

CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 00000	(X2) MULTIPLE CONSTRUCTION A. BUILDING <u>00</u> B. WING _____		(X3) DATE SURVEY COMPLETED 11/16/2018
NAME OF PROVIDER OR SUPPLIER ROSE'S FAMILY PHYSICIAN			STREET ADDRESS, CITY, STATE, ZIP CODE 123 Main Street Anywhere, US 77000		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
J-0043	<p>PHYSICAL PLANT AND ENVIRONMENT CFR(s): 491.6(b)(2)</p> <p>The clinic . . . has a preventive maintenance program to ensure that:</p> <p>This STANDARD is not met as evidenced by: Based on interviews, document review and observations the facility failed to ensure expired supplies and medications were not available for patient use. Additionally, the facility failed to ensure multidose vials had a beyond use date affixed to the vial after the vial was opened and available for patient use.</p> <p>Findings include:</p> <p>Policy:</p> <p>According to the policy, Management, Handling and Dispensing of Drugs and Biologicals, all drugs and biologicals are stored according to manufacturer package instructions. Expiration dates are clearly written on the container in a manner that does obscure the expiration date.</p> <p>References:</p> <p>According to the manufacturer's instructions for Beckman Coulter Hemocult ICT immunochemical fecal occult blood test, the instructions read do not use the test devices and reagents beyond the labeled expiration dates.</p> <p>Excelsior Medical Swab flush read, indications for use - 0.9% sodium chloride injection, prefilled syringes are intended for flushing of IV catheters and IV tubing only. Solution is injected as a single dose. Use by the expiration date on package. For single use only.</p> <p>1. The clinic staff failed to ensure expired supplies were not available for patient use throughout the clinic setting.</p>	J-0043			

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	<p>a. On 4/8/19 at 4:37 p.m., a tour of the facility was conducted. Multiple patient care supplies were found available for patient use throughout the clinic to be expired. Example of the expired supplies included:</p> <p>One, 10 mL (milliliter) 0.9% sodium chloride syringe (a syringe used to inject fluid into an intravenous catheter to keep it working) expired on 05/01/15, almost four years prior to the survey. A continued tour found 12 - 10 mL 0.9% Sodium Chloride Injection syringes which all had expired on 02/01/18. Three of the syringes had been used and capped with remaining solution left in the syringe in the drawer. This was in contrast to the manufacturer's instructions which stated the syringes were for single use only.</p> <p>282 various sized needles used to draw a patient's blood were found throughout the clinic. The expiration dates dating back three years prior to the survey. Examples included: 30 - 21 g x 1¼ needles which had expired 5/16 and 110 - 22 g x 1¼ needles all of which had expired between 9/17 and 1/19.</p> <p>14 bottles of Hibiclens (Chlorhexidine Gluconate solution 4.0% w/v) (a solution for cleaning the skin) which had expired on 1/19.</p> <p>23 Beckman Coulter hemocult ICT immunochemical fecal occult blood test (a screening card used to test for blood in feces) cards: 7 cards had expired on 1/17, 6 cards had expired on 9/17, and 10 cards had expired on 12/18.</p>				

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OMB NO. 0938-0391

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	<p>9 Medline Industries Inc. PVP Prep Solution Topical Antiseptic (used to clean the skin) bottles: 1 bottle expired on 8/16, this was three years prior to the survey. Another two bottles expired on 7/18, five bottles expired on 2/19, and 1 bottle expired 1/19.</p> <p>The findings were in contrast to facility and manufacturer's instructions which stated the supplies should not be used past the expiration date.</p> <p>b. On 4/10/19 at 3:08 p.m., an interview was conducted with Registered Nurse (RN) #5. RN #5 stated, nurses were to check each assigned area for expired supplies. RN #5 was unsure why nurses had not checked and removed expired supplies as required. RN #5 stated the safety of expired supplies could not be guaranteed and should not be used for patient care.</p> <p>c. On 4/10/19 at 3:34 p.m., an interview was conducted with Clinical Supervisor (CS) #1. CS #1 stated expired supplies were not to be used for patient care. CS #1 stated nurses has assigned duties in each area of the clinic, to include Disposal of expired supplies. CS #1 stated she was unsure why the nurses had not checked and disposed of expired supplies. CS #1 stated expired supplies could lose their effectiveness therefore the supply might not function as expected.</p> <p>d. On 4/9/19 at 3:31 p.m., the Medical Director (Physician) #3 was interviewed. Physician #3 stated due to staff turnover and a lack of process to check the supplies, the nurses had not been checking supplies for expiration dates. Physician #3 stated expired supplies were not acceptable to use in patient care as they "could have mold or anything that could cause an infection" for patients.</p> <p>2. Multidose medication vials were found opened and without a beyond use date applied to the vial or expired.</p>				

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	<p>a. On 4/8/19 at 4:37 p.m., a tour of the facility was conducted. Several multidose vials of medication were found opened with no beyond use date noted. Examples included:</p> <p>3 bottles Lidocaine HCL 1% 200 mg/20mL (milliliter) multidose 2 bottles Lidocaine HCL 1% & Epinephrine 1:100,000 1 bottle Sensorcaine 0.5% 50 mL</p> <p>b. Also found on tour were single use medication vials which had expired. Examples included:</p> <p>3 Sterile diluent 0.7 mL vials which had expired on 12/05/18 10 sterile diluent 0.7 mL vials which had expired on 3/14/18 1 vial of Promethazine HCL Injection 25 mg/mL 1 mL vial which had expired on 4/4/19</p> <p>These findings were in contrast to the policy, Management, Handling and Dispensing of Drugs and Biologicals, which required expiration dates to be clearly written on the vial.</p> <p>On 4/10/19 at 3:34 p.m. the Clinical Supervisor (CS) # 1 was interviewed. CS #1 stated multidose vials were to be dated by the nurse who opened the vial. The dated was to be 28 days after it had been opened, which would be the expiration date. CM #1 stated if the vial was not dated, it was to be thrown away because the expiration date would be unknown. CS #1 stated this was to ensure the patient was not given an expired medication. CM #1 reported an expired medication could cause a patient to experience an unexpected reaction.</p>				

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	<p>c. On 4/9/19 at 9:07 a.m., Licensed Practical Nurse (LPN) #2 was interviewed. LPN #2 stated all medication vials were required to have an expiration and for multidose vials a beyond use date placed on the bottle after it was opened. LPN #2 stated for a multidose medication the expiration date would be 28 days from when the vial was opened. On review of the Promethazine vial, LPN #2 verified the expiration date on the vial to be 4/4/19. LPN #2 stated the vial was expired and should have been thrown away. LPN #2 stated once a medication was considered expired it could not be used for patients because "it wasn't safe".</p> <p>d. On 4/9/19 at 3:31 p.m., the Medical Director (Physician) #3 was interviewed. Physician #3 stated medications were required to have an expiration date and it was unacceptable to use expired medication. Physician #3 stated the multi dose medication vials also required a label on the vial to indicate the expiration and discard date. Physician #3 stated expired medication would be ineffective for patient care.</p>				