Office of Inspector General

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	300200	A. BUILDING _____ B. WING _____	10/11/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
EMW WOMEN'S SURGICAL CENTER, PSC	136 WEST MARKET STREET LOUISVILLE, KY 40202

(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) COMPLETE DATE
E 000	Initial Comments A Relicensure Survey was conducted on 10/10/19 to 10/11/19 and found the facility not meeting relicensure requirements with deficiencies cited.	E 000	E 340 All single use vials are being used as single use vials, discarding any excess. To correct this problem, multiple dosing vials have been ordered and will be exclusively used to stay in compliance. Prescription drugs Cytotec and Zofran have been placed in a locked cabinet in lab with cabinet locked when staff is out of the room. Staff have been instructed to keep cabinet locked at all times when leaving the room. Phenergan and other medications are stored in a locked cabinet in pre-op. Staff have been instructed to keep cabinets locked at all times when they leave the room. Influenza vaccine and Rhogam are stored in a locked refrigerator on top floor separate from laboratory equipment controls. Lab staff have also been instructed to place collection tubes with blood in a bio hazard bag with label when keeping in refrigerator. The purple top collection tube is a control for Rh-Neg blood. The tube has been and will always be placed in a bio hazard bag. Staff have been	10-12-19
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 established on the label of medications. (c) A thermometer accurate to ± three (3) degrees Fahrenheit shall be maintained in these refrigerators. (d) Only authorized personnel shall have access to storage enclosures. (e) Controlled substances and ethyl alcohol, if stocked, shall be stored under double locks and in accordance with applicable state and federal laws. This requirement is not met as evidenced by: Based on observation, interview, and facility policy review, it was determined the facility failed to maintain pharmaceutical services provided in accordance with accepted professional practice and federal, state, and local laws for medicine storage. Single use, preservative free dosing vials were used as multiple dosing vials. In addition, prescription drugs of Cytotec, Zofran,	E 340		

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Northern Enforcement Branch

LABORATORY DIRECTOR S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

X

TITLE

X Medical Director

(X6) DATE

X 11/1/19

STATE FORM

FIMM11

If continuation sheet 1 of 9

Medical Director 11/15/19

Office of Inspector General

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E 340	Continued From page 1 Phenergan, Influenza Vaccine, and Rho (D) Immune Globulin were not secured. In addition, medications stored in the refrigerator were stored with blood specimens and laboratory equipment controls. The findings include: Review of facility policy, "The Actual Abortion Procedure, To Include The Use Of:", not dated, revealed an intravenous (IV) catheter was inserted in the arm of a patient when she was in the pre-op area. The IV was used for administration of Phenergan, IV sedation medications, and any other medication the physician may order. Observation of Examination Room 1, on 10/10/19 at 1:05 PM, during tour, revealed an unlocked, and unsupervised base cabinet, and the top right drawer contained three (3) coin sized yellow envelopes stapled, and labeled as "Cytotec (Abortion Pill) x4" Insert four (4) pills vaginally on (blank space). The envelope included Patient (blank space) and Date (blank space). Tablets were palpated tablets in the enclosed, stapled envelopes. In addition, the top left drawer contained one (1) bottle of Cytotec 200 micrograms (mcg) tablet with three (3) white tablets inside the bottle. Continued observation revealed one (1) bottle of Ibuprofen 400 milligram (mg) tablets, quantity 500 tablets was over half full of tablets, placed on the counter top. Interview with Registered Nurse (RN) #1, on 10/10/19 at 1:05 PM, revealed the staff left the bottle of Cytotec in the top drawer in the exam room for use with the patients going to stay for the same day procedure. She stated "We administer out of the bottle, labeled ",	E 340	cont. E340 instructed to lock the refrigerator as soon as the medications are taken out. Director makes sure all cabinets are locked at the end of the day. In the exam rooms, Cytotec envelops and remaining bottle have been removed from drawers. Staff have been coached to keep drawers free from Cytotec envelopes and bottle. Cytotec envelopes are to be retrieved by nurses and physicians from the locked cabinet in lab only in quantity needed for the day. No medications are to be kept in exam room drawers. The lab person has been instructed not to place any yellow envelopes in exam room drawers. Ibuprofen bottles are kept in a separate room in a locked drawer. Staff have been instructed never to leave the medication on the counter top in the exam room and return the bottle to the locked drawer immediately after use. Everyone using the rooms have been asked to assure medications are not left in drawers and counter top. Director makes sure all cabinets are locked at the end of the day.	10·12·19 10·12·19

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E 340	Continued From page 2 as this is what we call the Doctor. If the patient was going home, then we give the packet of pills with instructions." She stated the pills were there so they were available. Continued Tour and observation of Examination Room 2, on 10/10/19 at 1:25 PM, revealed one (1) bottle of Ibuprofen 400 milligram (mg) tablets, quantity 500 tablets, was over 3/4 full of tablets. The bottle remained on the counter top, unsecured and accessible. Observation of the Laboratory, on 10/10/19 at 2:07 PM, revealed the door open to the facility, accessible, with no staff present. Continued observation revealed an unlocked cabinet with eight (8) bottles numbered one (1) through eight (8) of Misoprostol (Cytotec), 200 mcg, and each bottle contained 100 tablets. In addition, Ondansetron (Zofran) (used to prevent nausea and vomiting) Orally Disintegrating four (4) mg tablets, with thirty (30) tablets per each of the four (4) boxes, plus four (4) tablets. In addition, the refrigerator contained thirty-nine (39) doses of Rho (D) Immune Globulin (Human) 1500 International Units (IU) injectable, and one (1) five (5) milliliter (ml) vial of Influenza vaccine, partially used, and without an open date on the bottle. A purple top blood collection tube, four (4) ml, contained blood and was lying on the shelf inside of the refrigerator with the controls, and medications. The purple top blood collection tube was not contained in a biohazard bag. Observation of the Recovery Lounge, on 10/10/19 at 3:10 PM, and on 10/11/19 at 8:43 AM, revealed one (1) bottle of Ibuprofen 400 mg, one (1) bottle of Tylenol 500 mg, and a large container of Ammonia Inhalants placed on the table in the corner behind the desk accessible to patients.	E 340	E340 All medications, Ibuprofen and Tylenol as well as Ammonia Inhalants have been placed in a locked drawer in the Recovery Lounge. Staff have been asked to lock the drawer at the end of the day as well as every time they leave the room. Director makes sure all cabinets and drawers are locked at the end of the day.	10-12-19

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E 340	Continued From page 3 Observation of the Pre-Op Room, on 10/10/19 at 3:25 PM, revealed no staff present. Unlocked cabinets contained thirty-seven (37) containers of Kefzol 1 Gram (gm) Phenergan, being prescription medications. The cabinet contained thirteen (13) Normal Saline, thirty (30) ml, single dose vials. Two (2) of the thirteen (13) single use vials were opened, and available for repeated use. Both vials had multiple punctures visualized in the grey diaphragm. There were five (5), five (5) ml syringes with a clear liquid drawn into the barrel of the syringe with an intravenous extension attached; however, the unidentified syringes were undated. There was a one hundred (100) ml normal saline bag with a label Phenergan 2 mg/1 ml laid over the five syringes. The cabinets contained Labetalol, Zofran, Hydralazine, and Oxytocin. Observation of RN #1, during pre-op saline lock preparation, on 10/11/19 at 1:30 PM, revealed she retrieved a saline lock, from a group of syringes available and unlabled, stating to each patient she was administering Phenergan, and the patient may experience an odd taste after receiving the medication. Interview with Licensed Practical Nurse (LPN) #1, on 10/11/19 at 3:40 PM, revealed medications and saline flush items identified as single use, are for one (1) time use. She stated staff should label and date the syringes with the name of the medication, as well as the date. Interview with RN #1, on 10/11/19 at 4:05 PM revealed the yellow envelopes were set up in advance with Cytotec tablets for staff convenience. She revealed there was a stored supply of Cytotec located in the laboratory. She	E 340	cont 340 In pre-op: All medications have been placed in a cabinet that is locked when staff is not present. All single dose Normal Saline vials are being used once, unused portion discarded. Multiple dosing vials will be used from now on to prevent any errors. Staff have been reminded and instructed to label and date syringes as soon as they are prepared. Nurses are no longer preparing flushes with Phenergan for the next day, but rather prepare them the day they are to be used. All medical staff have been asked to be observant and make sure we stay in compliance with these regulations. Director makes sure all cabinets are locked at the end of the day. Nurse manager, nurses, medical assistants as well as physicians have been asked to all be vigilant regarding handling, labeling, storing and administering medications to stay in compliance and minimize any potential errors in practice.	10-12-19

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E 340	Continued From page 4 stated the lab person set up the yellow envelopes and placed them in the drawers of the exam rooms. She stated the nurses were responsible for the medications. She stated the nurses required a license to administer and manage medications. Additionally, she stated nurses, physicians, nurse practitioners, physician assistants, and pharmacist have license, with access to manage, and administer medications. She stated the Normal Saline, 50 ml single use vials are in use multiple times, as a multi-dose vial. She reported she does prepare the Phenergan in a saline bag of fluids for a 2 mg/1 ml of saline. She stated she prepares the flushes with the Phenergan so the syringes were ready available for the next day. Interview with the Medical Director, on 10/11/19 at 4:15 PM, revealed he would have to refer any medication questions to the nurse. He stated he would not have a concern for the Tylenol and Ibuprofen to be in the room. Interview with the Executive Director, on 10/11/19 at 5:45 PM, revealed the nurses take care of the medications; however, she was not aware of any medication concerns. She reported she had not completed any audits with the medications; nor had any discussion in the QAPI meeting.	E 340		
E 700	902 KAR 20:360 15(1) Section 15. Infection Control (1) There shall be an infection control program developed to prevent, identify, and control infections. This requirement is not met as evidenced by: Based on observation, interview, record review,	E 700	E 700 Infection control issues are addressed during staff meetings. Nurse manager and physicians will bring up issues of concern as well as ensure staff are up to date on new topics and regulations. cont.	10-12-19

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E 700	Continued From page 5 and facility policy review, it was determined the facility failed to implement an infection control program to prevent, identify or control infections. Observations revealed single use vials available for repeated use after initial use, pre-drawn, unlabeled syringes of a clear liquid and staff failure to perform hand hygiene between tasks/patients. The findings include: Review of facility policy "Infection Control and Sanitation Procedures," undated, revealed the facility provided patient care under the guidelines of the Occupational Safety and Health Administration regulations. Additionally, the facility utilized universal precautions to protect patients and employees during pre-operative care, during procedure, and during post-operative care. Observation, on 10/10/19 at 3:25 PM, revealed two (2) of thirteen (13) single-dose vials of normal saline, were opened and not dated. The exposed gray diaphragm revealed multiple visible puncture marks. The manufacturer's label identified the normal saline was for single-dose use. Continued observation revealed five (5) five-milliliter (ml) syringes containing clear liquid with no label or date on the syringe. Observation, on 10/11/19 at 8:53 AM revealed two (2) of thirteen (13) fifty (50) ml vials of normal saline single use available for staff use. Continued observations revealed multiple punctures on the diaphragm. Observation, on 10/11/19 at 9:15 AM revealed staff failed to perform hand hygiene between patients.	E 700	Cont. E700 Blood borne pathogens and Hazard communications are reviewed annually. In order to maintain a high standard of infection control, both nurse manager and the doctors will assure that medical staff adhere to guidelines when giving care. Nurses will not use single use vials a second time, and all medications are to be labeled and dated in order to be identifiable to other medical professionals, CRNAs and physicians, who administer medications outside of their areas at times. Staff have been instructed to be mindful specifically of hand hygiene as well as any other practices outlined in the policy and procedure manual to prevent the spread of disease.	10-12-19

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E 700	Continued From page 6 Observation, on 10/11/19 at 9:21 AM revealed staff, with gloved hand, scratched their head, and continued patient care without glove change or hand hygiene. Observation, on 10/11/19 at 12:35 PM revealed the Certified Registered Nurse Anesthetist (CRNA) obtained an unlabeled, pre-filled syringe from the cabinet and administered the solution/medication to a patient upon starting an intravenous line in the pre-op room. Observation, on 10/11/19 at 12:35 PM, revealed Registered Nurse (RN) #1 obtained and used an unlabeled, pre-filled syringe and administered the solution/medications to a patient during an intravenous placement on three (3) patients. Interview with Licensed Practical Nurse (LPN) #1, on 10/11/19 at 3:40 PM, revealed she considered the purpose of hand hygiene to prevent the spread of disease and protect the patients and staff. LPN #1 stated staff performed hand hygiene before and after patient contact, before and after eating and using the restroom. Additionally, staff practiced hand hygiene when changing gloves. Interview with the Medical Director, on 10/11/19 at 4:40 PM, revealed staff use of single use vials of medication/solutions for multi-use was concerning for infection control concerns and general sterility of the product. Interview with the Executive Director, on 10/11/19 at 5:56 PM, revealed she was not clinical in nature and she could not verbalize the process for infection control.	E 700	cont. E700 All mentioned medical staff have been coached in being mindful of not touching contaminated areas and then continuing patient care without proper hand hygiene or changing gloves. All medical staff have been reminded to label and date medications and syringes and to make sure single dose vials are not used multiple times.	10.12.19 10.12.19

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B 095	Continued From page 7	B 095		
B 095	902 KAR 20:205 5(2) SECTION 5. ANNUAL TB RISK ASSESSMENTS & TESTS (2) A health care worker included in the TB screening program, as determined by the health facility ' s TB infection control plan, shall also have annual TB testing. This requirement is not met as evidenced by: Based on facility policy and record review it was determined the facility failed to perform annual Tuberculosis testing of employees for two (2) staff members, Licensed Practical Nurse #1 and the Medical Assistant. The findings include: Review of facility policy "TB-Test and. Documentation," undated, revealed facility employees with direct patient contact must show results of a TB test within the last twelve (12) months and an intradermal method was used for yearly tests thereafter. Review of facility personnel records and the Tuberculosis (TB) test records, on 10/11/19, for Licensed Practical Nurse (LPN) #1 revealed the most recent TB test results dated 02/06/18.	B 095	B 095 The TB test administering and documentation have been given extra steps to assure that tests are not missed. In addition to the binder with everyone's records there is a big visual board in the lounge next to the time clock with employee name and date when TB test is due. Director have also taped a note to the desk in each employees work area with their name and specific date when test is due. Employees who were more than 12 months late have been given a two-step test. All employees are up to date on their tests and all results are negative for TB. All employees will be given a test in their birth month and or prior in order not to exceed 12 months. Employees, physicians and the director all all responsible to ensure no more TB tests are missed.	10·12·19 10·26·19

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B 095	Continued From page 8 Additionally, the review of the personnel record for the Medical Assistant revealed a TB test result dated 08/28/18. Interview with the Executive Director, on 10/11/19 at 5:56 PM, revealed she designated Registered Nurse (RN) #1 to continue with the Infection Control needs of the facility. She stated RN #1 had a binder with the documented results of the staff TB test. She stated completed annual TB test results and TB screening were in the binder. Telephonic interview with Registered Nurse #1, on 10/11/19 at 6:00 PM, revealed she was aware some staff were due or late. She stated she was planning to do a sweep to complete the entire late TB test. She revealed she just wanted to do them all at once. She stated the TB test was to identify an exposure, or active disease, in an effort to prevent others from becoming infected.	B 095		