PLANNED PARENTHOOD - GLENDALE

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Health Survey Comments

The following deficiency was found during the unannounced, onsite State Compliance Survey conducted on 1/13/20, 1/16//20, and 1/24/20. Based on the rules found in R9-10 Article 10-Outpatient Treatment Centers, and R9-10 Article 15 Abortion Services, the Department is approving the facility to continue operations as an Outpatient Treatment Center providing Reproductive Health Services which includes: Medication Services, Clinical Laboratory Services, Diagnostic Imaging, Physical Health Services, and Abortion Services (medical and surgical). Margaret Ohton, RN - Healthcare Compliance Surveyor - 01/29/2020

Findings Report Summary

Findings for: Citation 1 **Corrected Date:** 04/22/2020	**Rule/Statute:** Infection Control **Rule Text:** R9-10-1028. Infection Control An administrator shall ensure that: 3. Policies and procedures are established, documented, and implemented to protect the health and safety of a patient that cover: a. If applicable: iii. Sterilization and disinfection of medical equipment and supplies;	**Survey Text:** **R9-10-1028.3.a.iii**~ Based on review of facility policy and procedures, document review, and staff interviews, the Department determined the administrator failed to ensure that the staff followed facility policy and procedure when obtaining, submitting, and receiving the weekly biological spore tests results for the two autoclaves (A. Ritter and B. Tuttnauer) in use at the facility. Failure to perform and follow up on the biological spore testing poses a potential risk of cross contamination and infection to their patients. Findings include: Review of policy and procedure "Sterilization Cycle" dated October 2014 revealed: "...Quality control test are to be performed weekly and the result logged on the autoclave log...Spore test written results will be returned to the health center from...contracting laboratory...The reports are to be filed on site and the results must be logged on the autoclave log...This log will be audited quarterly..."Sterilization" dated October 2014 revealed: "...Sterilization completely kills or eliminates all microorganisms...." Review of the "Weekly Biological Spore Test Record" revealed: "...Directions: Spore Testing should be conducted weekly on the same day of the week...The person sending out the test must document by initialing the date they sent the spore test out and the person recording the results should also document the date and their initials...Test Results can be viewed anytime by going to www.CheckYourtest.com...Tests that read as

FAILED require Center Manager Notification and follow up documentation...." Review of policy and procedure "Management of Positive Biological/Spore Test Indicators in a Steam Sterilizer" revealed: "...If spore tests are positive indicating growth...Clinical staff must...Immediately check the autoclave for proper use and function and repeat the spore test...Discontinue use of the autoclave...Immediately notify center manager immediately...Remove all sterilized packs from inventory dated after the last negative spore test result...Use alternative equipment (e.g. Disposable speculum)...Call for service...When repair is completed, rerun biological spore test prior to sterilizing equipment for use...Place service report in the compliance log...." Review of the Contracting Laboratory's procedure for testing and returning results revealed: "...All spore tests are processed the same day our lab receives them to ensure that results are known as soon as possible...website allows all our customers to check the results of their spore tests on a daily basis...All negative spore tests (passed) are recorded, and lab reports are sent out either by fax or mail...In the event of a positive spore test (failure), the lab performs a Gram stain to validate the result...This is done to verify that the growth was indeed caused by sterilizer malfunction and not from any outside contamination...A confidential phone call is immediately made to notify the customer of the failure and to provide them with technical support per CDC (Center for Disease Control) guidelines...Pass...No spore growth observed in TEST strip after required incubation...Growth observed in CONTROL strip...Fail...Gram stain confirmed spore growth observed in TEST strip and CONTROL strip...." A. RITTER APRIL-AUGUST 2019: Review of weekly facility "Biological Spore Test Record" from 4/2/19 through 8/13/19 revealed: "...4/2/19, 4/9, 4/16, 4/23, 4/30/19... 5/7/19, 5/14, 5/21, 5/28/19... 6/4/19, 6/11, 6/18, 6/25/19... 7/2/19, 7/9, 7/16, 7/23, 7/30/19... 8/6/19, and 8/13/19...." The "Sterilizer Test Report" from the contracting laboratory revealed the above spore test samples were received at the testing laboratory on 9/9/19 with a pass date of 9/10/19. Center Manager #8 verified, during an interview conducted on 1/13/20, that the autoclave was in continuous use from 4/2/19 through 8/13/19. Center Manager

#8 verified, during an interview conducted on 1/13/20, that there was no explanation as to why the contracting laboratory identified receipt of the above spore test samples as being received as late as 34-160 days after samples were obtained. Center Manager #8 verified, during an interview conducted on 1/13/20, that the Ritter autoclave was in full use throughout the testing time period of 4/2/19 through 8/13/19. Center Manager #8 verified, during an interview conducted on 1/13/20, that the facility has been having difficulty obtaining spore test results from the contracting laboratory. Review of the "Sterilization Monitoring Service" receipt from "CheckYouTest.com", provided by Center Manager #8, from the contracting laboratory, has documented biological spore test samples submitted for 1/3/19 through 2/25/19. There is no registration of biological spore test samples submitted after 2/12/19 for the Ritter autoclave. Center Manager #8 verified during an interview on 1/13/20, that there was no explanation for the lack of documentation indicating there were no biological spore test samples submitted to the contracting laboratory from the facility after 2/12/19. Center Manager #8 verified, during an interview conducted on 1/13/20, that the quarterly reports for the weekly spore tests and results have been audited. There is no evidence of corrective active taken addressing the above discrepancies. RITTER OCTOBER 2019: Review of the facility "Weekly Biological Spore Test Record" dated from 10/1/19 through 10/29/19 revealed: "...Week...Test Date Sent Out...Test Date Received...Results ...10/1/19... 10/6/19... ____ ... ____ ...10/8/19... 10/9/19... ____ ... ____ ...10/15/19... 10/21/19... ____ ... ____ ...10/22/19... 10/25/19... ____ ... ____ ...10/29/19... 10/30/19... ____ ... ____...." Center Manager #8 verified, during an interview conducted on 1/13/20, that the above documentation identified no weekly spore test results have been obtained for the month of 10/2019. The monthly audit has been signed off by Center Manager #8. Review of the contracting laboratories printed results from their website "Checkyourtest.com" revealed no weekly spore testing samples were submitted by the facility for analysis for 10/2019. Review of the facility autoclave form "Sterilized Instrument Cycle Log" revealed the autoclave was in use from 10/1/19 through 10/30/19 sterilizing

unwrapped instruments and pouches. RITTER NOVEMBER 2019: Review of the facility "Weekly Biological Spore Test Record" dated from 11/5/19 through 11/26/19 revealed: "...Week...Test Date Sent Out...Test Date Received...Results ...11/5/19... 11/8/19... ____..____ ...11/12/19... 11/15/19... ____ ...____ ...11/19/19... 11/26/19... ____ ...____...." Center Manager #8 verified, during an interview conducted on 1/13/20, that the above documentation identified no weekly spore test results had been obtained for the month of 11/2019. The monthly audit had been signed off by Center Manager #8. Review of the contracting laboratories printed results from their website "Checkyourtest.com" revealed no weekly spore testing samples were submitted for analysis for 11/2019. RITTER DECEMBER 2019: Review of the facility "Weekly Biological Spore Test Record" dated from 12/3/19 through 12/30/19 revealed: "...Week...Test Date Sent Out...Test Date Received...Results ...12/3/19... 12/6/19... _____ ...____ ...12/10/19... 12/15/19... _____... ____ ...12/17/19... 12/22/19... _____ ... ____ ...12/24/19... 12/27/19... _____ ... ____ ...12/30/19... 1/3/2020... _____ ... ____...." Center Manager #8 verified, during an interview conducted on 1/13/20, that the above documentation identified no weekly spore test results had been obtained for the month of 12/2019. The monthly audit had been signed off by Center Manager #8. Review of the contracting laboratories printed results from their website "Checkyourtest.com" revealed no weekly spore testing samples were submitted for analysis for 12/2019. Review of the facility Midmark (Ritter) autoclave form "Sterilized Instrument Cycle Log" revealed the autoclave was in use from 12/2/19 through 12/31/19 sterilizing unwrapped instruments and pouches. RITTER JANUARY 2020: Review of the facility "Weekly Biological Spore Test Record" dated from 1/7/2020 through 1/21/2020 revealed: "...Week...Test Date Sent Out...Test Date Received...Results...Corrective Action/Solution if Failed ...1/7/20... 1/7/20... _____ ... ____ ... Not in Service ...1/14/20... 1/20/20... _____ ... ____ ... Not in Service ...1/21/20... 1/23/20... _____ ... ____ ... Not in Service...." Review of the facility Midmark (Ritter) autoclave form "Sterilized Instrument

Cycle Log" revealed: "...Date (month/day/year)...Program (...Unwrapped...)...Temp...Pressure (psi) ...01/07/2020... Unwrapped... 270... 27.1 ...01/14/2020... Unwrapped... 270... 27.1 ...01/21/2020... Unwrapped... 270... 27.1...." Center Manager #8 verified, during an interview conducted on 1/13/20, that the Midmark autoclave was primarily used to sterilize vaginal speculums. Center Manager #8 verified, during an interview conducted on 1/13/20, that the above documentation identified no weekly spore test results had been obtained for the month of 1/2020. Center Manager #8 verified, during an interview conducted on 1/13/20, that documentation of the "Weekly Biological Spore Test Record" revealed weekly documentation on the form that the autoclave was "...Not in service...." There is no further documentation as to why this autoclave was taken out of service and weekly samples were sent to the contracting laboratory. Review of the contracting laboratories printed results from the website "Checkyourtest.com" revealed no weekly spore testing samples were submitted for analysis for 12/2019. Center Manager #8 verified, during an interview conducted on 1/13/20, that the Ritter autoclave was not out of service for the month of 1/2020, as documented on the "Weekly Biological Spore Test Record" form. B. TUTTNAUER: Review of the facility Tuttnauer "Weekly Biological Spore Test Record" dated 7/2019 revealed: "...Week...Test Date Sent Out...Test Date Received...Results...If 'FAILED', CM Notified?... 1- 7/2/19... Tuesday...7/2/19... 7/23/19... Fail... YES...Service Notified: YES... 2- 7/9/19... Wednesday...7/10/19... 7/25/19... Pass... 3- _____... Tuesday...7/16/19... 9/30/19... Pass... 4- _____... Tuesday...7/23/19... 8/8/19... Pass... 5- _____... Tuesday...7/30/19... 8/8/19... Pass...." Center Manager #8 verified, during an interview conducted on 1/13/20, that she was notified of the "Failed" spore test taken on 7/2/19, and returned on 7/23/19, but does not recall when she was notified. Center Manager #8 verified, during an interview conducted on 1/13/20, that there was no documentation that the Tuttnauer autoclave was taken out of service until a "Pass" spore test was received after 7/23/19. The "Pass" spore test result was obtained on 8/8/19, 16 calendar days later. Review of the contracting

laboratories printed results for spore test samples dated 6/25/19 through 8/6/19 on their website "Checkyourtest.com" revealed: "...Test Date...Date Received...Date Out...Results ...6/25/19... 7/23/19... 7/24/19...Pass ...7/2/19... 7/23/19... 7/24/19...Fail ...7/9/19... 7/25/19... 7/26/19...Pass ...7/23/19... 8/8/19... 8/9/19...Pass ...7/30/19... 8/8/19... 8/9/19...Pass ...8/6/19... 8/14/19... _____...Pending...." Center Manager #8 verified, during an interview conducted on 1/13/19, that there was no documentation that all the packs/pouches autoclaved after the last "Pass" spore test on 6/25/19, were removed from inventory and re-sterilized when the failed spore test result was returned on 7/23/19. Center Manager #8 verified, during an interview conducted on 1/13/20, that the clinic staff does not check the spore test results via a telephone call or through the consulting laboratory's website on a regular basis. Center Manager #8 verified, during interview conducted on 1/13/20, that the filed spore test was submitted on 7/2/19, results obtained on 7/23/19, and a spore test sample was re-submitted on the same day of 7/23/19. Center Manager #8 verified, during interview conducted on 1/13/19, that there was no documentation the autoclave was taken out of service, and/or if any repairs made to the autoclave before obtaining the 7/23/19 spore test. Review of the contracting laboratory's "Sterilizer Test Report" revealed: "...Test Date: 7/16/19...Dated Received...8/26/19...Results...INVALID 8/26/19... This test is INVALID as we received too many Test strips...Please retest ASAP (as soon as possible)...." Center Manager #8 verified, during interview conducted on 1/13/20, that the spore test (described above) was submitted on 7/16/19, and testing results from the contracting laboratory were not received until 8/26/19 (41 calendar days later). Review of the contracting laboratory "Sterilizer Test Report" revealed a second spore test sample was submitted on "...Test Date: 7/16/19...Dated Received...9/30/19...Results: PASS...10/1/19...." Center Manager #8 verified, during an interview conducted on 1/13/20, that there was no explanation as to why the staff did not check their contracting laboratory's online account for the 7/16/19 spore test results sooner than they received the result on 10/1/19 (77 calendar days later).

		Center Manager #8 verified, during interview conducted on 1/13/20, that there was no follow up with the contracting laboratory to determine what "...we received too many Test strips..." meant. Center Manager #8 verified, during interview conducted on 1/13/20, that the week after 7/9/19, that a second spore test was obtained on the Tuttnauer and sent out to laboratory on 7/16/19. These spore testing results were received in the facility on 9/30/19 (76 calendar days later). Center Manager #8 verified, during an interview conducted on 1/13/20 and 1/16/20, that the staff was not following the facility policy and procedure when obtaining, submitting, and receiving the weekly biological spore tests results for the two autoclaves (Ritter and Tuttnauer) in use at the facility.