

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  01/10/2019
NAME OF PROVIDER OR SUPPLIER  <b>ROSE'S FAMILY PHYSICIAN</b>			STREET ADDRESS, CITY, STATE, ZIP CODE <b>123 Main Street Anywhere, US 77000</b>		
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J-0043	<p><b>PHYSICAL PLANT AND ENVIRONMENT</b> CFR(s): 491.6(b)(2)</p> <p>The clinic . . . has a preventive maintenance program to ensure that:</p> <p>491.6(b)(2) Drugs and biologicals are appropriately stored; and</p> <p>This STANDARD is not met as evidenced by:</p> <p>I. Based on review of clinic policies, documentation, observation, and staff interview, the clinic failed secure vaccines and the "Tornado Bag" from unauthorized access.</p> <p>Failure to secure vaccines and the clinic's "Tornado Bag" from unauthorized access could potentially lead to unauthorized access, theft, and/or tampering with the medications/vaccines and/or medical supplies. This could potentially lead to unauthorized use or cause the staff to use a medication, vaccine, or supply which someone tampered with. Use of a medication, vaccine, or supply which someone had tampered with could potentially result in the manufacturer no longer guaranteeing the efficacy or integrity of the item, and potentially placing the patients at risk for illness or death.</p> <p>The clinic reported an average of 91 patient visits per-month. Findings for observation of 1 of 1 refrigerated vaccine storage area and 1 of 1 "Tornado Kit" include:</p> <p>1. Review of an untitled policy presented by the Chief Clinic Administrator, included in part, "Emergency Kit ... The clinic shall maintain an emergency kit sufficient to meet the demands of an emergency situation typical of a medical clinic. Contents shall include all items necessary to provide emergency medical treatment of patients in the RHC (rural health clinic), as determined by the services provided, equipment utilized and the decision of the Medical Director... The emergency kit is located in the center Procedure Room of the clinic..."</p>	J-0043			

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	<p>Review of the clinic policy "Medication Storage and Handling," policy RHC-SV-002, dated March 2018, included in part, "Drugs are stored in original containers and labels. Access to drugs is controlled, so that drugs are limited to authorized clinic personnel ... All medications are stored in areas away from patient accessibility. Medication storage areas are locked when clinics are closed."</p> <p>2. Observations on 1/9/19, beginning at 10:13 AM, showed a refrigerator in an area identified by the clinic staff as "Doc's office" located in the back of the clinic in a room labeled as "Doctor's Office." Closer observation of the room showed a refrigerator that lacked identification of the contents. Inspection of the refrigerator revealed the staff stored vaccines in the refrigerator.</p> <p>3. During an interview on 1/9/19 at 12:15 PM, the Clinic Manager reported the refrigerator located in "Doc's office" held the clinic vaccines. The staff did not lock the refrigerator during clinic hours or when the clinic was closed. The Clinic Manager reported the housekeeping staff provided housekeeping services weekly after the clinic staff left for the day. The Clinic Manager acknowledged the housekeeping staff should not have access to the vaccines.</p> <p>4. Observation and interview on 1/9/19 at 12:30 PM showed a bag labeled " Tornado Bag" located in a room shared by the clinic providers. The "Tornado Bag" contained medical supplies, needles, and normal saline (a fluid designed for administration into a patient's veins). LPN (Licensed Practical Nurse) A, with the Clinic Manager nearby, reported the "Tornado Kit" was not locked during or after clinic hours when the clinic was closed. Recently, with permission from the physician, the staff moved the "Tornado Bag" from the secure storage room to the providers' work room.</p>	J-0043			

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	<p>The Clinic Manager reported the "Tornado Bag" functioned as the clinic's emergency evacuation bag and contained supplies for use in an emergency. The housekeeping staff cleaned the offices and work room on a weekly basis after the clinic staff left for the day. The Clinic Manager acknowledged the housekeeping staff should not have access to the "Tornado Bag."</p> <p>II. Based on review of clinic policy, documentation, observation, and staff interview, the clinic failed to ensure staff could not use outdated medications for patient care. The clinic also failed to ensure staff performed consistent monitoring on a monthly basis to identify outdated medications.</p> <p>Failure to ensure staff monitored medications in accordance with the clinic policy and ensure staff could not use outdated medication for patient care could potentially lead to staff administering medication in which the manufacturer can no longer guarantee the integrity and/or efficacy. This could potentially lead to patients treated with medications that are no longer effective or contaminated with bacteria, viruses, or fungi, potentially leading to poor patient outcomes and/or illness.</p> <p>The clinic reported an average of 91 patient visits per-month. Findings for observation of 1 of 1 emergency kit and 1 of 1 laboratory include:</p> <p>1. Review of the clinic policy "Medication Storage and Handling", Policy RHC-SV-002 dated March 2018, included in part, "Policy ... To provide guidance concerning storage, handling, and administration of pharmaceuticals ... Access to drugs is controlled, so that drugs are limited to authorized clinic personnel..."</p>	J-0043			

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	<p>The medications are checked at least monthly by licensed staff. All medications are stored in areas away from patient accessibility. Medication storage areas are locked when clinics are closed. Multiple-dose vials will be discarded 28 days after opening. All such vials will be dated upon opening."</p> <p>2. Review of the clinic checklist " CLINIC MONTHLY SAFETY COMPLIANCE CHECKLIST." The checklist showed a section titled "Section Eight: Lab/Med Survey," included in part, "... Medical supply expiration checked..." Closer review of the checklist showed the checklist had been monitored monthly beginning January 2018 through December 2018.</p> <p>Review of the clinic log titled "EMERGENCY KIT CONTENTS" revealed the last time staff documented checking the kit for expired medications and/or supplies occurred on 11/28/18.</p> <p>3. Observation on 1/9/19 at 9:48 AM showed 1 tube labeled "ACTIDOSE - AQUA, activated charcoal suspension" (used for emergency treatment of poisoning) with an expiration date of 12/2018 located in a locked container, identified by the clinic staff as the clinic emergency kit, in the bottom cupboard of the laboratory.</p> <p>4. Observation and interview with the Clinic Manager on 1/9/19 at 12:05 PM showed 4 of 4 packages labeled "ASPIRIN" with an expiration date of 11/2018, 1 vial labeled "Xylocaine 1%" with an open date of 11/2/18 (shortened expiration of 11/30/18), and 1 open vial labeled "Depo-Estradiol" that lacked documentation of when the staff first accessed the vial located in a cupboard identified as "injectables" in the laboratory. The Clinic Manager acknowledged the expired medications.</p>	J-0043			

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OMB NO. 0938-0391

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	<p>The Clinic Manager, at the time of the observations, reported the nursing staff should follow the clinic's checklist on a monthly basis. The nursing staff should place a check mark under the column "Medical supply expiration dates checked" once the staff had checked if any medications expired that month. The Clinic Manager reviewed the checklist and acknowledged the clinic staff failed to check the emergency kit for expired supplies and medications since 11/2018.</p> <p>The Clinic Manager, at the time of the observations, reported the nursing staff should document the date they opened a multiple dose medication vial (medication vials designed to allow the nurses to use the medication in the vial for more than one patient). The Clinic Manager expected the nursing staff to discard the opened multiple dose medication vial 28 days after they first opened it.</p>	J-0043			