Hope Medical Group for Women

September 25, 2018

[redacted]

Program Manager
Health Standards Section

RE: Annual Licensing Survey Plan of Correction (Amended)
State ID BO0004728

Ms. [redacted]

Please find attached the amended plan of correction we are submitting in response to the deficiencies cited during the survey of 8/16/18. Please note the PoC is a separate document following the statement of deficiencies.

Sincerely,

[redacted]

Administrator

Physical Location: 210 Kings Highway, Shreveport, LA 71104
24 hour telephone assistance (318) 221-5500 or (800) 448-5004 fax (318) 221-0432
website address: http://www.hopemedical.com

Health Standards Section

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	BO0004728	A. BUILDING: _____ B. WING _____	08/16/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOPE MEDICAL GROUP FOR WOMEN	210 KINGS HIGHWAY SHREVEPORT, LA 71104

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S 000	Initial Comments Re-licensing Survey and Complaint #LA00049010. No deficiencies cited as a result of Complaint #LA00049010.	S 000		
S 169	4425 - E-F Patient Med Records/Reporting Requirements E. Other Reports. The outpatient abortion facility shall maintain a daily patient roster of all patients receiving a surgical or chemically induced abortion. Patients may be identified corresponding to the patient's medical record. This daily patient roster shall be retained for a period of three years F. Reporting Requirements 1. The outpatient abortion facility shall maintain documentation to support that the outpatient abortion facility is compliant with all reporting requirements, including, but not limited to, the induced termination of pregnancy (ITOP) form and other documentation as required by federal, state, and local statutes, laws, ordinances, and department rules and regulations. 2. The outpatient abortion facility shall report in accordance with all applicable state laws for the reporting of crimes against a child that include but are not limited to: a. rape; b. sexual battery; c. incest; and d. carnal knowledge of a juvenile This Rule is not met as evidenced by: Based on record review and interview, the facility failed to ensure documentation was maintained to	S 169	[redacted], RN PM 9/28/2018	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE [redacted] TITLE Administrator (X6) DATE 9/7/18

S [redacted]

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S 169	Continued From page 1 support the facility was in compliance with the state statute requiring ITOP (Induced Termination of Pregnancy) reports to be signed by the attending physician and submitted to the Louisiana Department of Health within thirty days after the date of the abortion for 2 (Patients #6 and #7) of 15 (Patients #1 - #15) sampled patients. Findings: Review of LA RS 40:1061.21 Reports, revealed, in part: "C. All abortions reports shall be signed by the attending physician and submitted to the Louisiana Department of Health within thirty days after the date of the abortion..." Patient #6 Review of Patient #6's Induced Termination of Pregnancy (ITOP) report revealed Patient #6's Date of Termination of Pregnancy was 04/07/2018 and the Date Certified was 05/10/2018. Patient #7 Review of Patient #7's Induced Termination of Pregnancy (ITOP) report revealed Patient #7's Date of Termination of Pregnancy was 04/07/2018 and the Date Certified was 05/09/2018. During an interview on 08/15/2018 at 11:40 AM, S1Adm (Administrator) reviewed the ITOP report for Patient #6 and verified that Patient #6's ITOP report indicated the abortion procedure was performed on 04/07/2018. S1Adm verified the Date Certified on the ITOP report was	S 169		

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S 169	Continued From page 2 05/10/2018. S1Adm reviewed the ITOP report for Patient #7 and verified that Patient #7's ITOP report indicated the abortion procedure was performed on 04/07/2018. S1Adm verified the Date Certified on the ITOP report was 05/09/2018. She verified the facility failed to ensure the 30 day reporting requirements were met as specified by state statutes/LEERS (Louisiana Electronic Event Registration System) for Patients #6 and #7.	S 169		
S 243	4447 B Infection Control A. The outpatient abortion facility shall develop, implement, enforce, monitor, and annually review, with the approval of the medical director, written policies and procedures for preventing, identifying, reporting, investigating, controlling, and immediately implementing corrective actions relative to infections and communicable diseases of patients and personnel. At a minimum, the policies shall address: 1. alcohol based hand rub and hand hygiene; 2. use of all types of gloves; 3. decontamination of equipment between each patient use, including, but not limited to, chairs and procedure room tables; 4. linen cleaning, if applicable; 5. waste management including, but not limited to, the requirements of Part XXVII of LAC Title 51, Public Health/Sanitary Code; 6. environmental cleaning; 7. reporting, investigating, and monitoring of surgical infections; 8. sterilization procedures and processes, if applicable; 9. single use devices; 10. disinfecting procedures and processes; and	S 243		

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S 243	Continued From page 3 11. breaches of infection control practices. This Rule is not met as evidenced by: Based on reviews of record, policy and procedure, and staff interview, the outpatient abortion facility failed to ensure procedures and processes were implemented, enforced, and monitored related to Central Supply and Sterilization. Findings: During a tour of the facility and interview with S1Adm (Administrator) on 8/13/2018 beginning at 1:30 PM, S1Adm explained that the abortion facility utilized two autoclave machines for use in sterilization of re-usable equipment for surgical procedures. S1Adm explained that the abortion facility monitored the autoclave machines weekly, on various days of the week, by conducting spore testing using spore testing strips. S1Adm explained that the spore testing strips were mailed off to a laboratory for processing and results of the spore testing were then mailed back to the abortion facility. S1Adm said the facility's returned spore testing results were kept in her/S1Adm's office. S1Adm also said that the abortion facility had no failed spore test results. During a review of the facility's spore test results and interview with S1Adm on 8/14/2018 at 1:35 PM, S1Adm revealed that the facility did not have evidence of weekly spore testing as she	S 243		

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S 243	Continued From page 4 previously stated during facility tour on 8/13/2018. On 8/14/2018 at 4:30 PM, a review of the abortion facility's policy and procedure for sterilization revealed the following in part: Central Supply and Sterilization: III: Sterilizer Protocol: C. Biological Monitoring: which read in part: _____ (Abortion Facility's name) adheres to Center For Disease Control (CDC) guidelines to ensure non-disposable items that come in contact with patients are properly sterilized. Weekly testing is completed and submitted off site to (name of spore testing laboratory), and the results are kept on file in the administrator's office. Any problems identified by (name of spore testing laboratory) will be addressed as soon as reasonably practicable by the Administrator and appropriate personnel. 1. Instructions for Testing: read in part: Remove the blue test strip envelope and integrator from the mailer. After processing, place the test strip envelope back inside the mailer and seal. Complete all data on the mailer and send off to (name of spore testing laboratory) for culturing. If the spore test fails after reaching the laboratory we will be contacted immediately with recommendations per CDC. "Pass" results are mailed. On 8/15/2018 at 8:45 AM, an interview was conducted with S1Adm. S1Adm presented copies of the abortion facility's Sterilizer Test Reports (Spore Testing Results) from (name of spore testing laboratory) with resulting test dates since 05/05/2018. The reports contained documentation which read in part:	S 243		

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S 243	Continued From page 5 "Monitor sterilizers at least weekly by using a biological indicator with a matching control (i.e., biological indictor and control from the same lot number)." CDC Guidelines Dec. 19, 2003 (www.cdc.gov). "OSHA is relying on guidelines published by the CDC as a weekly recognized and accepted standard to be followed by employees in carrying out their responsibilities under Occupational Safety and Health Act." OSHA Technical Note No. 23 March 1, 1990 Please retain this report as verification that this office uses a Sterilization Monitoring Service as part of a formal Infection Control Program. During interview on 8/15/18 at 8:45 AM, S1Adm verified the abortion facility failed to implement policy and procedure for Central Supply and Sterilization by failing to have documentation of weekly Sterilizer Test Reports for the weeks of: May 27th - June 02, 2018, June 24th - 30, 2018, July 1st - 7th, 2018, and July 15th - 21, 2018.	S 243		

Plan of Correction (Amended)

S 169 4425 - E-F Patient Med Records/Reporting Requirements

Effective 8/20/18 Physicians providing abortion care at Hope Medical Group for Women will certify ITOPs within the required 30 days. In the event a physician has exceeded the 30 days, he or she will refrain from performing abortions until the certifications are current. The administrator will monitor pending ITOPs weekly and make appropriate schedule changes for physicians who are in violation.

No patients are known to have been affected by this prior deficiency.

S 243 4447 B Infection Control

Effective 8/20/18 weekly spore tests will be logged as they are completed and submitted (see attached log). The administrator will review and maintain completed logs on a weekly basis.

No patients are known to have been affected by this prior deficiency.

Midmark Log (Mark 1)

V200704

Month/ Year _____

1. Each day in use: Wipe down surface & chamber.
2. Weekly: Wipe down, drain & refill. Run spore test, record & sign.
3. Monthly: Drain, flush with Speed Clean and refill sterilizer.

Day	Drained, Cleaned & refilled	Test Started	Test Reviewed & Mailed	Comments	Signature
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
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30					
31					

In-service Record

Program Title: Spore Testing

Speaker: [redacted]

Date(s) and Time(s) of Presentation: 9/8/18 @ 12:00

Target Audience: Medical Assistants

Total Attendance:

Need for Program Identified By: Administration

Teaching Method Used: Lecture & Handouts

Attendance List

	Signature		Signature
1	[redacted]	16	
2		17	
3		18	
4		19	
5		20	
6		21	
7		22	
8		23	
9		24	
10		25	
11		26	
12		27	
13		28	
14		29	
15		30	

Remember:

Spore tests must be mailed. Pre-printed labels are specific to each sterilizer. DO NOT switch them. Before mailing be sure to fill in date & person testing.

If the integrator strip shows failure or incomplete you must immediately re-run the test to rule out a dud test.

Notify administrator immediately if there is a failure.

Be careful when removing packs and spore tests from the sterilizers. If the test is dropped it is contaminated.

Log every step!!!

Caring for Your M9 & M11 Sterilizer

WEEKLY

WARNING *- BE SURE THAT UNIT IS COOL WHEN CLEANING TO PREVENT POSSIBILITY OF BURNS.*

1. **CLEAN EXTERNAL SURFACES**

   (a) Wipe with a soft dry cloth and occasionally with a damp cloth and mild soap or detergent.

2. **CLEAN INTERNAL SURFACES**

   (a) Drain water from reservoir using drain tube located on front of unit.

   EQUIPMENT ALERT *- FAILURE TO CHANGE WATER PROMOTES GROWTH OF ALGAE IN RESERVOIR AND MAY CAUSE STERILIZER TO MALFUNCTION.*

   (b) Using a mild soap or **Speed-Clean Sterilizer Cleaner™** and distilled water, wash inside of chamber, trays, door gasket and door gasket mating surface. Examine door gasket for possible damage that could prevent a good sealing surface.

   (c) Refill reservoir with clean, distilled water.

MONTHLY

EQUIPMENT ALERT *- FAILURE TO FLUSH UNIT WITH* ***SPEED-CLEAN STERILIZER CLEANER ™,*** *OR USE OF* ***OTHER*** *STERILIZER CLEANERS MAY CAUSE SOME COMPONENTS IN UNIT TO FAIL PREMATURELY.*

1. **FLUSH SYSTEM**

   (a) Drain reservoir and fill with clean distilled water. Add 1 oz. of **Speed-Clean Sterilizer Cleaner ™** to a cool chamber.

   (b) Run one **POUCH** cycle. Instruments ***should not*** be sterilized while cleaning the sterilizer.

   (c) Drain cleaning solution from reservoir. Then, refill reservoir with clean, distilled water and run one **UNWRAPPED** cycle.

   (d) Drain reservoir and allow sterilizer to cool to room temperature.

   (e) Remove door and dam gaskets from gasket housing channel. Clean channel and gaskets using a mild soap or **Speed-Clean Sterilizer Cleaner ™** and clean, distilled water. A small stiff bristle brush will aid procedure. After cleaning gaskets, inspect for damage, shrinking, or swelling and replace if necessary. Press gasket into the channel and reinstall dam gasket.

   (f) Remove trays, tray rack, and tray plate. Pressing downward on top band of tray rack, pull upward on end of tray plate and slide assembly out of chamber.

   (g) Locate chamber filters on bottom and back of chamber. Grasp filter and pull outward while twisting slightly. (If necessary, a pair of pliers may be used). Filter may be cleaned with mild soap or **Speed-Clean Sterilizer Cleaner™** and clean, distilled water. A small stiff bristle brush or ultrasonic cleaner may be helpful to remove foreign objects from filter surface. Rinse filter with clean, distilled water. **NOTE - If cleaning methods do not effectively clean the filter, replacement may be necessary.** Reinstall filters by pressing inwards and twisting slightly.

   EQUIPMENT ALERT *- DO NOT OPERATE STERILIZER WITHOUT FILTERS IN PLACE.*

   (h) Wipe off trays, tray rack, and tray plate. Reinstall assembly by placing back edge of tray plate in chamber. Pushing downward on top of tray rack, slowly push assembly into chamber.

   EQUIPMENT ALERT *- ANGLED END OF PLATE MUST BE TOWARD BACK OF CHAMBER TO PREVENT INTERFERENCE WITH TEMPERATURE PROBE IN BACK OF CHAMBER.*

   (j) Fill the reservoir with clean, distilled water. Sterilizer is now ready for use

2. **PRESSURE RELIEF VALVE CHECK**

   Refer to the Installation and Operation Manual for this procedure.

Remember to ask your dealer for Speed-Clean Sterilizer Cleaner™ (#002-0396-00) or call 1-800-MIDMARK for information

Midmark Corporation
60 Vista Drive
PO Box 286
Versailles, Ohio 45380-0286
937-526-3662
Fax 937-526-5542
midmark.com

OVER FOR M9 / M11 OPERATION

Operating Your M9 & M11 Sterilizer

PRE PROGRAMMED OPERATION

STEP 1 Select and press the appropriate sterilization pre programmed button.

*{**NOTE:** Refer to Standard Cycle Parameters (below) to select the proper sterilization program time and temperature.}*

STEP 2 Press the **START** button.

***WARNING:** STOP BUTTON MAY BE DEPRESSED AT ANY TIME TO STOP OR INTERRUPT A CYCLE. GOODS MUST NOT BE CONSIDERED STERILE IF THIS OCCURS BEFORE THE DRY CYCLE BEGINS.*

PROGRAMMING

STEP 1 Press button 1 (1) or 2 (2).

STEP 2 Press **PROGRAM** (P) button.

*(**NOTE:** Sterilization temperature can be adjusted from a minimum of 230°F {110°C} to a maximum of 275°F{135°C})*

The (+) button **raises** temperature 1°.

The (−) button **lowers** temperature 1°.

*(**NOTE:** If **STOP** (▽) button is pressed anytime during the Programming Mode any settings entered will be aborted and programming will revert back to the original settings.)*

STEP 3 Press **PROGRAM** (P) button

*{**NOTE:** Sterilization time can be adjusted from a minimum of 3 minutes to a maximum of 90 minutes.}*

The (+) button **raises** time 1 minute.

The (−) button **lowers** time 1 minute.

STEP 4 Press **PROGRAM** (P) button

The (+) button changes venting to **FAST**

The (−) button changes venting to **SLOW**

STEP 5 Press **PROGRAM** (P) button

*(**NOTE:** Drying time can be adjusted from a minimum of 0 minutes to a maximum of 60 minutes.)*

The (+) Button **raises** time 1 minute.

The (−) Button **lowers** time 1 minute.

STEP 6 Press **PROGRAM** (P) Button

The display shows the new programmed settings for the button that was programmed 1 (1) Or 2 (2).

*(**NOTE:** The programmed settings entered are retained under that Program button (1 or 2). If power is interrupted or the unit is unplugged, the settings will be retained.)*

STANDARD CYCLE PARAMETERS

EQUIPMENT ALERT

Using an incorrect sterilization program could result in non-sterile goods and may damage instruments. Consult instrument manufacturer for specific sterilization instructions.

Unwrapped	270°F (132°C) 27.1 Psi (186 Kpa) Sterilize For3 Minutes Dry For30 Minutes	• Instruments loose on a tray • Open glass or metal canisters • Tubing not used in surgical procedures • Loose items manufacturers recommend for exposure at 270°F (132°C) *The sterility of unwrapped items is compromised on exposure to a non-sterile environment*
Pouches	270°F (132°C) 27.1 Psi (186 Kpa) Sterilize For5 Minutes Dry For30 Minutes	• Pouched or loosely wrapped instruments • Multiple layers of instruments separated by fabric • Wrapped trays of loose instruments • Tubing not used in surgical procedures • Wrapped items manufacturers recommend for exposure at 270°F (132°C)
Packs	250°F (121°C) 15 Psi (104 KPa) Sterilize For30 Minutes Dry For30 Minutes	• Textiles and surgical packs wrapped for sterilization • Items, except liquids, manufacturers recommend for exposure at 250°F (121°C) for 30 minutes
Handpieces	270°F (132°C) 27.1 Psi (186 KPa) Sterilize For6 Minutes Dry For30 Minutes	• Dental handpieces
1 2	Programmable User Defined 230°F (110°C) To 275°F (135°C) 6 Psi (41 KPa) To 31 Psi (214 KPa) 3 Min. To90 Min.	• Items appropriate for user's defined parameters **CAUTION** Temperatures below 250°F (121°C) should only be used disinfection unless otherwise recommended by manufacturer.