitting in floor in the bathroom with wheelchair sitting at bathroom door. Resident stated that he was attempting to go to the bathroom and got too fast...Resident stated that he was not hurt...No complaint of pain or discomfort..." (sic)

11/28/17 at 4:18 p.m. - "Heard loud noise...resident was sitting in the floor on roommates side of the room. Resident stated that the chair turned around on him and he fell into the floor..." (sic)

11/28/17 at 9:15 p.m. - "Resident found on the floor by CNA, call writer to room. Resident observed on the floor with call bell in hand bleeding from what appears to be left eye. Blood also noted to the back of head. facial swelling

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noted...resident responsive at time of fall and still responsive when sent to er [emergency room]...Sent to Er for eval [evaluation] per MD [physician] order. Resident's third fall of the day..."

Resident #1 was seen by the physician on 11/27/17 for evaluation of the laceration to the right middle finger that occurred on 11/26/17 and the physician's note made no mention of the resident's Dilantin dosage. This progress note dated 11/27/17 documented, "I was called over the weekend that [Resident #1] had some falls... He had several additional falls and it was the nurse's opinion that he was putting himself on the floor, not actually falling...Medication administration record is reviewed in chart...Speech is quite garbled. He is generally up in a wheelchair, but has had more falls recently..." The physician's note made no mention of the resident's Dilantin levels, inaccurate Dilantin entry on the MAR or the missed Dilantin level lab due on 11/24/17.

The facility's investigation of the Dilantin error was not conducted until after the resident's discharge. The investigation included documentation dated 11/29/17 stating, "On 11/18/17 orders transcribed to MAR incomplete + lab work illegible on labbook no requisition filled out resulted in residents increased impairment + freq [frequent] falls resulted in resident being admitted to hospital." (sic)

A physician's progress note for Resident #1 dated 11/30/17 documented, "I received a call from [director of nursing], informing me that several weeks ago I was called about a lab result. I was told the patient's Dilantin Level was very low and I

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asked if the patient was actually receiving and taking his prescribed dose of 100 mg bid [twice per day]. She said he was taking it regularly. I ordered a significant increase in dose and a follow-up Dilantin level, but the order was not taken off and the lab was not done until the patient went to the hospital ER [emergency room]..."

Resident #1's emergency room report dated 11/28/17 documented the resident was diagnosed upon arrival with Dilantin toxicity due to an abnormally high Dilantin level. The ER report lab report dated 11/28/17 documented Resident #1's Dilantin level as a "critical value" measuring 40.6 ug/mL (micrograms per milliliter) with a reference range of 10.0 to 20.0 ug/mL. The resident was diagnosed with multiple bruises and abrasions in addition to a laceration above his left eye and a laceration to the right middle finger. The ER history and physical report dated 11/28/17 documented, "Pt [patient] arrives to the ED [emergency department] with multiple injuries. Pt has bandaged laceration to the right middle finger. Bruising to the left hand. abrasion under the chin and both knees. Abrasion to the back of the left ear as well as left eye. EMS [emergency medical services] states that nurse states the pts speech is normally slurred however it has worsened tonight...Lab called to report abnormal Dilanton [Dilantin] of 40.6..." The report documented the laceration above the resident's left eye as superficial and measured 1.5 centimeters in length. The note documented the resident had "... a deep abrasion on the right middle finger that appears to be old... also has contusion/hematoma of the entire left hand...is able to make a fist with the right hand and the middle finger flexes against resistance, but there

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is a deep laceration at the PIP [proximal interphalangeal] joint which extends into the joint capsule and the finger can be hyperextended at the PIP joint. The wound will be cleaned, finger splinted and antibiotics given..."

The resident was admitted to the hospital with treatment that included intravenous fluids, antibiotics, withholding all seizure medications along with daily monitoring of Dilantin levels. The laceration above the resident's left eye was cleansed and closed with skin glue. An orthopedic consultation report dated 11/30/17 documented, "evidently was admitted with superficial injuries after reported multiple falls... With these falls, apparently, had some other injuries contusion to his face with a 2 cm laceration to the left lateral eyebrow area that was managed in the emergency room. He also apparently had both knees with abrasions, but function intact...attention to the right hand x-rays demonstrated no acute fracture of the middle finger...The wound was not repaired. It was a traverse laceration approximately of 2 cm across the volar [palm] aspect of the proximal interphalangeal joint... Since the wound is at least a good 48 hours post injury, this will heal secondarily requiring no sutures..."

A physician consultation report dated 12/3/17 documented, "...He [Resident #1] was admitted with falls and several orthopedic injuries. This appears to have been secondary to Dilantin toxicity..." The resident remained hospitalized from 11/28/17 until 12/8/17. The hospital discharge summary dated 12/8/17 listed the resident's primary diagnosis as acute Dilantin toxicity. This summary report documented, "...He [Resident #1] presented to the hospital with

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F 760	Continued From page 7 reported multiple falls at the local nursing home resulting in multiple abrasions and bruises as well as a 1.5 cm simple laceration to the left lateral eye brow region...His Dilantin level was checked and it was found to be significantly elevated at 32 [on 11/29/17] (reference range is 10 - 20)... He was admitted with Dilantin toxicity. His gait instability was likely related to this. Dilantin was discontinued and levels were checked until it trended back close to normal..." Further review of Resident #1's clinical record reveal no physician's order for a "free" Dilantin level. Resident #1's plan of care (revised 7/26/17) documented prior to November the resident required minimal assistance with activities of daily living. This care plan stated the resident had potential for injury due to history of seizures. Interventions for seizure prevention included, "Administer medications as ordered by the physician...Monitor for adverse side effects of medication, i.e., headache, drowsiness, insomnia, anxiety depression, psychosis, blurred vision, diplopia [double vision], dizziness, numbness, ataxia [poor muscle coordination], tremor, nausea, vomiting, diarrhea, gingival hyperplasia, and rash and notify physician for evaluation and intervention...Obtain and monitor serum anticonvulsant medication levels as ordered and notify physician of results..." The nurse that communicated the resident's Dilantin lab test to the physician on 11/18/17 and inaccurately entered the Dilantin order on the MAR was not available for interview as she no longer worked at the facility.	F 760		

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On 1/3/18 at 2:00 p.m. the licensed practical nurse (LPN #1) that worked on Resident #1's living unit was interviewed. LPN #1 stated Resident #1 routinely propelled himself around the facility and was "alert and active." LPN #1 stated prior to November 2017 the resident had no history of frequent falls and the resident was able to make his needs known.

On 1/3/18 at 2:15 p.m. the resident's physician was interviewed about the diagnosed Dilantin toxicity and associated injuries related to increased falls. The physician stated he was called by the nurse working on 11/18/17 and advised that the resident's Dilantin level was 2.5. The physician stated he had ordered a regular Dilantin level and not a "free" Dilantin level. The physician stated the normal range for regular Dilantin was 10 to 20 so he understood the resident's Dilantin level was low. The physician stated he asked the nurse if the resident had been taking his current dose of Dilantin as ordered and the nurse advised that the resident was routinely taking medications as ordered. The physician stated the nurse never told him that the lab result of 2.5 was a "free" Dilantin level so he thought the result was a regular Dilantin level. The physician stated the normal ranges were very different for a "free" Dilantin (1.0 to 2.0) as compared to a regular Dilantin level (10.0 to 20.0). The physician stated he understood the Dilantin level of 2.5 to be very low so he ordered an increase in the Dilantin. The physicians stated, "I doubled what he [Resident #1] was on which was already high." The physician stated there was a miscommunication about the lab result that resulted in the toxicity. When asked if the resident's increased falls in November 2017 were related to the Dilantin toxicity, the physician

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stated, "That's certainly possible." The physician stated Dilantin toxicity could cause loss of balance and visual changes. The physician stated Resident #1 may have not been able to report or verbalize any visual changes associated with the excess Dilantin levels. The physician also stated he had ordered a follow up Dilantin level (due on 11/24/17) and that lab was never done. The physicians stated he was not aware of the Dilantin toxicity until the emergency room findings on 11/28/17 were reported to the facility on 11/30/17.

On 1/3/18 at 2:40 p.m. the administrator and director of nursing (DON) were interviewed about the Dilantin error with Resident #1. The administrator stated she was made aware of the Dilantin toxicity when adult protective services came to the facility on 11/30/17 and advised them of the emergency room findings of 11/28/17. The administrator stated the resident did not have a history of frequent falls and the pattern of falls in November 2017 was not typical for Resident #1. The administrator stated when the physician gave the order for the Dilantin level it was entered into the lab system as a "free" Dilantin level instead of a total Dilantin. The administrator stated this nurse also transcribed the Dilantin order of 11/18/17 wrong onto the resident's medication administration record. The administrator stated there was miscommunication of the lab result on 11/18/17 with the physician thinking the 2.5 level reported was a total Dilantin level instead of a "free" Dilantin level. The DON stated on 11/26/17 a nurse performing a monthly review of the MAR and physician orders found the Dilantin error listed inaccurately on Resident #1's MAR. The DON stated when this discrepancy was found on 11/26/17 the MAR was corrected and the resident

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started getting a total of 500 mg of Dilantin per day as originally ordered by the physician on 11/18/17. When asked if the physician was notified when this error was found on 11/26/17 so that Dilantin levels could have been re-checked, the DON had no response. Concerning the repeat Dilantin level ordered and scheduled to be done on 11/24/17, the DON stated this lab test was not done. The DON stated it was listed on the lab sheet but the lab employees stated the entry was "illegible" so they did not draw blood or complete the test.

On 1/4/18 at 10:45 a.m. the DON displayed the options in their lab entry system for Dilantin levels. The DON stated there were three options in the computer system for Dilantin. The options included a Dilantin level, Dilantin Free + total and Dilantin Free. The DON stated if a regular Dilantin level was ordered the nurses should have selected option 1 "Dilantin level" and not "Dilantin Free." The DON stated, "There is a big difference in the results."

The facility's undated policy titled Medication Administration stated, "...The attending physician shall be notified immediately of all significant medication errors...No medication shall be administered unless the nurse is familiar with the pharmacology of the drug, its potential toxic effects and contraindications...Any deviation from the following principles shall be considered a medication error...To the right resident...Administration of the right medication...In the right dose...by the right route...By the right method...At the right time..."

The Nursing 2017 Drug Handbook on pages 1171 through 1173 described Dilantin (Phenytoin) as

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an anticonvulsant used to prevent and treat seizures. This reference lists adverse effects of Dilantin to include decreased coordination and muscle control, mental confusion, slurred speech, dizziness, headache, blurred vision, nausea, vomiting and insomnia. This reference lists nursing considerations for Dilantin administration to include, "Monitor drug level. Therapeutic level of total phenytoin is 10 to 20 mcg/mL [micrograms per milliliter]. The therapeutic range of free phenytoin is 1 to 2 mcg/mL...Alert: Doubling the dose doesn't double the level but may cause toxicity. Consult pharmacist for specific dosing recommendations..." (1)

These findings were reviewed with the administrator and DON on 1/4/18 at 10:30 a.m.

(1) Rader, Janet, Dorothy Terry and Leigh Ann Trujillo. Nursing 2017 Drug Handbook. Philadelphia: Wolters Kluwer, 2017.
Laboratory Services
CFR(s): 483.50(a)(1)(i)

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