Alabama Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	C5432	A. BUILDING: _____ B. WING _____	11/05/2009

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ALABAMA WOMEN'S CENTER FOR REP	612 MADISON STREET SOUTH HUNTSVILLE, AL 35801

(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
L 100	ALABAMA LICENSURE DEFICIENCIES THE FOLLOWING ARE LICENSURE DEFICIENCIES AND REQUIRE A PLAN OF CORRECTION. This Rule is not met as evidenced by: 420-5-1-.02 Administration. (2) Policies & Procedures. Policies and procedures for operation of the facility shall be formulated and reviewed annually by the governing authority. They shall include at least the following: (a) Purpose of the facility, to include scope and quality of services; (b) Method to ensure compliance with all relevant federal, state, and local laws that govern operations of the facility; (k) Patient Care Policies and Procedures. Findings include: During a review of the policy and procedure book on 11/03/09 the surveyor observed the clinic failed to have a policy and procedure for Mandatory reporting and Parental consent. The Administrator was asked 11/05/09 if the clinic had a written policy for Mandatory reporting and Parental consent. He stated that they followed the law but he did not have a written policy. ********** 420-5-1-.04(5)(d) Supplies Medications and supplies which have deteriorated or reached their expiration dates shall not be used for any reason. All expired or deteriorated items shall be disposed of promptly and properly.	L 100		

Health Care Facilities
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

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L 100	Continued From page 1 Each facility shall examine all stored medications and supplies no less frequently than once a month and shall remove from its inventory all deteriorated items and all items for which the expiration date has been reached. The facility shall maintain a log recording each such examination, and a description of each item or group of items removed from inventory and the reason for such removal. Based on observation and interview, it was determined the facility failed to remove from inventory supplies and medications which had expired. This had the potential to affect all patients served. Findings include: During a tour of the facility on 11/03/08 at 1:00 PM the surveyors observed: Pitocin vials 1 milliliter each for a total of 9 vials with an expiration date of 4/2009 and Mircette starter kits a total of 5 packs that all expired on 1/2008. During a tour of the procedure room # 1 on 11/04/09 at 10:50 AM the surveyors observed 10 disposable plastic suction tip/curettes which expired on 8/2009. There was no documentation the supplies or medications had been reviewed for expiration dates. The Administrator was asked 11/03/09 regarding the expired drugs not being removed and he stated that only one doctor used the Pitocin and she did not come very often and that was probably why no one noticed it needed to be removed.	L 100		

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L 100	Continued From page 2 The administrator was asked about the suction curettes on 11/05/09 and he stated they did not use that size often and he had not noticed the expiration date. 420-5-1-.04(7) Pharmaceutical Services. (a) Safety. Drug rooms shall be provided with safeguards to prevent entrance of unauthorized persons, including bars on accessible windows and locks on doors. Controlled drugs and ethyl alcohol, if stocked, shall be stored under double locks and in accordance with applicable Federal and State laws. (b) Administering, Dispensing, and Prescribing Drugs and Medicines. Only physicians and properly credentialed nurse practitioners and physician assistants may prescribe or order medications. Nurse practitioners and physician assistants may prescribe only those medications described in their individual collaborative agreements. Except for standing orders as permitted below, medications shall be prescribed for patients of the facility by patient name after an appropriate medical evaluation. Oral and telephone orders shall be received only by a physician, nurse practitioner, physician assistant, registered professional nurse, licensed practical nurse, or a pharmacist. Oral and telephone orders shall be immediately documented in writing by the individual receiving the order. Prescribing, dispensing, and administration of medications shall meet all standards required by law and by regulations of the State Board of Medical	L 100		

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L 100	Continued From page 3 Examiners and the State Board of Pharmacy. Based on observation and interview it was determined the clinic failed to prepare medications for intravenous(IV) use to meet the standards required by law and regulations of the State Board of Pharmacy. The clinic failed to label syringes as to medication in the syringe and date it was prepared. This had the potential to affect all patients served. Findings include: USP (United States Pharmacopeia) 797 Pharmaceutical Compounding-Sterile Preparations "The standards of this chapter are intended to apply to all persons who prepare CSPs (Compounded Sterile Products) and all places where CSPs are prepared (e.g., hospitals and other healthcare institutions, patient treatment clinics, pharmacies, physicians's practice facilities, and other locations and facilities in which CSP's are prepared, stored, and transported). Person who perform sterile compounding include pharmacists, nurses, pharmacy technicians, and physicians. "Low-Risk Level CSPs "2. The compounding involves only transfer, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile products and not more than two entries into any one sterile container or package (e.g., bag, vial) of sterile product or administration container/device to prepare the CSP.	L 100		

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L 100	Continued From page 4 "4. For a low-risk level preparation, in the absence of passing a sterility test (see Sterility Tests {71}), the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and are exposed for not more than 48 hours at controlled room temperature (see General Notices and Requirements), for not more than 14 days at a cold temperature (see General Notices and Requirements), and for 45 days in solid frozen state between -25 (degrees) and -10 (degrees). "Low-Risk Level CSPs with 12-Hour or Less BUD "2. The segregated compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors or high traffic flow, or that is adjacent to construction sites, warehouses, or food preparation. Note that this list is not intended to be all inclusive. "Personnel Training and Evaluation in Aseptic Manipulation Skills "Compounding personnel shall perform didactic review and pass written and media-fill testing of aseptic manipulative skills initially, at least annually thereafter for low- and medium-risk level compounding, and semiannually for high-risk level compounding. "Immediate-use CSPs "The immediate-use provision is intended only for those situations where there is a need for emergency or immediate patient administration of a CSP. "Immediate-use CSPs are not intended for storage for anticipated needs or batch	L 100		

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compounding. Preparations that are medium-risk level and high risk level CSPs shall not be prepared as immediate-use CSPs.

"1. The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturer's original containers and not more than two entries into any one container of package (e.g., bag, vial) of sterile infusion solution or administration container/device.

"4. Administration begins not later than 1 hour following the start of the preparation of the CSP.

"6. If administration has not begun within 1 hour following the start of preparing the CSP, the CSP shall be promptly, properly, and safely discarded.

"Single-Dose and Multiple-Dose Containers

"Opened or needle-punctured single-dose containers, such as bags, bottles, syringes, and vials of sterile products and CSPs shall be used within 1 hour if opened in worse than ISO Class 5 air quality, and any remaining contents must be discarded. Single-dose vials exposed to ISO Class 5 or cleaner air may be used up to 6 hours after initial needle puncture. The BUD after initially entering or opening (e.g., needle-punctured) multiple-dose containers is 28 days unless otherwise specified by the manufacturer.

"Stability

"Syringes -Diazepam 5 milligrams/milliliter (mg/ml) was filled into ...plastic syringes and

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stored. Diazepam concentration losses, presumably due to sorption to surfaces and/or the elastomeric plunger seal, ranged from 6% ... to 1 %. Long-term storage for seven days...resulted in losses of 4 to 8 % and 5 to 13 %..."

2005 Mosby's Nursing Drug Reference book:
Page 350
IV route- into large vein; give IV 5mg(milligrams) or less/ 1 minute or total dose over 3 minutes or more.
Diazepam(Valium) use IV only, within 6 hours, flush line after use...
Page 864
Promethazine(Phenergan) IV route- after diluting each 25-50 mg/9ml(milliliter) of NACL(sodium chloride) for injection; give 25 mg or less/2 minutes.

Clinic Observations:

During a tour of the clinic 11/03/09 the surveyors observed an unlocked drawer with four 15ml syringes filled with a clear liquid, two of the syringes had spinal needles attached to them. The syringes were in a biohazard ziplock bag with a sticker on the outside of the bag dated 9/29/09. The Administrator was asked what was in the syringes and stated Lidocaine 1%. He stated that they had been previously told if the bag was labeled they did not have to label each syringe. The Administrator was asked how long the clinic kept the medications before using and was unable to give a time limit.

The surveyor observed a narcotic count with the Registered Nurse (RN) 11/04/09 and during the count observed five syringes in a ziplock bag in the bottom of the container which held the narcotics. The ziplock bag had a label on the

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L 100	Continued From page 7 outside with 10/31/09 documented. The surveyor asked the RN what was in the syringes and when they had been prefilled. She stated that they had Demerol 50 mg, Phenergan 25 mg, and Valium 10mg in the syringes diluted with saline that she had drawn up Saturday the 31st of October but did not use. The surveyor asked the RN how long she kept medication like that drawn up before using and the RN was unable to give any specific time frame. On 11/04/09 the Registered Nurse (RN) was observed drawing up Valium 5 milligrams/milliliter (ml), Demerol 50 mg/ml and Phenergan 25 mg/ml into 10 cc syringes and diluted with Normal Saline (NS). The Normal Saline was drawn from a 500 cc bag in which the rubber stopper on the NS bag was accessed with each of the nine syringes. A total of nine syringes with the mixture of medications were placed in a clear zip-lock bag with a label on the outside of the bag that had the date and initials of the RN who prepared the medications. The pre-filled syringes were placed in a locked medication container and stored for later use. A review of medical records showed consistent documentation by the RN of Valium 10mg, Demerol 50 mg, and Phenergan 25 mg given IV push as sedation and the time given. There was no time period the medication was administered over. The pre-filling of the syringes and administration of the medications were not in accordance with the manufacture recommendations or United States Pharmacopeia (USP) 797.	L 100		