Reviewed on 04/16/20 by Melanie Purcell

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FORM APPROVED

Texas Health and Human Services Commission

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	130193	A. BUILDING: _____ B. WING _____	03/10/2020

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF GREATER TEXAS SURG	7989 WEST VIRGINIA STE 102 DALLAS, TX 75237

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T 000	Ambulatory Surgery Centers Note: The State Form is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be referred to the Office of the Texas Attorney General (OAG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately. An entrance conference was held with the facility Regional Director of Health Services and Health Center Manager on the morning of 03/09/20. The purpose and process of the licensure resurvey were discussed, and an opportunity given for questions. Continued licensure is recommended, with an approved plan of correction. An exit conference was held with the facility Regional Director of Health Services, Health Center Manager, and Regional Quality Manager on the afternoon of 03/10/20. Preliminary findings of the survey were discussed, and an opportunity given for questions.	T 000		
T 125	135.4(l) ASC OPERATION (l) An ASC that performs abortions shall adopt, implement and enforce a policy to ensure compliance with Health and Safety Code, Chapters 245 and 171, Subchapters A and B (relating to Abortion and Informed Consent). This Requirement is not met as evidenced by: Based on record review and interview the facility	T 125	Staff were reminded by the VP of RQM of the following requirement: If a patient is staying somewhere other than their home during their abortion procedure, staff must provide the patient with (1) the name and number of the hospital closest to where they are staying AND (2) the name and number of the hospital closest to their residence. This information was again reiterated to staff by the manager. RQM staff will audit for compliance in May 2020.	3/27/2020 May 2020

SOD - State Form

[redacted] Health 6/20

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

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T 125	Continued From page 1 failed to ensure that the facility to enforce a policy to ensure compliance with Health and Safety Code, Chapters 245 and 171, Subchapters A and B (relating to Abortion and Informed Consent). Findings included: The TEXAS HEALTH AND SAFETY CODE, TITLE 2. HEALTH, SUBTITLE H. PUBLIC HEALTH PROVISIONS, CHAPTER 171. ABORTION stated in part, "SUBCHAPTER A. GENERAL PROVISIONS... Sec. 171.0031. REQUIREMENTS OF PHYSICIAN; OFFENSE. (a) A physician performing or inducing an abortion: (2) shall provide the pregnant woman with: (A) a telephone number by which the pregnant woman may reach the physician, or other health care personnel employed by the physician or by the facility at which the abortion was performed or induced with access to the woman's relevant medical records, 24 hours a day to request assistance for any complications that arise from the performance or induction of the abortion or ask health-related questions regarding the abortion; and (B) the name and telephone number of the nearest hospital to the home of the pregnant woman at which an emergency arising from the abortion would be treated.... Review of facility medical records revealed the following: * 3 patients were from states outside of Texas (Patient #3 and 5). Patient 5#'s medical record	T 125		

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T 125	Continued From page 2 revealed the patient's home address was listed as in Colorado on her medical history this was confirmed on the driver's license provided. However the facility provided the name and phone number of a hospital located in Dallas. This is not the the name and phone number of nearest hospital to the home of the patient at which an emergency arising from the abortion would be treated. In an interview on 03/10/20 staff member #7 verified the above findings.	T 125		
T 218	135.9(j)(12) MEDICAL RECORDS IN A LICENSED ASC (j) The (ASC) shall include the following in patients' medical records: (12) evidence that the patient left the facility in the company of a responsible adult, unless the operating surgeon or advanced practice registered nurse, writes an order that the patient may leave the facility without the company of a responsible adult; and This Requirement is not met as evidenced by: Based on a review on medical records and interview, the facility failed to ensure the medical record contained evidence that the patient left the facility in the company of a responsible adult, unless the operating surgeon or advanced practice registered nurse, writes an order that the patient may leave the facility without the company of a responsible adult. Findings included: Facility based policy entitled, "Chapter 20:	T 218	Staff were reminded by the VP of RQM of the following requirement: Staff must ensure that there is documentation in the medical record that the patient left the facility in the company of a responsible adult, unless the physician writes an order that the patient can leave the facility without a responsible adult. This information was again reiterated to staff by the manager. RQM staff will audit for compliance.	3/27/2020 May 2020

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T 218	Continued From page 3 Recovery Area Care" stated in part, "20.2 Discharge Criteria... II. Patient must be discharged to the care of a responsible person who will accompany them home." Review of medical records revealed the following: * 5 out of 8 surgical abortion patients (Patients #1, 2, 3, 7, and 15) did not have the box checked on their discharge to indicate that they were "released to a driver". The above finding were verified in an interview with staff member #7 on 03/10/20.	T 218		
T 258	135.11(b)(11)(A-G) ANESTHESIA & SURGICAL SVCS IN A LIC ASC (11) A safe environment for treating surgical patients, including adequate safeguards to protect the patient from cross-infection, shall be assured through the provision of adequate space, equipment, and personnel. (A) Provisions shall be made for the isolation or immediate transfer of patients with communicable diseases. (B) All persons entering operating rooms shall be properly attired. (C) Acceptable aseptic techniques shall be used by all persons in the surgical area. (D) Only authorized persons shall be allowed in the surgical area. (E) Suitable equipment for rapid and routine sterilization shall be available to assure that operating room materials are sterile. (F) Environmental controls shall be implemented to assure a safe and sanitary environment. (G) Operating rooms shall be appropriately	T 258	The COO will engage a mechanical engineer to advise us as to what we need to do to resolve the problem and ensure that temperatures are maintained between 68 degrees F to 73 degrees F (20 to 23 degrees C) within the operating room suite and general work areas in sterile processing. Relative humidity should be maintained between 30% and 60% within the perioperative suite, including operating rooms, recovery area, cardiac catheterization rooms, endoscopy rooms, instrument processing areas, and sterilizing areas and should be maintained below 70% in sterile storage areas.	5/9/2020

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T 258	Continued From page 4 cleaned before each operation. This Requirement is not met as evidenced by: Based on review of facility documents, review of facility logs, and staff interview, the facility failed to ensure environmental controls were implemented to assure a safe and sanitary environment as the facility failed to maintain acceptable temperature and humidity throughout. Findings included: AORN (Association of Perioperative Registered Nurses) document titled "Perioperative Standards and Recommended Practices for a Safe Environment of Care" stated in part, "Temperature should be maintained between 68 degrees F to 73 degrees F (20 to 23 degrees C) within the operating room suite and general work areas in sterile processing. Relative humidity should be maintained between 30% and 60% within the perioperative suite, including operating rooms, recovery area, cardiac catheterization rooms, endoscopy rooms, instrument processing areas, and sterilizing areas and should be maintained below 70% in sterile storage areas. Low humidity increases the risk of electro static charges, which pose a fire hazard in an oxygen-enriched environment or when flammable agents are in use and increases the potential for dust. High humidity increases the risk of microbial growth in areas where sterile supplies are stored or procedures are performed. Humidity should be monitored and recorded daily using a log format or documentation provided by the HVAC (heating, ventilation, and air conditioning) system. Temperature should be monitored and recorded	T 258		

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T 258	Continued From page 5 daily using a log format or documentation provided by the HVAC (heating, ventilation, and air conditioning) system." Facility-based policy titled "Facilities and Environment" stated in part, "Temperatures and humidity ... B. Storage room, sub utility and autoclave room temperatures will be maintained at 59-80 degrees Fahrenheit. C. Operating room temperatures will be maintained at 68-73 degrees Fahrenheit with a humidity of 30-60% D. Recovery room temperatures will be maintained at 70-75 degrees Fahrenheit with a humidity of 30-60% ...F. ...Incident reports will be submitted for out of range readings." Review of the temperature and humidity logs on 3/9/20 for January through present of 2020 revealed they were consistently out-of-range in all their rooms (Storage Room, Sub-utility Room, Autoclave Room, OR 1, OR 2, OR 3 and Recovery Room). For example, on 1/15/20, all three OR rooms were too high in humidity at 67.8°, 69.9°, and 69.8°. On 2/14/20, all rooms were out-of-range: the temperature in the Storage Room, Sub-utility Room, Autoclave room, and Recovery room were too low at 54.1°, 54.2°, 54.6°, and 57.7°, respectively; while OR 1, OR 2 and OR 3 were too low in both temperature and humidity at 54.2° and 23.8%, 54.6° and 23.9%, and 54° and 23.1%, respectively. Review of the incident report dated 3/3/20 stated in part, "Dallas ASC had out range temps and humidities during the month of February for the following dates listed below: 2/3, 2/4, 2/5, 2/6, 2/7, 2/10, 2/11, 2/12, 2/13, 2/14, 2/18, 2/19, 2/20, 2/21, 2/24, 2/25, 2/26, 2/27, and 2/28." The	T 258		

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T 258	Continued From page 6 corrective action stated in part, "will continue to monitor and document when temperature is out of range." In an interview with staff #5 on 3/9/20 at 2:52 pm, they stated, "Yes, we have problems with our temp and humidity." When asked what happens when they're out of range, staff #5 stated, "Once a month we send out a report." When asked if anything was done in real time, staff #5 stated, "No." They went on to say their HVAC [heating, ventilation and air conditioning] people came out and attempted to fix the problem but were unable to and the facility was told to monitor and submit incident reports at the end of each month. In an interview with staff #12 on 3/9/20 at 3:12 pm, when asked how long they have had problems with temperature and humidity, staff #12 stated "It's been going on since we moved into this building ... about five years." The above was verified in an interview with administrative staff on the afternoon of 3/10/20.	T 258		
T 259	135.11(b)(12)(A-D) ANESTHESIA & SURGICAL SVCS IN A LIC ASC (12) Written policies and procedures for decontamination, disinfection, sterilization, and storage of sterile supplies shall be developed, implemented and enforced. Policies shall include, but not be limited to, the receiving, cleaning, decontaminating, disinfecting, preparing, and sterilization of critical items (reusable items), as well as for the assembly, wrapping, storage, distribution, and the monitoring and control of sterile items and equipment. (A) Policies and procedures shall be developed	T 259	Staff were reminded by the VP of RQM of the following requirement: Staff must sterilize hinged instruments in an open position. Gauze may not be used. This information was again reiterated to staff by the manager. RQM staff or HCM will audit for compliance.	3/27/2020 May 2020

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T 259	Continued From page 7 following standards, guidelines, and recommendations issued by the Association of periOperative Registered Nurses (AORN), the Association for Professionals in Infection Control and Epidemiology (APIC), the Centers for Disease Control and Prevention (CDC) and, if applicable, the Society of Gastroenterology Nurses and Associates (SGNA). Standards, guidelines, and recommendations of these organizations are available for review at the Department of State Health Services, Exchange Building, 8407 Wall Street, Austin, Texas. Copies may also be obtained directly from each organization, as follows: AORN, 2170 South Parker Road, Suite 300, Denver Colorado, 80231, (800) 755-2676; APIC, 1275 K Street, Northwest, Suite 1000, Washington, District of Columbia, 20005-4006, (202)789-1890; CDC, 1600 Clifton Road, Atlanta, Georgia, 30333, (800) 311-3435; SGNA, 401 North Michigan Avenue, Chicago, Illinois, 60611-4267, (312) 321-5165. (B) Policies and procedures shall also address proper use of external chemical indicators and biological indicators. (C) Performance records for all sterilizers shall be maintained for a period of six months. (D) Preventive maintenance of all sterilizers shall be completed according to manufacturer's recommendations on a scheduled basis. A preventive maintenance record shall be maintained for each sterilizer. These records shall be retained at least one year and shall be available for review to the facility within two hours of request by the department. This Requirement is not met as evidenced by: Based on review of facility-based policies,	T 259		

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T 259	Continued From page 8 observations, and staff interview, the facility failed to implement and enforce written policies and procedures for decontamination, disinfection, and sterilization. Findings included: Centers for Disease Control and Prevention (CDC) website article, "Guidelines for Disinfection and Sterilization in Healthcare Facilities, 2008" found at: <http://www.cdc.gov/hicpac/Disinfection_Sterilization/13_11sterilizingPractices.html>, stated in part, "Once items are cleaned, dried, and inspected, those requiring sterilization must be wrapped or placed in rigid containers and should be arranged in instrument trays/baskets according to the guidelines provided by the AAMI [Association for the Advancement of Medical Instrumentation] and other professional organizations. These guidelines state that hinged instruments should be opened ... Steam Sterilization ... The basic principle of steam sterilization, as accomplished in an autoclave, is to expose each item to direct steam contact at the required temperature and pressure for the specified time."" Facility-based policy titled "Sterilization of Critical Items" stated in part, "IV Guidelines for loading trays: A. Sterilizer loading is critical to effective sterilization. A proper load for a sterilizer is determined by the number of items to be sterilized, their characteristics, and how they are prepared and positioned within the sterilizer ... The sterilization process will be effective it items are properly prepared and positioned, so they get adequate contact with steam for the correct amount of time ... B. General guidelines: ...3. Sterilize jointed	T 259		

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T 259	Continued From page 9 instruments in an open, unlocked position with ratchets not engaged." Facility-based policy titled "Packaging Instruments" stated in part, "I. Packaging Instruments ... G. Items to be sterilized must be positioned in an open or unlocked position to allow sterilant contact with all surfaces. II. Disposable Peel Pouches 1. Place the instrument into the peel pack ... Items to be sterilized should be placed in the package in an open or unlocked position. For items with hinges, gauze should be used to hold the instrument open ... III. Wrapped Packs ...4. Instruments should be placed in opened, unlocked positions." Observation of the sub-sterile room on the afternoon of 3/10/20 revealed 13 hinged instruments in the closed position with gauze in the teeth of the instruments. During the tour on 3/10/20 in an interview with staff #8, a staff member responsible for sterilizing instruments, when shown the packs and asked if the instruments were closed with cotton gauze in between the teeth of the instruments, staff #8 stated, "Yes, they told us to do that. We put the gauze and clamp them shut." When asked what instruments were processed this way, staff #8 stated, "Scissors, forceps ... anything that is bigger than these [pointing at the small hemostats in the open position]." When asked if all instruments with hinges were processed this way, even those in the wrapped packs, staff #8 stated, "Yes." When asked about the gauze, staff #8 stated, "They prevent them [the instruments] from opening and puncturing the pack."	T 259		

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T 259	Continued From page 10 On the afternoon of 3/10/20 in an interview with staff #7, another staff member responsible for sterilizing instruments, when asked if hinged instruments were processed with gauze in the closed position, staff #7 stated, "Yes, but they should be open in the packs." When discussed staff #8 stated they were closed in the packs, staff #7 stated, "They should be open." Hinged instruments processed in the closed position does not allow for all surfaces to have direct steam contact, also the gauze between the teeth of instruments has the potential to retain moisture with possible bacterial growth; therefore, these closed instruments were processed ineffectively. The above was confirmed in an interview with administrative staff on the afternoon of 3/10/20.	T 259		