Approved 4/03/18

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FORM APPROVED

Ohio Dept Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	0286AS	A. BUILDING: _____ B. WING _____	01/18/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD SOUTHWEST OHIO I	2314 AUBURN AVENUE CINCINNATI, OH 45219

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C 000	Initial Comments Licensure Compliance Inspection Complaint Inspection Complaint Number OH00095591 Administrator: Jerry Lawson County: Hamilton 3 Procedure Rooms The following violations are issued as a result of the Licensure Compliance Inspection completed on 01/18/18. No violations were cited in regard to the Complaint Inspection, Complaint Number OH00095591, completed on 01/18/18.	C 000		
C 132	O.A.C. 3701-83-09 (D) Infection Control Policies & Procedures Each HCF shall establish and follow written infection control policies and procedures for the surveillance, control and prevention and reporting of communicable disease organisms by both the contact and airborne routes which shall be consistent with current infection control guidelines, issued by the United States centers for disease control. The policies and procedures shall address: (1) The utilization of protective clothing and equipment; (2) The storage, maintenance and distribution of sterile supplies and equipment; (3) The disposal of biological waste, including blood, body tissue, and fluid in accordance with	C 132	C 132 Response: At the time of the survey, PPSWO had a policy for sterilizing the aspirator, a piece of equipment that does not enter the body. PPSWO's policy explained how to clean and sterilize the aspirator. At the time of the survey PPSWO followed its policy and cleaned and sterilized the aspirator accordingly. In the many years PPSWO has used the aspirator cleaning and sterilization procedures, there have been no reported infections; nor have ODH surveyors found a deficiency.	

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C 132	Continued From page 1 Ohio law; (4) Standard precautions/body substance isolation or equivalent; and (5) Tuberculosis and other airborne diseases. This Rule is not met as evidenced by: Based on observations, staff interview and review of manufacturers instructions, the facility failed to ensure devices were re-processed per the manufacturer's directions. This had the potential to affect any patient receiving services at the facility. The facility had an annual census of 3,186 patients. Findings include: Observations were made on tour of the patient care areas, including the waiting room, education room, procedure rooms and reprocessing room on 01/16/18 beginning at 9:00 AM. The re-processing room was located on the first floor. The reprocessing room had storage cabinets and drawers for the surgical instruments used for all procedures, three open shelves, two steam sterilization devices, and an L-shaped counter with sinks. One item in the storage cabinet was a white plastic aspiration device, used for manual vacuum aspiration of products of conception, for patients diagnosed with a nine week or less gestation period. Six of these aspiration devices were observed in a tray on a shelf in a storage cabinet in the room.	C 132	C 132 - Plan of Correction As of February 6, 2018, PPSWO changed its policy and procedures for cleaning and sterilizing the aspirator to follow the most recent version of the manufacturer's instructions, which were obtained by PPSWO and given to ODH during the survey visit. In addition, PPSWO will employ a consultant to review the manufacturer's instructions to ensure they, and PPSWO's revised policies and procedures, are consistent with the current infection control standards. The new policies and procedures are attached. All relevant staff will complete training as of February 16, 2018.	2/6/18

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C 132	Continued From page 2 The devices were white plastic, with the appearance of an extra large syringe and review of a manufacturer insert diagram revealed it had seven pieces, including a plunger, a plunger O-ring, a valve, a cap, a cylinder, a liner and a collar stop. In an interview during the tour on 01/16/18 at 9:00 AM Staff C stated the six devices in the storage cabinet tray were clean, not sterile, and each item had been re-processed and was ready for re-use. Staff C provided a manufacturer instruction brochure that was packaged with each device. In an interview on 01/17/18 on a second tour of the re-processing area Staff C stated the aspiration devices were disassembled and placed unwrapped in a steam autoclave at 270 degrees Fahrenheit for three minutes. Review of the manufacturer insert dated 03/2010 for the product revealed reprocessing procedures involved disassembly of the device, and placing the components, unwrapped, not touching each other, in a steam sterilizer at 250 degrees Fahrenheit for 30 minutes. A second, updated manufacturer insert was provided on 01/18/18 at 8:55 AM and revealed the aspiration device re-processing procedure was "Steam autoclave at 121 degrees Celsius/ 250 degrees Fahrenheit for 30 minutes. Place disassembled Ipas MVA Plus (aspirator device) on linen, paper, or other autoclave compatible pouch with biological indicator. Steam must penetrate all surfaces. Parts should not touch and should be arranged so openings are not obstructed, permitting drainage." In an interview on 01/17/18 at 12:50 PM Staff A and Staff B confirmed that the facility's method for	C 132		

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C 132	Continued From page 3 re-processing the aspiration device was 270 degrees Fahrenheit for three minutes. Staff A and Staff B acknowledged that the manufacturer's insert instructions for re-processing was for steam sterilization at 250 degrees Fahrenheit for 30 minutes. Staff B said the aspiration device had been in use at the clinic for "many years." In an interview on 01/18/18 at 8:55 AM with Staff A, Staff B, and Staff D presented updated manufacturer's instructions, which revealed guidance for re-processing of the device at 250 degrees Fahrenheit for 30 minutes, unchanged from the 03/2010 version of the manufacturer's insert.	C 132		
C 133	O.A.C. 3701-83-09 (E) Equipment Maintenance The HCF shall maintain equipment in a safe manner and in accordance with the manufacturer's instructions. This Rule is not met as evidenced by: Based on observations, staff interview and review of manufacturer instructions, the facility failed to ensure devices were monitored related to re-use. This violation had the potential to affect any patient receiving services at the facility. The facility had an annual census of 3,186 patients. Findings include: Observations were made on tour of patient care areas, including the waiting room, procedure rooms and reprocessing room beginning on 01/16/18 at 9:00 AM. The re-processing room	C 133	C 133 Response: PPSWO has maintained the aspirators in a safe manner and tested the aspirators after processing in accordance with the manufacturer's instructions for all the years it has used the aspirator brand in question. The manufacturer instructs that aspirators should be discarded and replaced if they fail a test to determine when parts become brittle, cracked, broken, or unable to be locked or hold a vacuum. The manufacturer instructions state that the number of uses can be "expected to be up to 25. Actual number of uses may vary." PPSWO performed the post processing tests on each aspirator part and discarded any aspirator that failed the testing.	

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C 133	Continued From page 4 was located on the first floor. The reprocessing room had an L-shaped counter with sinks, storage cabinets, two steam sterilizers, and drawers for the surgical instruments used for all procedures. One item was a white plastic aspiration device, used for manual vacuum aspiration of products of conception, for patients diagnosed with a nine week or less gestation period. Six of these devices were observed in a tray on a shelf in a storage cabinet in the room. The devices were white plastic, with the appearance of an extra large syringe, and review of a manufacturer insert diagram revealed it had seven pieces, including a plunger, a plunger O-ring, a valve, a cap, a cylinder, a liner and a collar stop. Review of the manufacturer insert for the product revealed "when aspirators are processed using the recommended methods, the number of uses can be expected to be up to 25. Actual number of uses may vary." In an interview during the tour on 01/16/18 at 9:00 AM Staff C said the six devices in the storage cabinet tray were clean, not sterile, and each item had been re-processed and was ready for re-use. Staff C showed there were also new, still packaged devices, that were in a box in the storage cabinet. The device packages were labeled "Ipas MVA Plus." Each new device was packaged in clear plastic with an exterior label on the packaging, but no distinct markings on the device itself to distinguish one from another. Once opened, used and re-processed the devices were placed in the storage cabinet or in a procedure room drawer until used again. In an interview on 01/17/18 Staff C said that the re-processed aspirators were kept in the storage	C 133	The manufacturer does not recommend, nor instruct, that a tracking system be used. PPSWO estimates no aspirator was used more than a dozen times. In the many years PPSWO has tested the aspirators after processing to determine if they needed to be replaced, there have been no reported infections; nor have ODH surveyors found a deficiency. C 133 - Plan of Correction As of February 16, 2018, in addition to PPSWO continuing to follow the manufacturer's instructions for testing aspirators after processing, it has added a tracking system. The tracking system will allow PPSWO to count the number of uses per aspirator so none are used more than 25 times. The new policy and procedure and tracking log are attached. All relevant staff will complete training as of February 16, 2018. The Administrative Director of Surgery will ensure compliance with this Plan of Correction. Surgery Director 4/3/18	2/16/18

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C 133	Continued From page 5 cabinet in the re-processing room, and in each of two procedure rooms, in a drawer, available for use. Staff C said the items were kept in use until the item failed to pass a post processing inspection where each was evaluated for such things as function related to holding a vacuum, cracks or malfunction of operation. There was no identification or tracking system to monitor how many times each had been used. The post processing evaluation was conducted by the reprocessing technician after steam sterilization and reassembly of the device. If a device failed to pass inspection, it was disposed as medical waste. Interview with Staff B at 11:38 AM revealed the aspiration devices were used for patients under nine weeks gestation, with an estimated use amount of 15-20 patients per week. Interview with Staff C on 01/17/18 at 11:39 AM revealed the items did not have any distinct marking or identification method to track the use for each device. Staff C said the determination of the quality of each device was made in each post re-processing inspection, the facility was not tracking or documenting the number of uses for each device. On 01/18/18 at 9:18 AM Staff A confirmed the facility did not track the devices for numbers of uses.	C 133		