

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 155802	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 09/21/2021
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NAME OF PROVIDER OR SUPPLIER PROVIDENCE HEALTH CARE CENTER	STREET ADDRESS, CITY, STATE, ZIP COD 1 SISTERS OF PROVIDENCE ST MARY OF THE WOODS, IN 47876
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F 0000 Bldg. 00	<p>This visit was for a Recertification and State Licensure Survey. This visit included a State Residential Licensure Survey.</p> <p>Survey dates: September 13, 14, 15, 16, 17, 20 and 21, 2021.</p> <p>Facility number: 003624 Provider number: 155802 AIM number: 200429840</p> <p>Census Bed Type: SNF/NF: 63 Residential: 32 Total: 95</p> <p>Census Payor Type: Medicare: 15 Medicaid: 37 Other: 11 Total: 63</p> <p>These deficiencies reflect State Findings cited in accordance with 410 IAC 16.2-3.1.</p> <p>Quality review completed on September 30, 2021.</p>	F 0000		
F 0692 SS=D Bldg. 00	<p>483.25(g)(1)-(3) Nutrition/Hydration Status Maintenance §483.25(g) Assisted nutrition and hydration. (Includes naso-gastric and gastrostomy tubes, both percutaneous endoscopic gastrostomy and percutaneous endoscopic jejunostomy, and enteral fluids). Based on a resident's comprehensive assessment, the facility must ensure that a resident-</p>			

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

TITLE

(X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined other safeguards provide sufficient protection to the patients. (see instructions.) Except for nursing homes, the findings stated above are disclosable 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 disclosed 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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	<p>§483.25(g)(1) Maintains acceptable parameters of nutritional status, such as usual body weight or desirable body weight range and electrolyte balance, unless the resident's clinical condition demonstrates that this is not possible or resident preferences indicate otherwise;</p> <p>§483.25(g)(2) Is offered sufficient fluid intake to maintain proper hydration and health;</p> <p>§483.25(g)(3) Is offered a therapeutic diet when there is a nutritional problem and the health care provider orders a therapeutic diet.</p> <p>Based on record review and interview, the facility failed to ensure a physician's order for weekly weights were obtained for a resident with a gastrostomy tube (a tube inserted through the stomach that provides nutrition) in order to be aware of a significant weight change for 1 of 3 residents reviewed for nutrition (Resident 34).</p> <p>Finding includes:</p> <p>Resident 34's record was reviewed on 9/15/21 at 2:34 p.m. Diagnoses included but were not limited to malignant neoplasm of glottis (throat cancer), acquired absence of larynx, acute respiratory failure with hypoxia, dependence on respirator (ventilator) status, an infection of the tracheostomy stoma, and protein-caloric malnutrition (PCM).</p> <p>A significant change in status Minimum Data Set (MDS) assessment, dated 8/9/21, indicated Resident 34 had a moderate cognitive impairment, was an extensive assistance of two staff for bed mobility and transfer, required total dependence</p>	F 0692	<p>It is the policy of Providence Health Care to ensure physicians' orders are followed regarding weight monitoring and to notify a physician with undesired or unanticipated weight gains/losses of 5% in 30 days, 7.5% in 90 days, or 10% in 180 days.</p> <p>I. <u>Corrective Action Taken Related to this Finding:</u> The facility corrected the deficiency practice for resident #34 by notifying the physician of the family's request to have the patient remain comfortable and order obtained by the physician to discontinue weekly weights.</p> <p>II. <u>Other residents with Potential to be Affected by this Finding will be Identified by:</u> Each resident chart was audited to ensure all physician orders for weight monitoring are accurate and that the physician has been notified of any undesired or</p>	10/12/2021	

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	<p>of one staff for nutrition, and received more than 51% of nutrition and hydration through a feeding tube.</p> <p>A physician's order, dated 9/3/21, indicated Resident 34 was to receive every day and night shift enteral feed of Jevity 1.5 (calorically dense, fiber-fortified therapeutic nutrition that provides complete, balanced nutrition for long- or short-term tube feeding) to run at 40 milliliters (ml) an hour with 40 ml water flush every hour.</p> <p>A physician's order, start date of 8/4/21, indicated notify physician if a gain or loss greater than 5 pounds weekly, every Wednesday.</p> <p>A care plan, initiated on 10/26/20, indicated the resident required tube feeding with the care plan goal, dated 11/8/21, indicated Resident 34 will maintain adequate nutritional and hydration status as evidenced by weight stable, with no signs or symptoms of malnutrition or dehydration through next review date with an intervention included, but not limited to, lab and diagnostic work as ordered, report results to the physician and Registered Dietitian (RD) to evaluate quarterly and prn (as needed) monitor caloric intake, estimate needs, make recommendations for changes to tube feeding as needed.</p> <p>An RD progress notes, dated 8/3/21 at 7:41 a.m., 8/10/21 at 9:01 a.m., dated 8/17/20 at 9:50 a.m., dated 8/24/21 at 9:10 a.m., and dated 8/31/21 at 8:33 a.m., indicated Resident 34 had diagnosis of PCM, as evidenced by a low body mass index (BMI) of less than (<) 22 according to Global Leadership Initiative on Malnutrition (GLIM) guidelines and the chronic inflammatory nature of resident's diagnoses.</p>		<p>unanticipated weight gains and losses. This audit was completed on 09/22/2021.</p> <p>III. <u>Measures and Systemic Changes put into place to assure deficient practices do not recur are as follows:</u></p> <p>All nursing staff were educated by the Director of Nursing on obtaining weights per physician order and educated on PHC Policy for weighing residents to monitor weight gain or loss at mandatory in-service on 10/11/2021. Each unit clinical support staff to monitor weights weekly for accuracy and communicating changes to the Physician and Director of Nursing.</p> <p>IV. <u>Corrective Actions will be Monitored to Ensure Compliance by:</u></p> <p>The Director of Nursing, or her designee, will be conducting weight audits (see attached) to ensure weights are being obtained and documented in resident charts in accordance with the physician order 5x per week times 4 weeks, then 3 x per week x 4 weeks, then 2 x per week x 4 weeks, then 1 x per week x 3 months. The outcome of the audit tool will be reviewed at the Quality Assurance meetings to determine if any additional action is warranted. Providence Health Care will review, update, and make changes to this plan of correction as needed for sustaining compliance for no less</p>	

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	<p>An RD progress note, dated 8/31/21 at 9:53 a.m., indicated Resident 34 was sent to the emergency room on 8/24/21, weight about 129.9 pounds (lbs.), returned to facility on 8/30/21.</p> <p>An RD progress note, dated 9/7/21 at 7:50 a.m. and 9/14/21 at 8:18 a.m., indicated Resident 34 had diagnosis of PCM, as evidenced by a low body mass index (BMI) of less than (<) 22 according to Global Leadership Initiative on Malnutrition (GLIM) guidelines and the chronic inflammatory nature of resident's diagnoses.</p> <p>The medical record lacked documentation the resident had been weighed since 8/2/21 at 129.9 lbs.</p> <p>On 9/16/21 at 10:15 a.m., the Director of Nursing (DON) provided a document, titled "POC Response History," of weight history for 30 days and indicated the resident had refused to be weighed on 8/19/21 and 9/2/21. She was unsure why staff had checked not applicable for weights on 8/18/21 and 9/9/21. The physician order was for Resident 34 to be weighed weekly.</p> <p>On 9/16/21 at 2:35 p.m., DON indicated the resident was palliative care due to throat cancer and the staff had stopped weighing the resident. The physician's order to weigh the resident weekly should have been discontinued and the resident's plan of care should have been revised.</p> <p>The DON, on 9/16/21 at 2:44 p.m., provided and identified an undated document as a current facility policy, titled "Weighing Residents," which indicated, "...Purpose: To monitor weight gain or loss...Each resident is weighed on admission and monthly thereafter, or in accordance with physician orders or plan of care..."</p>		than six months.	

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F 0698 SS=G Bldg. 00	<p>3.1-46(a)(1)</p> <p>483.25(l) Dialysis §483.25(l) Dialysis.</p> <p>The facility must ensure that residents who require dialysis receive such services, consistent with professional standards of practice, the comprehensive person-centered care plan, and the residents' goals and preferences.</p> <p>Based on observation, record review, and interview, the facility failed to ensure communication was received post dialysis (filters blood to rid the body of harmful wastes) from the dialysis center, post dialysis assessments were completed, care plans were revised, and assessments of an prostatic arteriovenous graft (used for dialysis treatment) site and an implanted permacath (a flexible tube inserted into a vein most commonly in the neck used for dialysis treatment) were completed which resulted in harm when the resident developed an infection to the graft site that led to the site opening and the resident losing one to two liters of blood, being hospitalized, and requiring a new graft placement for 1 of 1 residents reviewed for dialysis (Resident 6).</p> <p>Findings include:</p> <p>During an observation, on 9/14/21 at 10:24, Resident 6 was observed to have sutures to the left forearm. At this time, the resident indicated she had recently had a revision to her dialysis graft site. The prior graft had been removed due an abscess that had "burst" and caused an active bleed.</p>	F 0698	<p>It is the policy of Providence Health Care to outline care for dialysis residents in order to prevent infections, complications, and to provide ongoing monitoring and interventions.</p> <p><u>I. Corrective Action Taken Related to this Finding:</u></p> <p>1. The facility corrected the deficiency practice for resident #6 by contacting the dialysis service provider on 9/22/2021 and educated on the expectation of the service provider supplying information and communication to Providence Health Care regarding treatments and event occurrences while resident #6 is under their care during hemodialysis.</p> <p>2. Physician order received for RI#6 to monitor site every shift and documentation of monitoring added to Medication Administration Record. RI#6 care plan updated to include post-dialysis communication, post-dialysis assessments, and care of the site.</p> <p>3. Perm-a-Cath sites will be</p>	10/12/2021	

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	<p>The resident's medical record was reviewed, on 9/15/21 at 1:26 p.m. A hospital notes, dated 7/6/20, indicated the resident had underwent creation of a non-autogenous left brachial antecubital veins prostatic arteriovenous (av) graft for hemodialysis.</p> <p>A Medication Administration Record (MAR), dated July 2021, indicated the resident went to the dialysis center every Monday, Wednesday, and Friday at 10:45 a.m.</p> <p>The resident's medical record lacked documentation of communication post dialysis from the dialysis center.</p> <p>A MAR, dated July 2021, lacked documentation the left forearm prostatic av graft had been assessed every shift for bleeding, increased pain, or signs of infection.</p> <p>A review of progress notes, dated July 2021, lacked documentation the left forearm prostatic av graft had been assessed every shift for bleeding, increased pain, or signs of infection.</p> <p>A skin wound progress note, dated 7/14/21 at 9:14 a.m., indicated the resident had an infection to the left forearm av graft site.</p> <p>A review of skin wound progress notes, physician orders, and nursing progress notes, dated 7/15/21 through 7/20/21, lacked documentation the resident received antibiotics and any monitoring for side effects.</p> <p>A dialysis nursing home information document, dated 7/21/21, and uploaded to resident's documents in the electronic medical record on 9/16/21, indicated the resident received two</p>		<p>assessed each shift for signs of bleeding, infection, and to ensure dressing/caps are intact. The care plan will be revised upon any change in resident status related to dialysis.</p> <p>II. <u>Other residents with Potential to be Affected by this Finding will be Identified by:</u> The facility realizes all hemodialysis residents have the potential to be affected. This has been addressed by the systems described below.</p> <p>III. <u>Measures and Systemic Changes put into place to assure deficient practices do not recur are as follows:</u></p> <ol style="list-style-type: none"> 1. Chart audits were conducted on 9/22/2021 for all residents currently receiving hemodialysis and physician orders obtained for monitoring dialysis residents in compliance with our updated policy. 2. All licensed nursing staff educated on the current dialysis policy and documentation guidelines at mandatory in-service on 10/11/2021. 3. Dialysis resident charts have been updated to include the correct access type including the site of access to be monitored. 4. Admission order set made to capture all policy orders upon admission for all dialysis residents (see attached). <p>IV. <u>Corrective Actions will be Monitored to Ensure Compliance</u></p>		

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	<p>antibiotics during dialysis treatment, vancomycin 750 milligrams (mg) and gentamycin 100 mg.</p> <p>A skin wound progress note, dated 7/21/21 at 8:47 a.m., indicated the resident was observed by the wound physician and the resident's left forearm prostatic av graft measured at 9.3 centimeters (cm) by 9 cm, dialysis was aware and following. The resident received antibiotic therapy at dialysis. The Certified Nursing Assistants (CNA) would observe skin with routine care notify the charge nurse of concerns. Nursing to complete any treatments and dressings and weekly skin assessments and notify the wound nurse with concerns.</p> <p>A physician wound note, dated 7/21/21, indicated the resident's left forearm prostatic av graft measured 15.4 cm by 4.86 cm by 4.55 cm and had new swelling. The site was being managed by physicians at the dialysis center. The management of care for this critical dialysis site would be deferred to the resident's nephrologists and surgeons and interventionalists who are monitoring the site.</p> <p>A review of the resident's medical record lacked documentation the resident received gentamycin (antibiotic) and vancomycin (antibiotic) at dialysis only a progress note that indicated the resident had received antibiotic therapy at dialysis. The record lacked documentation to support vancomycin troughs had been monitored or an order for them to be monitored and lacked documentation the resident's antibiotic use was being monitored for side effects.</p> <p>A care plan, initiated, 3/4/20, indicated the resident received dialysis related to renal failure. Interventions included but were not limited to</p>		<p><u>by:</u> The Director of Nursing, or her designee, will be conducting chart audits (see attached) for completion of dialysis communication forms and documentation of access site assessment on Medication Record each shift. These audits will be conducted 5x per week times 4 weeks, then 3 x per week x 4 weeks, then 2 x per week x 4 weeks, then 1 x per week x 3 months. The outcome of the audit tool will be reviewed at the Quality Assurance meetings to determine if any additional action is warranted. Providence Health Care will review, update, and make changes to this plan of correction as needed for sustaining compliance for no less than six months</p>	

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	<p>apply ice to left arm for 20 minutes twice daily and initiated on 4/7/21; check and change dressing daily at access site; observe for and report to the physician any signs or symptoms of infection such as redness, swelling, warmth, or drainage to the access site; and observe for and report to the physician any signs or symptoms of bleeding, hemorrhage, bacteremia (infection), or septic shock. The care plan lacked documentation the resident had received antibiotic therapy for an abscess to the left forearm graft site.</p> <p>A health status progress note, dated 7/23/21 at 10:54 a.m., indicated the writer was called to the resident's room at approximately 7:15 a.m., The resident was observed sitting on side of the bed with staff member holding pressure to the resident's left arm. An abscess to the resident's left arm had broken open and was "squirting out" blood. Staff continued to hold pressure to site and monitor level of alertness while 911 was called and family was notified. Resident was transferred via stretcher by emergency medical services to the emergency room. At the time of transfer the resident was observed to be lethargic and skin color was pale.</p> <p>A hospital notes, dated 7/23/21, indicated the resident presented to the emergency room from a long-term care facility (LTC) with complaints of spontaneous bleeding from the left forearm av graft site. Per Emergency Medical Services (EMS) report she had lost approximately one to two liters of blood prior to their arrival to the long-term care facility with low blood pressures in the 70's. She was symptomatic with syncope when sat upright by LTC facility staff. The EMS staff controlled the bleeding and no further episodes of syncope. An abscess was reported to the av graft site prior to the bleeding and the resident was on unknown</p>			

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	<p>oral antibiotic for seven days. Last known dialysis treatment was Monday 7/19/21.</p> <p>A hospital physician diagnosis and assessment plan, dated 7/23/21, indicated the patient was examined at bedside in the emergency room, the resident was alert/oriented and was in no acute distress. The av graft site was noted with evidence of an abscess/ulceration and would need repaired. A chronic dialysis catheter would be placed today. Laboratory blood tests were completed and included, but were not limited to, hemoglobin (a protein in red blood cells that carry oxygen to organs and tissues and transports carbon dioxide from your organs and tissues back to the lungs) 8.2 (low) with no active bleeding from AV graft site.</p> <p>A hospital progress note, dated 7/25/21, indicated the resident's av site had evidence of an abscess/ulceration. Revision and excision were performed to the ulcerated left brachial antecubital veins and prosthetic arteriovenous graft due to bleeding and localized infection of the perforated graft segment. The resident now had a permacath placed. A general post operation note indicated the following: A fluoroscopic guided placement to the right internal jugular vein, glide path, tunneled with a chronic dual lumen hemodialysis catheter placed. And finally, a revision and excision to the ulcerated left brachial antecubital veins and prosthetic arteriovenous graft due to bleeding and localized infection of the perforated graft segment.</p> <p>A nurse's progress note, dated 7/25/21 at 7:05 p.m., indicated the resident returned to the facility from the hospital and the resident's physician gave an order to follow hospital discharge instructions.</p>			

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	<p>A wound note, dated 7/26/21 at 11:00 a.m., indicated the resident had a port placed to the right neck that measured 1.7 centimeters (cm) by 0.1 cm by 0 cm and was left open to air. A left forearm dialysis surgical site that measured 10.5 cm by 0.9 cm by 0.4 cm. A hospital dressing was noted in place. The CNA to observed skin with routine care and notify the charge nurse of concerns. The nursing staff would complete treatments and dressings and weekly skin assessments.</p> <p>The MAR, dated July and August 2021, lacked documentation the port to the right neck and the left forearm dialysis surgical site were assessed every shift for bleeding, increased pain, or signs of infection.</p> <p>During an interview, on 9/15/21 at 2:53 p.m., Registered Nurse (RN) 6 indicated Resident 6 went to the dialysis center on Monday, Wednesday, and Friday every week. She had a fistula to the left forearm, and it had gone bad and was recently replaced. She was unsure if the resident had an order to monitor the fistula site or what the facility policy was.</p> <p>During an interview, on 9/15/21 at 2:55 p.m., RN 7 indicated Resident 6 had a fistula to the left forearm that became infected and busted that required pressure to be held to the site due to heavy bleeding. The resident had to be sent to the hospital for treatment. She also indicated she checked for bruit and thrill and the fistula site for signs of infection or bleeding, but she was unsure if there was anywhere to document the assessment on the MAR and she would not typically document the assessment in the progress notes. She was unsure what the facility policy was for documentation of the assessment.</p>			

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	<p>During an interview, on 9/16/21 at 9:24 a.m., the Director of Nursing indicated all dialysis communication would be uploaded in the documents tab on the electronic record, the facility did not have a binder or any other place the communication would be kept. She was unsure if dialysis had sent the communication after each dialysis visit but she was aware the medical records staff had been behind on uploading documents into resident's medical records. The resident had an abscess to the graft site, and she indicated staff should have monitored the site for signs and symptoms per the facility policy. In July the resident had been sent to the emergency room due to a bleed that occurred at the facility when the abscess to the graft site had burst opened. The graft site was removed at the hospital and new graft site was placed. She was unsure when the permcath had been placed. The permcath site should also be monitored per the facility.</p> <p>During an interview, on 9/16/21 at 10:33 a.m., RN 5 from the dialysis center indicated the resident had an av graft site to her left forearm which was an artificial loop with a created fistula. He indicated the bruit and thrill should be monitored and was completed every Monday, Wednesday, and Friday while the resident was at dialysis receiving treatment. He was unsure what date the abscess had developed to the resident's graft site but the physician over dialysis had started gentamycin 100 mg and vancomycin 750 mg on 7/19/21. The resident received a total of 6 intravenously infused antibiotic treatments while at dialysis. It would have been up to the resident's physician to order any troughs to be drawn with vancomycin treatment and the dialysis facility would not have drawn labs for that, it would have been up to the</p>			

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	<p>facility to follow up on that. Some facilities would send a post communication form that included what care was provided to the resident during the resident's dialysis treatment. He was unsure if communication with Resident 6's facility had been done after each treatment but was able tell me that the facility had called the dialysis center earlier that day and requested all of the post communication documentation to be faxed to them at the facility. The resident's new graft site to the left forearm was currently not being used and the permcaath the right side of the neck was being used for all dialysis treatments at this time. This site should also be monitored.</p> <p>On 9/13/21 at 2:00 p.m., the Administrator provided a document, undated, and titled, "Dialysis," and indicated it was the policy currently being used by the facility. The policy indicated, "Policy: This policy is to outline care and services for dialysis residents in order to prevent infections, complications, and to provide for ongoing monitoring and interventions. Procedure: ...a. The dialysis center will be asked to provide information with regards to the residents visit, weights, and any order pertinent information...5. Fistula/shunt site will be checked every shift for bruits, bleeding, increased pain, and signs of infection. Will be documented on the TAR...."</p> <p>On 9/16/21 at 3:02 p.m., the DON provided a document, updated 2/2019, and titled, "Medication Administration Policy," and indicated it was the policy currently being used the facility. The policy indicated, "...Standards....28. The assessment of the effectiveness of medication is based on staff observations, resident perceptions and information from the medical record and</p>			

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F 0758 SS=D Bldg. 00	<p>medication profiles."</p> <p>On 9/16/21 at 3:03 p.m., the DON provided a document, undated, and titled, "Resident Care Plan Policy" and indicated it was the policy currently being used the facility. The policy indicated, "Purpose: To provide an individualized plan of care for each resident...Additions and modifications will be made by each disciplinary team member to assist facility personnel in meeting the needs of the resident. Plans will be reviewed at least quarterly and revised at any time the condition of the resident changes...Nurses on each shift are responsible for revising and updating the resident care plan whenever the resident's condition changes...."</p> <p>3.1-37(a)</p> <p>483.45(c)(3)(e)(1)-(5) Free from Unnec Psychotropic Meds/PRN Use §483.45(e) Psychotropic Drugs. §483.45(c)(3) A psychotropic drug is any drug that affects brain activities associated with mental processes and behavior. These drugs include, but are not limited to, drugs in the following categories: (i) Anti-psychotic; (ii) Anti-depressant; (iii) Anti-anxiety; and (iv) Hypnotic</p> <p>Based on a comprehensive assessment of a resident, the facility must ensure that--</p> <p>§483.45(e)(1) Residents who have not used psychotropic drugs are not given these drugs unless the medication is necessary to treat a specific condition as diagnosed and</p>			

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	<p>documented in the clinical record;</p> <p>§483.45(e)(2) Residents who use psychotropic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs;</p> <p>§483.45(e)(3) Residents do not receive psychotropic drugs pursuant to a PRN order unless that medication is necessary to treat a diagnosed specific condition that is documented in the clinical record; and</p> <p>§483.45(e)(4) PRN orders for psychotropic drugs are limited to 14 days. Except as provided in §483.45(e)(5), if the attending physician or prescribing practitioner believes that it is appropriate for the PRN order to be extended beyond 14 days, he or she should document their rationale in the resident's medical record and indicate the duration for the PRN order.</p> <p>§483.45(e)(5) PRN orders for anti-psychotic drugs are limited to 14 days and cannot be renewed unless the attending physician or prescribing practitioner evaluates the resident for the appropriateness of that medication. Based on record review and interview, the facility failed to ensure an abnormal involuntary movement scale (AIMS) assessment (an assessment to check for abnormal movements associated with certain medications) was completed when an antipsychotic medication was prescribed for 2 of 5 residents reviewed for unnecessary medications (Residents 41 and 31).</p> <p>Findings include:</p>	F 0758	<p>It is the policy of Providence Health Care to notify a physician of a change in an Abnormal Involuntary Movement Scale (AIMS) assessment to monitor and document antipsychotic drug side effects. To assess the presence of movement and non-movement side effects.</p> <p>I. <u>Corrective Action Taken Related to this Finding:</u></p>	10/12/2021	

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	<p>1. Resident 41's record was reviewed on 9/15/21 at 1:38 p.m. Diagnoses on the resident's profile included, but were not limited to, brief psychotic disorder.</p> <p>A quarterly Minimum Data Set (MDS) assessment, dated 8/20/21, indicated the resident had a moderate cognitive impairment and received an antipsychotic medication seven days of the assessment period.</p> <p>A social services note, dated 6/23/21, indicated the resident had increased agitation, refusal of care, and talked to people in her room who were not there. The resident was sent to the emergency room (ER) for evaluation and treatment.</p> <p>A physician's order, dated 7/7/21, indicated Zyprexa (an antipsychotic) 2.5 milligrams (mg) in the morning and 5 mg in the evening.</p> <p>A social services note, dated 7/8/21, indicated the resident returned to the facility the evening of 7/7/21. The resident was started on Zyprexa which seemed to calm her.</p> <p>A monthly pharmacist report, dated 8/12/21, indicated the resident received Zyprexa, and the pharmacist was unable to locate a recent abnormal involuntary movement scale (AIMS) assessment (an assessment to check for abnormal movements associated with certain medications) in the resident's record.</p> <p>An AIMS assessment, dated 8/13/21, indicated a score of zero. The record lacked documentation an AIMS assessment was completed prior to 8/13/21.</p> <p>A care plan, target date of 11/18/21, indicated the resident received an antipsychotic medication.</p>		<p>The facility corrected the deficiency practice for resident #41 and resident #31 by performing an Abnormal Involuntary Movement Scale Assessment (AIMS) for comparison of the previous assessment (see attached). The current AIMS do not show a variation of the baseline AIMS.</p> <p>II. <u>Other residents with Potential to be Affected by this Finding will be Identified by:</u> The facility realizes all residents have the potential to be affected. This has been addressed by the systems described below.</p> <p>III. <u>Measures and Systemic Changes put into place to assure deficient practices do not recur are as follows:</u></p> <ol style="list-style-type: none"> Chart audits were conducted on 9/22/2021 for residents currently receiving psychotropic medications to ensure a completed AIMS assessment has been completed in compliance with the current policy. The electronic AIMS assessment will be initiated upon the start of any psychotropic medications. The electronic AIMS assessment will be initiated with any new admission and a baseline AIMS assessment will be conducted for anyone on antipsychotic medication. Staff education will be provided on the updated AIMS assessment and policy during 	

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	<p>Interventions included, but were not limited to, administer medications as ordered and observe for side effects.</p> <p>During an interview, on 9/16/21 at 11:15 a.m., the Director of Nursing (DON) indicated the AIMS assessment should have been completed within 30 days of the start date of the antipsychotic medication.</p> <p>2. Resident 31's record was reviewed on 9/15/21 at 1:25 p.m. The profile indicated the resident's diagnoses included but were not limited to dementia with Lewy bodies (a type of progressive dementia that leads to a decline in thinking, reasoning and independent function because of abnormal microscopic deposits that damage brain cells over time) and gastroesophageal reflux disease (GERD) (a digestive disease in which stomach acid or bile irritates the food pipe lining).</p> <p>A physician's order, dated 3/25/21, indicated Nuplazid (pimavanserin tartrate) capsule (an antipsychotic medication used to treat hallucinations and delusions caused by psychosis) 34 milligrams (mg), 1 capsule by mouth one time daily, for dementia for 14 administrations.</p> <p>A care plan, dated 3/26/21, indicated the resident was receiving antipsychotic medication related to dementia with Lewy bodies. Interventions included, but were not limited to, observed the resident for, and report as needed (PRN) to the physician, side effect and adverse reactions which included, but were not limited to, tardive dyskinesia (repetitive, involuntary movements) and extrapyramidal symptoms (EPS) (drug-induced movement disorders, describe the side effects caused by certain antipsychotic and other drugs.</p>		<p>mandatory in-service on 10/11/2021.</p> <p>4. Staff education will be provided on the Psychotropic Medication Policy and a copy of policies will be provided.</p> <p>IV. <u>Corrective Actions will be Monitored to Ensure Compliance by:</u></p> <p>1. The Director of Nursing, or her designee, will be audit the AIMS assessments of those who start or continue taking antipsychotic medications (see attached). Audits will be done after each AIMS assessment to ensure compliance. The resident charts will be audited during their quarterly care plan meeting.</p> <p>2. New orders will be reviewed daily in the Point Click Care Dashboard and discussed and signed off on in IDT Clinical daily meeting.</p> <p>3. AIMS assessments audits will be conducted and discussed at Quality Assurance meetings to determine if any additional action is warranted. Providence Health Care, through the QAPI program, will review, update, and make changes to this plan of correction as needed for sustaining compliance for no less than six months.</p>		

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	<p>A physician's order, dated 4/11/21, indicated Nuplazid (pimavanserin tartrate) capsule 34 mg, 1 capsule by mouth one time daily for dementia.</p> <p>A physician's order, dated 4/28/21, indicated Reglan (metoclopramide HCl) tablet (a drug that increases the motility of the stomach and upper intestine, used to treat certain stomach problems) 10 mg, 1 tablet three times a day (TID) for GERD. The medication was first developed as an antipsychotic medication in the 1960's.</p> <p>The record lacked documentation that a baseline abnormal involuntary movement scale (AIMS) assessment (a rating scale that was designed to measure involuntary movements known as tardive dyskinesia) had been completed, on the resident, in a timely manner.</p> <p>A Pharmacy recommendation, dated 5/5/21, recommended an AIMS assessment related to the administration of metoclopramide HCl (Reglan) be completed. Documentation indicated the assessment was completed on 5/7/21.</p> <p>During an interview, on 9/15/21 at 2:26 p.m., the Director of Nursing (DON) indicated if the baseline AIMS assessment was not found in the electronic record, then it had likely not been completed. The only assessment she was able to see in the electronic record, had been completed on 5/7/21. A baseline AIMS assessment should have been completed when the antipsychotic medication was initially ordered in March 2021.</p> <p>On 9/15/21 at 2:15 p.m., the DON provided an undated document, titled, "AIMS Side Effect Monitoring (Abnormal Involuntary Movement Scale)," and indicated it was the policy currently being used by the facility. The policy indicated,</p>			

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F 0759 SS=D Bldg. 00	<p>"Purpose: To monitor and document antipsychotic drug side effects. To assess the presence of movement and non-movement side effects...Equipment: AIMS Standard Test. Procedure: ...2. Using the facility approved form the test will be performed and documented within 30 days of starting an antipsychotic medication...."</p> <p>3.1-48(a)(3)</p> <p>483.45(f)(1) Free of Medication Error Rts 5 Prcnt or More §483.45(f) Medication Errors. The facility must ensure that its-</p> <p>§483.45(f)(1) Medication error rates are not 5 percent or greater; Based on observation, record review, and interview, the facility failed to ensure a medication error rate of less than five percent based on medication errors observed during 2 of 36 opportunities for errors during random medication administration observations, resulting in a medication error rate of 5.6 percent (Residents 6 and 44).</p> <p>Findings include:</p> <p>1. During a random medication administration observation, on 9/16/21 at 9:29 a.m., Licensed Practical Nurse (LPN) 16 administered sevelamer (a medication to control phosphate levels in the blood for people with kidney disease) 800 milligrams (mg) by mouth to Resident 6. The resident was not eating and was not offered a snack at the time of the medication administration.</p> <p>Resident 6's record was reviewed on 9/17/21 at 2:21 p.m. Diagnoses on the resident's profile</p>	F 0759	<p>It is the policy of Providence Health Care to authorize licensed nursing personnel and QMA's to prepare and administer medications in accordance with the manufacturer's recommendations and the prescribing physician's order.</p> <p><u>I. Corrective Action Taken Related to this Finding:</u> The facility corrected the deficiency practice for resident #6 by auditing medication times and correlating the medication time to be administered with resident #6's meal times to ensure medication is taken with food. The facility corrected the deficiency practice related to resident #44 by providing education to all nursing staff regarding the manufacturer's guidance on priming the insulin</p>	10/12/2021	

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	<p>included, but were not limited to, chronic kidney disease (longstanding disease of the kidney leading to failure) unspecified.</p> <p>A quarterly Minimum Data Set (MDS) assessment, dated 6/28/21, indicated the resident was cognitively intact.</p> <p>A physician's order, dated 12/2/20, indicated sevelamer 800 mg by mouth with meals related to dependence on renal dialysis.</p> <p>During an interview, on 9/16/21 at 1:47 p.m., Resident 6 indicated she ate breakfast between 8:30 a.m. and 8:45 a.m. that morning.</p> <p>During an interview, on 9/20/21 at 11:13 a.m., the Director of Nursing (DON) indicated if a medication was ordered to be administered with a meal it should have been administered with meal or the resident should have been offered a snack at the time of administration.</p> <p>On 9/16/21 at 3:02 p.m., the DON provided a document titled, "MEDICATION ADMINISTRATION POLICY," and indicated it was the policy currently being used by the facility. The policy indicated, "...14. Drugs shall be administered with or without food or milk in accordance with current pharmaceutical references...."</p> <p>2. During a random medication administration observation, on 9/16/21 at 12:18 p.m., Registered Nurse (RN) 17 prepared a Novolog mix 70/30 (an insulin mix of short and long acting insulins) KwikPen (a pen prefilled with insulin) and administered seven units (u) to Resident 44. The KwikPen was not primed (removing air bubbles from the needle to ensure an accurate amount of</p>		<p>pen with 2 units of insulin prior to administration. Providence Health Cares policy was updated to reflect this guidance on 9/22/2021.</p> <p>II. <u>Other residents with Potential to be Affected by this Finding will be Identified by:</u> The facility realizes all residents have the potential to be affected. This has been addressed by the systems described below.</p> <p>III. <u>Measures and Systemic Changes put into place to assure deficient practices do not recur are as follows:</u></p> <ol style="list-style-type: none"> 1. If medication cannot be administered at the time of a meal the administering nurse will provide a snack with medication. 2. All licensed nursing personnel and QMA's educated on providing a snack with medication at mandatory in-service on 10/11/2021. 3. Order set for insulin pen administration to include priming the pen prior to administration in the order. 4. All licensed nursing staff and QMA's educated on the updated policy for insulin administration and provided a copy of the policy at mandatory in-service on 10/11/2021. <p>IV. <u>Corrective Actions will be Monitored to Ensure Compliance by:</u> The Director of Nursing, or her designee, will be conducting audits (see attached) regarding</p>	

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F 0761 SS=D Bldg. 00	<p>insulin is administered) before the administration of the insulin.</p> <p>Resident 44's record was reviewed on 9/17/21 at 2:52 p.m. Diagnoses on the resident's profile included, but were not limited to, type two diabetes (adult onset diabetes) without complications.</p> <p>A physician's order, dated 8/16/21, indicated Novolog mix 70/30 inject seven units subcutaneously (SQ) (an injection into the fatty layer between the skin and the muscle) before meals and at bedtime for diabetes.</p> <p>During an interview, on 9/20/21 at 11:35 a.m., the DON indicated the Novolog 70/30 KwikPen should have been primed before the insulin was administered.</p> <p>On 9/20/21 at 11:35 a.m., the DON provided a document titled, "Insulin Aspart Protamine and Insulin Aspart (Lexi-Drugs)," and indicated it was the policy currently being used by the facility. The policy indicated, "...For prefilled pens, prime the needle before each injection with 2 units of insulin...."</p> <p>3.1-48(c)(1)</p> <p>483.45(g)(h)(1)(2) Label/Store Drugs and Biologicals §483.45(g) Labeling of Drugs and Biologicals Drugs and biologicals used in the facility must be labeled in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions, and the expiration date when applicable.</p>		<p>medication administration by nursing staff to ensure pens are prime prior to administration and that snacks are provided with medications that are to be given with meals 5x per week times 4 weeks, then 3 x per week x 4 weeks, then 2 x per week times 4 weeks, then 1 x per week x 3 months. e outcome of this audit tool will be reviewed at the Quality Assurance meetings to determine if any additional action is warranted. Providence Health Care, through the QAPI program, will review, update, and make changes to this plan of correction as needed for sustaining compliance for no less than six months.</p>		

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	<p>§483.45(h) Storage of Drugs and Biologicals</p> <p>§483.45(h)(1) In accordance with State and Federal laws, the facility must store all drugs and biologicals in locked compartments under proper temperature controls, and permit only authorized personnel to have access to the keys.</p> <p>§483.45(h)(2) The facility must provide separately locked, permanently affixed compartments for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse, except when the facility uses single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.</p> <p>Based on observation, record review, and interview, the facility failed to ensure over the counter (OTC) medications were properly labeled and topical (on the skin) treatments were stored separately from medications for 1 of 2 medication carts reviewed (Residents 6, 20, 30, 19, and 41).</p> <p>Findings include:</p> <p>On 9/16/21 at 9:07 a.m., Licensed Practical Nurse (LPN) 16 was observed preparing medications, on the east medication cart, for Resident 6. LPN 16 removed one capsule from an OTC medication bottle of EB C3 supplement (a supplement to improve memory) labeled with Resident 20's last name only and placed it in a medication cup with other pills for Resident 6. When questioned regarding the name on the OTC bottle, LPN 16 indicated she had placed a capsule for the wrong resident into Resident 6's medications and removed it. LPN 16 then removed a pill from an</p>	F 0761	<p>It is the policy of Providence Health Care to ensure all medications will be labeled and stored in accordance with state and federal regulations</p> <p><u>I. Corrective Action Taken Related to this Finding:</u></p> <p>A. The facility corrected the deficiency practice for resident #6, #19, #20, #30, and #41 by updating all OTC medications currently in the medication carts with the patient's full name, prescribing practitioner, and patient room number. All over-the-counter medication labeling to include the original medication label to be affixed to the exterior surface of the original container and contain the following:</p>	10/12/2021

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	<p>OTC bottle of Methyl Folate (a medical food for people with folate deficiency), labeled with Resident 6's last name only, and placed it into the medication cup for Resident 6.</p> <p>On 9/16/21 at 9:40 a.m., the east medication cart was observed with LPN 16. An OTC bottle of fruit punch glucose (sugar) tablets was labeled with Resident 30's first and last name. A second OTC bottle of EB C3 supplement was labeled with Resident 20's last name only. An OTC bottle of Tylenol was labeled with Resident 19's last name only. An opened tube of diclofenac (a pain relieving ointment) topical ointment for Resident 41 was observed.</p> <p>During an interview, on 9/20/21 at 11:13 a.m., the Director of Nursing (DON) indicated the OTC medications should have been labeled with the residents' full names. Topical ointments should not have been stored in the medication cart.</p> <p>On 9/20/21 at 11:35 a.m., the DON provided a document titled, "MEDICATION LABELING POLICY," and indicated it was the policy currently being used by the facility. The policy indicated, "...Purpose: To ensure that only medications properly labeled, in accordance with applicable laws will be distributed or administered...Policy: It is the policy...that all medications will be labeled in accordance with state and federal regulations...Standards: 1. Medication labels affixed to the exterior surface of the container shall contain: a. Resident name b. Prescribing practitioner's name...8...OTC medications prescribed by the attending physician, will be labeled with the original manufacturer's label in the original container, and include, at a minimum, the resident's name...."</p>		<ul style="list-style-type: none"> · Resident's name including first and last name · Prescribing practitioner's name · Resident room number <p>B. The facility corrected the deficiency practice for resident #41 by auditing all the facility medication carts and removing any external medications in compliance with Providence Health Cares policy on storing external medications separately from internal medications in a treatment cart.</p> <p>II. <u>Other residents with Potential to be Affected by this Finding will be Identified by:</u> The facility realizes all residents have the potential to be affected. This has been addressed by the systems described below.</p> <p>III. <u>Measures and Systemic Changes put into place to assure deficient practices do not recur are as follows:</u></p> <ol style="list-style-type: none"> 1. Over-the-counter medications will be labeled by the nursing staff upon receiving in compliance with the updated medication labeling policy (see attached). 2. All licensed nursing personnel and QMA's to be educated on the revised medication storage and labeling policy and given a copy of the policy at mandatory in-service on 10/11/2021. <p>IV. <u>Corrective Actions will be Monitored to Ensure Compliance</u></p>		

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F 0842 SS=D Bldg. 00	<p>On 9/20/21 at 11:35 a.m., the DON provided a document titled, "MEDICATIONS STORAGE POLICY," and indicated it was the policy currently being used by the facility. The policy indicated, "...Policy: It is the policy...that drugs and biologicals shall be stored in a safe, sanitary and orderly manner...Standards: ...14. External use drugs will be stored separately from drugs for internal use in a section marked 'Externals' in the treatment cart...."</p> <p>3.1-25(j)</p> <p>483.20(f)(5), 483.70(i)(1)-(5) Resident Records - Identifiable Information §483.20(f)(5) Resident-identifiable information. (i) A facility may not release information that is resident-identifiable to the public. (ii) The facility may release information that is resident-identifiable to an agent only in accordance with a contract under which the agent agrees not to use or disclose the information except to the extent the facility itself is permitted to do so.</p> <p>§483.70(i) Medical records. §483.70(i)(1) In accordance with accepted professional standards and practices, the</p>		<p>by: The Director of Nursing, or her designee, will be conducting audits (see attached) of the medication carts throughout the facility to ensure all medications are appropriately labeled and that no topical medications are stored with oral medications. This audit will be done 5x per week times 4 weeks, then 3 x per week x 4 weeks, then 2 x per week x 4 weeks, then 1 x per week x 3 months. The outcome of this audit tool will be reviewed at the Quality Assurance meetings to determine if any additional action is warranted. Providence Health Care, through the QAPI program, will review, update, and make changes to this plan of correction as needed for sustaining compliance for no less than six months.</p>		

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	<p>facility must maintain medical records on each resident that are-</p> <ul style="list-style-type: none"> (i) Complete; (ii) Accurately documented; (iii) Readily accessible; and (iv) Systematically organized <p>§483.70(i)(2) The facility must keep confidential all information contained in the resident's records, regardless of the form or storage method of the records, except when release is-</p> <ul style="list-style-type: none"> (i) To the individual, or their resident representative where permitted by applicable law; (ii) Required by Law; (iii) For treatment, payment, or health care operations, as permitted by and in compliance with 45 CFR 164.506; (iv) For public health activities, reporting of abuse, neglect, or domestic violence, health oversight activities, judicial and administrative proceedings, law enforcement purposes, organ donation purposes, research purposes, or to coroners, medical examiners, funeral directors, and to avert a serious threat to health or safety as permitted by and in compliance with 45 CFR 164.512. <p>§483.70(i)(3) The facility must safeguard medical record information against loss, destruction, or unauthorized use.</p> <p>§483.70(i)(4) Medical records must be retained for-</p> <ul style="list-style-type: none"> (i) The period of time required by State law; or (ii) Five years from the date of discharge when there is no requirement in State law; or (iii) For a minor, 3 years after a resident reaches legal age under State law. 			

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	<p>§483.70(i)(5) The medical record must contain-</p> <ul style="list-style-type: none"> (i) Sufficient information to identify the resident; (ii) A record of the resident's assessments; (iii) The comprehensive plan of care and services provided; (iv) The results of any preadmission screening and resident review evaluations and determinations conducted by the State; (v) Physician's, nurse's, and other licensed professional's progress notes; and (vi) Laboratory, radiology and other diagnostic services reports as required under §483.50. <p>Based on record review and interview, the facility failed to ensure medications and treatments were documented as administered for 2 of 18 Medication Administration Records (MAR) reviewed (Residents 6 and 57).</p> <p>Findings include:</p> <p>1. Resident 6's medical record was reviewed, on 9/15/21 at 1:26 p.m. Diagnoses on the resident's profile included, but were not limited to, chronic kidney disease (the kidneys filter waste and excess fluid from the blood. As kidneys fail, wastes build up), heart failure (a chronic condition in which the hear does not pump blood as well as it should), and hypothyroidism (a condition in which the thyroid gland does not produce enough thyroid hormone).</p> <p>A Medication Administration Record (MAR), dated July 2021, indicated give one tablet of bumex 2 milligrams (mg), by mouth daily for edema and give one tablet of Synthroid 88 micrograms (mcg) by mouth in the morning for hypothyroidism. The record lacked</p>	F 0842	<p>It is the policy of Providence Health Care that all licensed personnel document all medications and treatments administered and/or in the event of a physician's order that cannot be followed the physician will be promptly notified.</p> <p>I. <u>Corrective Action Taken Related to this Finding:</u> The facility cannot correct the cited concerns for resident #6 and resident #57 as the event has already occurred. Physician notified of potentially missed doses for Rl#6 and #57. Documentation of medications and treatments are to be completed promptly after each administration by the individual who administered the medication/treatment.</p> <p>II. <u>Other residents with Potential to be Affected by this Finding will be Identified by:</u> The facility has audited all</p>	10/12/2021
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	<p>documentation the medications had been administered on 7/6/21.</p> <p>2. Resident 57's medical record was reviewed, on 9/20/21 at 9:42 a.m. Diagnoses on the resident's profile included, but were not limited to, surgical amputation absence of right leg below the knee, pressure ulcer of left heel, and protein caloric malnutrition.</p> <p>A Medication Administration Record (MAR), dated September 2021, indicated collagen antimicrobial disk to be applied to the sacrum topically every shift for wound care, Medi honey wound dressing paste to be applied to the left great every night for wound care, zinc oxide cream to applied to the sacrum every night for wound care. The MAR lacked documentation these treatments had been completed on 9/5/21 and 9/8/21. Daily weights were ordered every shift. The MAR lacked documentation weights had been obtained during night shift on 9/11/21 and 9/12/21. There was an order to apply skin prep to left lower extremity every day and night shift for wound care. The MAR lacked documentation this had been completed during day shift on 9/11/21 and 9/12/21 and during night shift on 9/5/21 and 9/8/21. There was an order for albuterol sulfate nebulization solution 2.5 milligrams (mg)/0.5 milliliters (ml), inhale 2.5 mg four times daily for shortness of breath and wheezing. The MAR lacked documentation the treatment had been completed on 9/1/21 at 5:00 p.m., on 9/6/21 at 9:00 a.m., 1:00 p.m., and 5:00 p.m.</p> <p>During an interview, on 9/20/21 at 11:45 a.m., the Director of Nursing (DON) indicated she was unsure why there were holes in the MAR for Residents 6 and 57. The nursing staff should document when medications and treatments were</p>		<p>medication administration records to identify other residents with holes on MAR and physician notified of potentially missed medications.</p> <p>III. <u>Measures and Systemic Changes put into place to assure deficient practices do not recur are as follows:</u></p> <p>A review during the IDT daily clinical meeting will include reviewing the administrative record to ensure all medications are recorded on the record promptly after each administration by the individual who administered the medication/treatment.</p> <p>IV. <u>Corrective Actions will be Monitored to Ensure Compliance by:</u></p> <p>1. The facility corrected the deficiency practice for resident #6 and resident #57 by educating staff on the current policy of medication administration and documentation and a copy of the Medication Administration Policy (see attached) provided to all licensed nursing staff and QMA's at mandatory staff-meeting on 10/11/2021.</p> <p>2. All Licensed nursing staff and QMA's educated on ensuring they verify all medications are documented in compliance with Providence Health Care's policy prior to the end of their shift during mandatory in-service on 10/11/2021.</p> <p>3. The Director of Nursing, or</p>		

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R 0000 Bldg. 00	<p>administered and if not administered, they should document why it was not administered.</p> <p>On 9/16/21 at 3:02 p.m., the DON provided a document, updated 2/2019, and titled, "Medication Administration Policy," and indicated it was the policy currently being used the facility. The policy indicated, "...Policy: It is the policy of the facility to authorize licensed nursing personnel and QMAs to prepare and administer drugs and biologicals. Standards: 1. Drugs will be administered in accordance with orders of licensed medical practitioners in the State of Indiana...Medications shall be recorded on the medication record promptly after each administration by the individual who administered the drug...."</p> <p>3.1-48(a)(3)</p> <p>This visit was for a State Residential Licensure Survey. This visit included a Recertification and State Licensure Survey.</p> <p>Survey dates: September 13, 14, 15, 16, 17, 20, and 21, 2021.</p> <p>Facility number: 003624</p> <p>Residential Census: 32</p>	R 0000	<p>her designee, will be conducting audits (see attached) of the medication administration record throughout the facility to ensure compliance of documentation of all medications administered and that documentation of all non-administered medications are in compliance with the policy. This will be completed 5x per week times 4 weeks, then 3 x per week times 4 weeks, then 2 x per week times 4 weeks, then 1 x per week x 3 months. The outcome of this audit tool will be reviewed at the Quality Assurance meetings to determine if any additional action is warranted. Providence Health Care, through the QAPI program, will review, update, and make changes to this plan of correction as needed for sustaining compliance for no less than six months.</p>	

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

PRINTED: 10/18/2021
FORM APPROVED
OMB NO. 0938-039

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	<p>Providence Health Care Center was found to be in compliance with 410 IAC 16.2-5 in regard to the State Residential Licensure Survey.</p> <p>Quality review completed on September 30, 2021.</p>				