

Melanie Purcell, RN

Texas Health and Human Services Commission

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 130148	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 09/17/2020
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NAME OF PROVIDER OR SUPPLIER PLANNED PARENTHOOD SURGICAL HEALTH NORT	STREET ADDRESS, CITY, STATE, ZIP CODE 6464 JOHN RYAN DRIVE FORT WORTH, TX 76132
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T 000	<p>Ambulatory Surgery Centers</p> <p>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.</p> <p>An entrance conference was held with the facility Center Manager on the morning of 09/16/20. The purpose and process of the licensure resurvey were discussed, and an opportunity given for questions.</p> <p>Continued licensure is recommended, with an approved plan of correction.</p> <p>An exit conference was held with the facility Center Manager and other administrative staff on the afternoon of 09/17/20. Preliminary findings of the survey were discussed, and an opportunity given for questions.</p>	T 000		
T 120	<p>135.4(g) ASC OPERATION</p> <p>(g) When a majority of its members are physicians, the governing body, either directly or by delegation, shall make (in a manner consistent with state law and based on evidence of the education, training, and current competence of the physician) initial appointments, reappointments, and assignment or curtailment of medical privileges. When a majority of the members of the governing body are not physicians, the ASC's bylaws or similar rules and regulations shall specify a procedure for establishing medical review for the purpose of</p>	T 120	<p>The VP of RQM will continue to ensure that the PPGT Board convenes and that the meeting minutes clearly demonstrate the involved physician is reappointed for another two year term.</p> <p>To ensure continued compliance, the VP of RQM will review all PPGT Board meeting minutes to ensure documentation of all physician initial appointments and reappointments.</p>	11/16/2020

SOD - State Form

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

TITLE

(X6) DATE

9/30/2020

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T 120	<p>Continued From page 1</p> <p>making (in a manner consistent with state law and based on evidence of the education, training, and current competence of the physician) initial appointments, reappointments, and assignment or curtailment of medical privileges.</p> <p>This Requirement is not met as evidenced by: Based on a review of documentation and interview, the facility failed to ensure that the bylaws or similar rules and regulations that specify a procedure for establishing medical review for the purpose of making (in a manner consistent with state law and based on evidence of the education, training, and current competence of the physician) initial appointments, reappointments, and assignment or curtailment of medical privileges were implemented and enforced.</p> <p>Findings included:</p> <p>Facility based Medical Staff Bylaws stated in part, "C. Section C: Duration and Condition of Appointment 1. All initial appointments and reappointments to the Medical Staff of the ASC shall be made by the Board. The Board shall act on appointments, reappointments and revocation of appointments. The Board may act on the basis of documented evidence of the applicant's professional and ethical qualifications ,obtained from any reliable source. 2. Initial appointments shall be for a period of not more than one (1) years. Reappointments shall be for a period of not more than two (2) years..."</p> <p>Facility based "Request for Planned Parenthood of Greater Texas Surgical Health Services Board</p>	T 120		

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T 120	<p>Continued From page 2</p> <p>Approval" stated in part, "VI. APPOINTMENTS A. The following two-year reappointments are requested from the Governing Board for Physicians, with approval to provide services in any PPGT ASC where they have hospital admitting privileges: a. [Staff member #1]"</p> <p>Review of documentation for staff member #1 (the only physician at the facility) revealed this physician was initially appointed on 12/28/16 (the year of hire). The last approved privileges for this physician were dated in 2017. There were no other updated appointments for this physician. According to the bylaw, initial appointments are only good for one year. This physician should have had updated appointments in 2017 and 2019 per facility bylaws.</p> <p>The above findings were verified on 09/17/20.</p>	T 120		
T 259	<p>135.11(b)(12)(A-D) ANESTHESIA & SURGICAL SVCS IN A LIC ASC</p> <p>(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 following standards, guidelines, and recommendations issued by the Association of periOperative Registered Nurses (AORN), the</p>	T 259	<p>RQM is revising the sterilization log to reflect the actual contents of the sterilization loads and specific description of the items, as per AAMI standards. The VP of RQM reminded staff in a RQM meeting to submit incident reports the day of the event or discovery of the event. The VP of RQM reminded health center staff to immediately notify RQM staff of any BI failures. RQM will monitor for compliance with an audit of sterilization logs in Q4 2020.</p>	10/23/2020

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T 259	<p>Continued From page 3</p> <p>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.</p> <p>(B) Policies and procedures shall also address proper use of external chemical indicators and biological indicators.</p> <p>(C) Performance records for all sterilizers shall be maintained for a period of six months.</p> <p>(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.</p> <p>This Requirement is not met as evidenced by: Based on a review of documentation and interview, the facility failed to ensure that written policies and procedures for the sterilization, the monitoring and control of sterile items and</p>	T 259		

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T 259	<p>Continued From page 4</p> <p>equipment were implemented and enforced.</p> <p>Findings included:</p> <p>Facility based policy entitled, "Sterilization of Critical Items" stated in part,</p> <p>"t. BI Results</p> <p>i. The unprocessed control must provide a positive result (indicating spore growth). ,</p> <p>ii. The Processed Biological Indicator results should yield a negative result. With a processed Biological Indicator, a positive(+) result indicates a steam sterilization process failure.</p> <p>iii. Act on any positive test as soon as the first evidence of growth is noted.</p> <p>iv. Record the processed and control biological indicator results on the sterilization log...</p> <p>6. Positive BI results</p> <p>Taking the following actions as soon as a positive BI occurs is an important part of a continuous quality improvement process to ensure patient-care products are safe for use. Data obtained during the action steps will identify steps to take to correct the problem, and improve the work practices and the outcome of the sterilization process.</p> <p>a. Immediately verbally report the positive BI results to the CQRM department so that recall policies and procedures can be implemented and items can be recalled before they contact the patient. If determined that suspected non-sterile devices have been involved in patient use, follow-up surveillance of patients will be initiated as determined by the Infection prevention Committee.</p> <p>b. This notification should be followed by a written report that includes the following information:</p> <p>i. The time and date of the questionable sterilizer cycle</p>	T 259		

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T 259	<p>Continued From page 5</p> <p>ii. Description of sterilizer and load, including lot control number</p> <p>iii. Results of physical monitoring and any internal CIs</p> <p>iv. Any other information that could be useful in determining if the report is valid or is questionable due to operator error...</p> <p>VII. QUALIFICATION TESTING Qualification testing is performed after an event occurs that could affect the performance of the sterilizer. Sterilizer qualification testing using a BI PCD is performed after:</p> <ol style="list-style-type: none"> 1. Installation 2. Relocation 3. Malfunctions 4. Major repairs - a major repair is a repair outside the scope of normal maintenance 5. Sterilization process failures <p>CQRM must be notified immediately for any of the above situations...</p> <p>X. DOCUMENTATION Staff will document all sterilization on the electronic log located on the shared drive. Documentation establishes accountability by documenting what instruments have been processed and provides monitoring control evidence for those items...</p> <p>Recommendations: AAMI ST79 recommends that the following information should be recorded and maintained for each sterilization cycle:</p> <ol style="list-style-type: none"> A. The lot number. B. The specific contents of the lot or load, including quantity, department, and a specific description of the items (e.g. towels, type/name of instrument sets). 	T 259		

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T 259	<p>Continued From page 6</p> <p>C. The exposure time and temperature, if not provided on the sterilizer recording chart. D. The name or initials of the operator. E. The results of biological testing, if applicable. F. The response of the CGI placed in the PCD (BI challenge test pack, BI challenge test tray, or CI challenge test pack), if applicable."</p> <p>Review of the sterilization logs revealed the following: * On 06/26/20 it was documented that the Biological Indicator test for a load failed. * There was documentation of 3 consecutive qualification tests meeting standards. * This BI test failure was not reported to CQRM per policy. Also an incident report regarding this failure was not completed until 08/03/20. * The sterilization logs for the year 2020 only listed "Dilators" and "Specs" as the contents. * Tour of the facility revealed recent packs of other sterilized items such as tenaculums, scissors and forceps.</p> <p>In an interview on 09/16/20, staff member #1 verified that other items beside dilators and speculums were sterilized at the facility, however the log did not reflect the actual contents of the sterilization loads and specific description of the items per AAMI standards. Staff member #1 also verified the failed BI results should have triggered an incident report and notification at the time of the occurrence per policy.</p>	T 259		
T 261	<p>135.11(b)(14) ANESTHESIA & SURGICAL SVCS IN A LIC ASC</p> <p>(14) Periodic calibration and/or preventive maintenance of all equipment shall be provided in accordance with manufacturer's guidelines.</p>	T 261	<p>Staff were reminded that heating pads must be inspected annually. RQM purchased luggage tags to ensure that the inspection stickers remain attached to heating pads. To ensure continued compliance, RQM created an equipment checklist for the health center manager to utilize during the annual equipment checks. This checklist contains all of the equipment that requires annual inspection, including heating pads. The ASC audit tool requires the health center manager to verify monthly that all equipment has been inspected annually.</p>	9/24/2020

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T 261	<p>Continued From page 7</p> <p>This Requirement is not met as evidenced by: Based on observation, record review, and interview, the facility failed to ensure periodic calibration and/or preventive maintenance of all equipment provided for patient care.</p> <p>Findings included</p> <p>During a tour of the recovery room on 9/17/2020, five electrical heating pads were found/observed draped behind the recovery room chairs ready for patient use.</p> <p>During an interview on 9/15/2020, Personnel #1 lead the tour to the recovery room and confirmed the patient use of the heating pads. Personnel #1 was asked if electrical safety testing had been completed for each heating pad. Personnel #1 reported she didn't believe so, but we could check the (tested equipment) log.</p> <p>The tested equipment log reflected testing in May 2020. The log did not include testing for the five heating pads.</p> <p>National Fire Protection Association (NFPA): NFPA 99 Standard for Health Care Facilities is the primary standard addressing electrical safety testing required in health care institutions. Other publications include NFPA 70, National Electrical Code, and NFPA 70E, Electrical Safety in the Workplace.</p> <p>Association for the Advancement of Medical Instrumentation (AAMI): ANSI/AAMI ES1 Safe Current Limits for Electro-medical Apparatus is another commonly-accepted standard.</p>	T 261		

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T 261	Continued From page 8 Underwriters Laboratories (UL): UL544, Medical Equipment requirements is a standard for manufacturers, not hospitals.	T 261		