

Office of Inspector General

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 300200	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED R 10/31/2018
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NAME OF PROVIDER OR SUPPLIER EMW WOMEN'S SURGICAL CENTER, PSC	STREET ADDRESS, CITY, STATE, ZIP CODE 136 WEST MARKET STREET LOUISVILLE, KY 40202
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{E 000}	Initial Comments Based on implementation of an acceptable plan of correction, the facility is deemed to be in compliance as of 10/31/18.	{E 000}		
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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
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E 000	Initial Comments A Relicensure Survey was conducted on 10/10/18 and found the facility not meeting relicensure requirements with deficiencies cited.	E 000	E 245	
E 245	902 KAR 20:360 5(3)(a)11 a-b Section 5. Administration and Operation (3) Personnel. (a) A facility shall have a staff that is adequately trained and capable of providing appropriate service and supervision to the patients. 11. A personnel file shall be maintained for each employee and for each volunteer as follows: a. The records shall be: (i) Completely and accurately documented; and (ii) Readily available and systematically organized to facilitate the compilation and retrieval of information; and b. The file shall contain: (i) A current job description that reflects the individual's responsibilities and work assignments; and (ii) Documentation of the individual's orientation, in-service education, appropriate licensure, if applicable, and TB testing. This requirement is not met as evidenced by: Based on interview, record review, and facility policy review, it was determined the facility failed to maintain personnel records with current Tuberculosis testing for four (4) of ten (10) staff members. The findings include: The facility did not provide a policy regarding Tuberculosis testing.	E 245	Violations in TB –Testing were corrected immediately, all completed by 10-17-18. Orderly, Surg. Tech and Receptionist #2 have been re-tested and Receptionist #1 had a TB test done. All results were negative. The TB-Test and Documentation policy has been updated to reflect that the Nurse Manager will have TB- test documents in a binder in her possession. In addition the TB-Test documents are noted on a yellow form to distinguish them from other forms, and thus not easily misplaced. Cont....	10-17-18

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

X
STATE FOR

MD

6899

QU7111

Physician/owner



(X5) DATE
10/30/18

If continuation sheet 1 of 8

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E 245	Continued From page 1 Review of four (4) personnel files revealed the Orderly and the Surgical Technician's most recent Tuberculosis tests were dated 11/16/16. Receptionist #1's file did not contain evidence of Tuberculosis testing conducted since the date of hire, 01/27/18, and Receptionist #2's file did not contain evidence of Tuberculosis testing conducted since the date of hire, 07/24/18. Interview with the Executive Director (ED), on 10/10/18 at 4:42 PM, revealed she was aware the facility did not perform Tuberculosis testing on one (1) recently hired staff member. The ED stated she instructed the nurses to ensure Tuberculosis testing occurred for new staff and annually during September and October. She stated she was unable to locate the proof of testing for the staff. She stated the purpose of Tuberculosis testing was to ensure infected staff was not in direct contact with clients, as many of the clients might be more susceptible to infections given their backgrounds.	E 245	Cont. E 245 Policy also notes that Nurse Manager is responsible for testing new employees immediately and will conduct yearly testing on all employees within a year from the most recent test. A one page table has all employees' test dates clearly visualized to prevent missing the date.	
E 340	902 KAR 20:360 7(3)(a-e) Section 7. Pharmaceutical Services Pharmaceutical services shall be provided in accordance with accepted professional practice and federal, state, and local laws. (3) Medicine storage. (a) Medicines and drugs maintained in the facility for daily administration shall not be expired and shall be properly stored and safeguarded in enclosures of sufficient size that are not accessible to unauthorized persons. (b) Refrigerators used for storage of medications shall maintain an appropriate temperature as determined by the requirements	E 340	E 340 Expired medications and supplies were discarded immediately, by 9AM on 10-11-18. Policy regarding Storage, Handling, and Administration of Drugs and Biologicals has been updated to specify steps in Cont...	10-11-18



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E 340	<p>Continued From page 2</p> <p>established on the label of medications.</p> <p>(c) A thermometer accurate to \pm three (3) degrees Fahrenheit shall be maintained in these refrigerators.</p> <p>(d) Only authorized personnel shall have access to storage enclosures.</p> <p>(e) Controlled substances and ethyl alcohol, if stocked, shall be stored under double locks and in accordance with applicable state and federal laws.</p> <p>This requirement is not met as evidenced by: Based on observation, interview, and facility policy review, it was determined the facility failed to ensure medications maintained in the facility, available for staff use, were not expired. In addition, observations revealed multiple medical supply items, which included surgical gloves, tape, curettes, and intravenous needles, were expired and available for staff use.</p> <p>The findings include:</p> <p>Review of the facility's policy, "Procedures to be Followed in the Storage, Handling, and Administration of Drugs and Biologicals", undated, revealed it did not address expired medications and/or supplies.</p> <p>Observation of Exam Room #3, on 10/10/18 at 9:15 AM, revealed under the base cabinet, there was a 1000 milliliter (ml) bottle of 0.9% Normal Saline, partially used, dated opened 06/22/09. In addition, there was a silicone donut pessary kit with an expiration date of October 2000, and a silicone incontinence dish with support, packaged identical to the pessary kit, with the expiration date missing.</p> <p>Observation of the laboratory, on 10/10/18 at</p>	E 340	<p>Cont. E 340</p> <p>monitoring and discarding expired medications. Items in Exam Room #3 were not used by EMW clinic staff or on EMW patients. That space was utilized by a previous gynecology practice no longer in practice. Items have been discarded.</p> <p>Outdated Micropore tape in laboratory has been discarded.</p> <p>Expired supplies in pre-op have been discarded, as have the items in the procedure room. The expired Epinephrine ampule has been discarded, a current Epinephrine ampule was available in the drawer.</p> <p>Cont...</p>	



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E 340	Continued From page 3 10:48 AM, revealed one (1) box containing twelve (12) rolls of Micropore surgical tape, 1 inch x 10 yards, with an expiration date of 01/2017. Observation of the pre-procedure room, on 10/10/18 at 11:12 AM, revealed two (2) Jelco intravenous catheters, 16 Gauge 1-1/4, with expiration dates of 01/2018. Observation of the procedure room, on 10/10/18 at 11:17 AM, revealed seven (7) disposable rigid, 15 curved curettes with expiration dates of 03/2018. In addition, there was one (1) ampule of Epinephrine with an expiration date of 01/01/18, in the anesthesia cart. Both the curettes and the Epinephrine were in areas with other items and available for staff use. Interview with the Certified Registered Nurse Anesthetist (CRNA), on 10/10/18 at 11:23 AM, revealed she worked from the anesthesia cart for the scheduled procedures on this date, which she used the medications in the cart to manage the clients during their procedures. She stated she was preparing the cart for the next client and procedure. She stated she checked her medications every day and was not aware the medication was outdated. She stated staff should not use outdated medications, as expired medication potentially was not as effective as they should be. Observation of the supply closet, on 10/10/18 at 11:38 AM, revealed one (1) opened box of size 7 Criterion surgeon gloves with an expiration date of 06/2018. Observation of the post-procedure room, on 10/10/18 at 11:53 AM, revealed the following items on cabinet shelves available for staff use:	E 340	Cont. E 340 The Criterion Surgery gloves, a free promo sample box, not utilized by physicians have been discarded from the supply room. The Transpore Tape in the post procedure room has been discarded. Other items in post procedure room were stored in cabinets not utilized by medical staff or used on patients. These items have been discarded. The non-aspirin pain reliever has been discarded and replaced. Cont....	



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E 340	<p>Continued From page 4</p> <p>five (5) rolls of Transpore tape, 1 inch x 10 yards, with expiration dates of 08/2016; and six (6) Terumo intravenous catheters, 20 gauge x 1 inch, three (3) expired 09/2006, two (2) expired 08/2004, and one (1) expired 05/2004.</p> <p>Continued observation of the post-procedure room revealed the following items in cabinet drawers available for staff use: one (1) BD PRN adapter with an expiration date of 04/2007, and one (1) opened box of one hundred (100) Kendall Monoject Hypodermic Needle Polypropylene Hubs, with an expiration date of 01/2017. Also available were three (3) BD eclipse needles 21 gauge 1-1/2 TW with expiration dates of 03/2011.</p> <p>Observation of the recovery lounge, on 10/10/18 at 12:01 PM, revealed an opened bottle of Gericare non-aspirin pain relief acetaminophen tablets, 100 count, with an expiration date of 08/2018.</p> <p>Interview with the Medical Assistant (MA), on 10/10/18 at 3:30 PM, revealed the expired bottle of Gericare non-aspirin tablets was available for staff use in the recovery lounge. The MA stated the use of expired medications potentially resulted in allergic responses, delayed reactions, or ineffective results. The MA stated she believed the nurse was responsible to check supplies for quantity and expiration.</p> <p>Interview with the Licensed Practical Nurse (LPN), on 10/10/18 at 4:00 PM, revealed she had no responsibility regarding medication or medical supply stock levels; however, she further stated she was involved with the other staff as they went through the items every couple of months to check for sufficient supplies and expiration dates. The LPN stated expired medications might not be</p>	E 340	<p>Cont. E 340</p> <p>All medical staff have been reminded to note and discard items that have or are about to expire. All spaces, even if not used to store items we currently use, have been cleared.</p> <p>The LPN, full time employee, had been responsible to check medications and supplies with two part time RNs. This duty has now been assigned to the full time Nurse Manager, who will do monthly checks on all medications and supplies as well as be responsible for ordering replacements. These monthly audits will be duly noted.</p>	



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E 340	Continued From page 5 as effective and expired supplies might have issues with sterility. In addition, the LPN stated she was unsure if the facility conducted audits related to expired medications or medical supplies. Interview with the Registered Nurse (RN), on 10/10/18 at 4:12 PM, revealed she was unsure of the facility processes related to inventory/audits of medications and medical supplies. The RN stated administration of expired pain medications might affect the potency of the medication, as the client might not receive the intended results. In addition, the RN stated plastic brittle with age, and as a result, medical supplies might be affected. Interview with the Executive Director (ED), on 10/10/18 at 4:42 PM, revealed the facility previously audited supplies monthly, but there had not been consistent staffing. The ED stated the facility might have supplies in areas in which staff did not often utilize and therefore, the staff might be unaware of the presence of the expired supplies. The ED stated expired medications and supplies might be ineffective or defective. The ED was unable to recall specific quality improvement items related to auditing medications and/or medical supplies.	E 340		
E 550	902 KAR 20:360 13(7) Section 13. Quality Improvement (7) The quality improvement program shall identify and establish indicators of quality care specific to the facility that shall be monitored and evaluated. This requirement is not met as evidenced by:	E 550	E 550 The Quality Improvement Policy will be updated by Oct. 31, 2018, to include specific steps to monitoring TB-testing and medications/supplies. The Nurse Manager will monitor and note TB-testing every three months. She will ensure Cont....	10-31-18



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E 550	<p>Continued From page 6</p> <p>Based on interview and facility policy review, it was determined the facility failed to have a Quality Assurance Program that monitored indicators of quality care, as evidenced by a repeated deficiency related to staff Tuberculosis testing.</p> <p>The findings include:</p> <p>The facility did not provide a Quality Improvement policy.</p> <p>Review of personnel files during survey revealed the files did not contain records of Tuberculosis testing. (Refer to E245) This deficient practice was cited during the last Relicensure Survey, 11/19/18.</p> <p>Interview with the Licensed Practical Nurse (LPN), on 10/10/18 at 4:00 PM, revealed the facility had a Quality Assurance (QA) type of meeting about every two (2) to three (3) months, in which the physicians facilitated the meeting. She stated the physicians brought forth concerns and presented the problems, followed by questions, regarding areas of concerns and improvement opportunities. Then, there was another meeting for follow-up to evaluate if the changes made resolved the issues. In addition, the LPN stated the Executive Director (ED) was involved in QA with the paperwork, such as signatures, discharge information, etc.</p> <p>Interview with the ED, on 10/10/18 at 4:35 PM, revealed she was involved with the QA Program for the facility, which had not been a priority. She stated staff Tuberculosis testing was not on her QA, even though it was previously cited.</p> <p>Interview with the Physician/Owner, on 10/10/18</p>	E 550	<p>Cont. E 550</p> <p>new employees are in compliance as soon as hired. As mentioned before, The Nurse Manager will monitor all supplies and medications monthly for expiration dates. Documentation of the above will be immediately placed in a binder to ensure quality assurance. Other things of concerns are discussed in the quarterly staff meetings where the problem is identified and discussed, plan of correction is designed and the issue is brought up again to see if it has been corrected. This plan of action will be documented in writing also to further ensure quality assurance.</p>		



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E 550	Continued From page 7 at 4:59 PM, revealed his only concern was for client care and he was not involved with audits, reviews, or the operation of the facility. He stated he was unable to answer any nursing questions and anything related to those nursing issues were referred to the ED.	E 550		





**CABINET FOR HEALTH AND FAMILY SERVICES
OFFICE OF INSPECTOR GENERAL**

Matthew G. Bevin
Governor

Belinda Beard, BS, RN, Regional Program Manager
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Adam M. Meier
Secretary

Steven D. Davis
Inspector General

December 3, 2018

via EMAIL:

Ms. Executive Director
Emw Women's Surgical Center, Psc
136 West Market Street
Louisville, KY 40202

Dear

The Division of Health Care received your plan of correction pertaining to the deficiencies identified during the state licensure survey completed on October 10, 2018. This office has accepted your plan of correction. Upon review of your plan of correction, it was determined that implementation of this plan should result in compliance with minimum licensure requirements. **OIG acknowledges that it is presently enjoined from requiring, and is not currently requesting, the written agreements required by KRS 216B.0435 and 902 KAR 20:360 Section 10, pursuant to the terms of the Order, filed April 10, 2017, in EMW Women's Surgical Center, P.S.C. v. Vickie Yates Brown Glisson, U.S. District Ct., W.D. KY, Case No. 3:17 cv-00189-GNS.**

If you have any questions, please contact our office.

Sincerely,

Belinda Beard, BS, RN
Regional Program Manager
Division of Health Care

BB/kt