**Missouri Department of Health and Senior Services**
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**Peter Lyskowski**
Director

**Jeremiah W. (Jay) Nixon**
Governor

November 2, 2016

Vicki Casey (vicki.casey@ppgreatplains.org )
Comprehensive Health of Planned Parenthood Great Plains
711 North Providence Road
Columbia, Mo 65203

Re: Comprehensive Health of Planned Parenthood Great Plains – Columbia Survey

Dear Ms. Casey:

The Department received the application for licensure of the Columbia Planned Parenthood location as an abortion facility. Department staff conducted an onsite survey of the location on October 11, 2016 to determine compliance with the terms of the 2010 settlement agreement and applicable statutes and regulations, including the Ambulatory Surgical Center Licensing Law (Section 197.200, RSMo, et seq.) and Chapter 188, RSMo (Regulation of Abortions).

Listed below are items the survey indicated were not in compliance. Until a written response is provided describing how all items below have been addressed, including acceptable evidence of compliance, an abortion facility license cannot be issued.

***19 CSR 30-30.060(1)(B) 12. The administrator shall be responsible for ensuring that the provisions of Chapter 188 RSMo, Regulation of Abortions, are adhered to.***

- Sections 188.027 and 188.080, RSMo, require that all physicians performing or inducing abortions have clinical privileges at a hospital which offers obstetrical or gynecological care located within thirty miles of the location at which the abortion is performed or induced. Neither of the facility's two physicians had the required privileges.
- Section 188.047 requires that tissue removed at the time of the abortion be submitted to a pathologist for necessary reporting. The facility did not have a finalized agreement with a pathologist to provide the required services.

***19 CSR 30-30.060(1)(C)4. Physicians performing abortions at the facility shall have staff privileges at a hospital within fifteen (15) minutes' travel time from the facility or the facility shall show proof there is a working arrangement between the facility and a hospital within fifteen (15) minutes' travel time from the facility.***

- The facility did not have a documented working arrangement with a hospital within the required proximity.
- Neither of the facility's two physicians had the required privileges.

***19 CSR 30-30.060(1)(C)1. The medical staff shall develop and, with the approval of the governing body, shall adopt policies governing physician activities in the abortion facility. Medical staff membership shall be limited to physicians.***

- The facility policy failed to limit medical staff membership to physicians. The policy stated that advance practice registered nurses could be a member of the medical staff.

***19 CSR 30-30.060(1)(C)3. The governing body, acting upon recommendations of the medical staff, shall approve or disapprove appointments. Written criteria shall be developed for privileges extended to each member of the staff. A formal mechanism shall be established for recommending to the governing body delineation of privileges, curtailment, suspension or revocation of privileges and appointments and reappointments to the medical staff.***

- The facility had two physicians on staff. Not all components of a fully credentialed file had been completed for the physicians, including a formal approval of internal facility privileges, appointment to the medical staff, a National Practitioner's Data Bank check, or certifications from BNDD or DEA.

***19 CSR 30-30.060(1)(B)8. The facility shall establish a program for identifying and preventing infections and for maintaining a safe environment.***

- The facility failed to demonstrate compliance with facility's established Infection Prevention Program, based on Association for the Advancement of Medical Instrumentation standards.
    - The facility did not maintain an autoclave log with the required components tracked (lot number, specific contents of the lot or load, exposure time and temperature, name and initials of the operator, results of biological testing).
    - The facility failed to have the supplies necessary for high level disinfection of vaginal ultrasound probes.

***19 CSR 30-30.060(3)(J). Each abortion facility shall develop a quality assurance program that includes all health and safety aspects of patient care and shall include a review of appropriateness of care. Results of the quality assurance program shall be reviewed at least quarterly by the administrator, director of patient care, a representative of the medical staff and the governing body.***

- The facility did not have a quality assurance program specific to their facility that included the required elements. Facility staff indicated a system-wide QAPI program that had removed elements required by Missouri rules some time before:
    - Intraoperative and postoperative complications
    - All cases that resulted in a length of stay of more than twelve (12) hours, and
    - All cases in which the gestational age was determined to be beyond eighteen (18) weeks.

***19 CSR 30-30.060(3)(K). The quality assurance program must show evidence of action taken as a result of the identification of the problems.***

- The facility program did not show identification of problems or follow-up of problems.

***19 CSR 30-30.060(4)(C). All tissue obtained from abortions, except tissue submitted to a pathologist for analysis, shall be submerged in a preservative solution and shall be transported in a leakproof container to a facility with a waste sterilizer or an incinerator approved by the Department of Natural Resources. If kept for more than twelve (12) hours, all tissue shall be refrigerated.***

- The facility failed to produce a final agreement with a pathologist.
- The facility did not have a preservative solution onsite.
- The facility did not have an agreement, approved by the Department of Natural Resources, with a waste sterilizer.
- The facility could not demonstrate whether adequate refrigeration space was available for preservation.

***19 CSR 30-30.060(4)(E). Anti-Rh immune globulin therapy shall be given to all Rh negative patients upon completion of the abortion procedure.***

- The facility failed to stock the required anti-Rh immune globulin.

***19 CSR 30-30.060(3)(I). An emergency tray equipped to treat seizures, bleedings, anaphylactic shock, respiratory arrest and cardiac arrest shall be immediately available to the procedure room and recovery room.***

- The facility had two lists of supplies, one for medical and one for surgical abortion procedures. Some necessary medications and supplies were not onsite or had not yet been ordered for either type of procedure (including filter needles, one milliliter syringes, and cervical needles from the surgical supply list).

***19 CSR 30-30.070(2)(N). The recovery room . . . shall be of sufficient size to accommodate at least four (4) recovery beds or recliners for each procedure room. There shall be three feet (3') of clear space on both sides and at the foot of each recovery bed or recliner.***

- Required space within the recovery room is not sufficient for at least four (4) recliners with three feet of clear space on both sides and at the foot of each recovery recliner. When this location was previously licensed in 2015, the facility had requested and been granted a variance for three (3) recliners. However, at that time the facility was only approved to provide medication procedures. It is now the facility's intent to also perform surgical procedures. The letter from the department dated July 15, 2015 states that the variance "will remain in effect until there is a change in procedure type performed at [the facility.]" The facility may submit a revised variance request in writing in accordance with 19 CSR 30-30.070(1).

***19 CSR 30-30.070(2)(X). A patient toilet with lavatory shall be located convenient to the recovery room. This room shall be equipped with a constant running exhaust.***

- The toilet room next to the recovery room has an exhaust fan which runs only when the light to the room is turned on and is activated by the same switch. A constant running exhaust in the patient toilet facility is specifically required in the 2010 settlement agreement (page 17).

Please respond in writing providing evidence/documentation that each of these items has been fully addressed and corrected.

If you have further questions, you may contact our office at 573-751-6083 or via email at the address noted below.

Sincerely,

John Langston, Administrator
John.Langston@health.mo.gov
Bureau of Ambulatory Care
Missouri Department of Health & Senior Services