Texas Health and Human Services Commission

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION A. BUILDING: B. WING	(X3) DATE SURVEY COMPLETED
	008118		03/12/2020

NAME OF PROVIDER OR SUPPLIER
TEXAS AMBULATORY SURGICAL CENTER

STREET ADDRESS, CITY, STATE, ZIP CODE
2505 NORTH SHEPHERD
HOUSTON, TX 77008

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
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 unannounced re-licensure survey of this ambulatory surgery center was conducted. This process was to determine the center's compliance with the State Licensing Regulations under Title 25 Texas Administrative Code (TAC), Chapter 135 (Ambulatory Surgical Centers), Subchapter A (Operating Requirements for Ambulatory Surgical Centers). An entrance conference was held on the morning of 03-10-2020 with key administrative personnel. The purpose, scope, and process of the visit was explained and an opportunity for questions and discussion was provided. An exit conference was held on the afternoon of 03-12-2020 with key administrative personnel. Findings of the survey were discussed and an opportunity for questions and discussion was provided.	T 000		
T 181	135.8(e) QUALITY ASSURANCE IN A LICENSED ASC (e) Problem identification and resolution activities shall be conducted as part of an ongoing, organized quality assurance program in which all practitioners in all clinical disciplines have an opportunity to participate. A variety of	T 181		

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T 181	Continued From page 1 self-assessment methodologies may be used to implement the quality assurance program. Assessment techniques shall examine the structure, process, or outcome of care, and shall be assessed prospectively, concurrently, or retrospectively. This Requirement is not met as evidenced by: Based on record review and interview the facility quality assurance program did not identify problems or utilize resolution activities as part of an ongoing, organized quality assurance program in which all practitioners in all clinical disciplines have an opportunity to participate. This includes assessment/review techniques to examine the structure, process, or outcome of the care provided within the facility. Findings included: Review of the facility's Quality Assurance Data revealed that there was no data or audits for follow up. No facility policy was found: Record review of the quality assurance report minutes dated January 6, 2020, October 2, 2019, July 3, 2019 and April 8, 2019 revealed no specific data regarding assessment or outcomes regarding patient or staff. The minutes stated there were no problems or occurrences that occurred including patient satisfaction and complaints. Interview on 03/12/2020 at 1500 with the administrator (ID#1) who stated she reviews what she is supposed to and does visual audits and does not document the findings. No additional information was received. She also stated the	T 181		

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T 181	Continued From page 2 facility does not track patient complaints.	T 181		
T 228	135.10(a)(2) FACILITIES AND ENVIRONMENT IN A LIC ASC (ASC) shall have the necessary personnel, equipment, and procedures to handle medical emergencies that may arise in connection with services sought or provided. At a minimum, the ASC shall provide: (2) procedures, including adequate surveillance techniques, that minimize sources and transmission of infections; This Requirement is not met as evidenced by: Based on observation, interview and record review, the facility failed to maintain an effective infection prevention program. The facility failed to ensure all areas (operating room 1 & 2, recovery room, sonogram room) of the ambulatory care unit were maintained, clean and rust free. Findings Included: 1. Equipment in the operating rooms 1 & 2, the patient procedure waiting room, sonogram room and recovery room was not maintained clean and rust-free and able to be disinfected. 2. Recovery room patient chairs had visible tears and cracks in the chair cover and not able to be properly disinfected. 3. Sonogram room ultrasound machine was not maintained and disinfected after each use. 4. Ensure medication was stored properly.	T 228		

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T 228	Continued From page 3 5. Ensure expired medical supplies were removed from the crash cart. 6. Ensure drugs were not available for use after expiration date. 7. Ensure refrigerator in the Recovery Room contained clean patient supplies only and no blood samples. 8. Ensure laryngoscope blades not stored and packaged per professional guidelines. 9. Ensure the humidity and temperature levels was monitored in OR #1, #2 and the sterile supply storage room. Record review of policies: On 3/11/2020 at 1400 of the facility's current Standard operating Procedures; Subject Drug Security and Storage; Approved D. Karpen ....All pharmaceuticals shall be stored at all times in a secure storage area. Pharmaceuticals dispensed within patient car areas should have their access to non-clinical persons limited. Drugs shall be stored at a safe and adequate temperature according to the manufactures requirements. No outdated drugs shall remain in stock. The clinical Manager/Director is responsible for daily inspections of all pharmaceuticals to ensure that they are stored in a secure manner and that no expired drugs are in stock. The Clinical Manager/Director will also check the security of pharmaceuticals ad expiration date of pharmaceuticals by inspection every six months.	T 228		

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T 228	Continued From page 4 Review of Association of Peri-Operative Registered Nurses (AORN) on 03/10/2020 recommended practices for cleaning, handling, and processing of anesthesia equipment, updated January 28, 2013, read :"Laryngoscope blades should be processed according to manufacturers' instructions by either high-level disinfection or sterilization and protected from contamination until used. Processed blades should be stored in packages, appropriate for the processing method selected, to ensure the blade is protected from contamination. The storage of unpackaged laryngoscope blades is unreliable and leads to questions regarding the safe use of the blades." Review on 03/11/2020 of the facility's current Environmental Controls Table 1 reveals Operation Room temperature parameters should be 68° F to 73° F (20° C to22° C) and humidity for operation Room 30% to 60%. References from American Institute of Architects Committee on Architecture for Health. Review on 3/11/2020 of the facility's current policy titled, "Handling of Contaminated Laundry". Employees involved in the handling of contaminated laundry will follow these procedures. Always use personal protective equipment such as gloves, ect. when handling all soiled laundry. Contaminated laundry must be containerized at the location where it was used and not sorted or rinsed. Contaminated laundry must be placed and transported in bags or containers which are labeled or color coded according to the OSHA standard.	T 228		

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T 228	Continued From page 5 Observation of the Sonogram Room on 03/10/2020 1020 along with the Facility Administrator Employee (ID #51) and Medical Technician Employee (ID #52) the following was observed: One Siemens Sonoline Prima ultrasound machine was observed with an accumulation of visible dust on the front lower panel and back lateral surface area. Plastic covering over keyboard was seen to have cracks and breaks which exposed the ultrasound keyboard to commination. Interview on 03/10/2020 with Facility Administrator Employee (ID #51) at 1020 stated it was the assistant that was helping the doctor that responsible for cleaning the ultrasound machine after each use. Interview with medical assistant Employee (ID #52) on 03/10/2020 at 1030 stated that she did not clean the machine after each use and usually cleaned it once a week. Observation of the Patient Procedure Room on 03/10/2020 at 1045 along with the Facility Administrator Employee (ID #51) the following was observed: One (1) Intravenous (IV) pole was with visible rust on four (4) metal legs of the pole and on the wheel canister. One (1) Portable privacy curtains were noted to have visible rust on the metal base legs and on six (6) of the wheel canisters. Storage of dirty linin (dirty blanket, a pillowcase and operation room cotton table straps) was observed on two (2) clean chairs in the patient procedure room.	T 228		

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T 228	Continued From page 6 Interview on 03/10/2020 at 1045 with the Facility Administrator, Employee (ID #51) who stated that she had not noticed the rust and confirmed the equipment could not be disinfected properly with the rust. Employee (ID #51) confirmed the dirty clothes was left in the clean chairs and should have been taken to the laundry room and not left out in the patient area. Observation of the Recovery Room area on 3/10/2020 at 1110 along with the Facility Administrator Employee (ID #51) revealed the following: Patient refrigerator in recovery room contained clean patient items and a test tube of blood. Two (2) of three (3) IV poles with visible rust on the four (4) metal legs of the pole and on the wheel canisters. Three (3) of seven (7) recovery room patient chairs had visible tears and cracks on the chair cover. One (1) bottle of Sodium Citrate Citric Acid Solution 534mg/500 ml was found open and not labeled. Interview with the Facility Administrator, Employee (ID #51) on 03/10/2020 at 1120 confirmed the rust on the IV poles and the torn areas on the patient chairs in the recovery room and stated they could not be cleaned properly. The Facility Administrator, Employee (ID #51) also confirmed the test tube of blood should not be stored in the clean refrigerator with patient items and the medication should be labeled with the date when opened.	T 228		

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T 228	Continued From page 7 Observation of the Operation Rooms (OR) #1 on 03/10/2020 1145 along with the Facility Administrator Employee (ID #51) the following was observed: Operation Room # 1: Visible rust and paint chips on the bottom and sides of the operation room table. X-Ray viewer with visible rust on the bottom surface and sides. Sticky dark tape residue substance on OR table lamp along with visible dust. OR #1 supply room one IV pole with visible rust on the bottom metal legs and wheel canisters. One (1) oxygen cylinder observed upright and unsecured int he supply closet of OR #1. Interview with the Facility Administrator (ID #51) confirmed on 03/10/2020 the rust and paint chips on equipment in the OR along with oxygen tank not being unsecured and sticky tape debris on the operation room table light. Operation Room # 2: Floor lamp with visible rust on the bottom of lamp base and metal pole of lamp along with paint chips on the surface of the lamp. Wall damage and sheet rock exposed approximately 1 x 6-inch area on wall near sink and cabinets along with several other smaller areas of sheet rock exposed. OR #2 supply room with two (2) cases of Propofol with 25 vials of 500 mg/50 ml of Propofol in each case. Medication was stored directly on the floor in the original packing boxes. Facility Administrator (ID #51) confirmed on 03/10/2020 at 1230 the rust on the lamp, sheet	T 228		

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T 228	Continued From page 8 rock damage and medications stored on the floor in the original containers. Facility Administrator stated that she was unaware that the containers of medication could not be stored on the floor. Storage of Laryngoscope blades: Observation on 3/10/2020 at 1215 of the anesthesia cart in OR #1 showed six (6) laryngoscope blades located in the anesthesia cart. Blades were identified as three (3) straight blades and three (3) curved blades. Blades were not wrapped in any type package. Observation on 3/10/2020 at 1200 of the emergency crash cart showed 6 laryngoscope blades located in the anesthesia cart. Blades were identified as three (3) straight blades and three (3) curved blades. Blades were not wrapped in any type package. Interview on 3/10/2020 at 1200 with Facility Administrator (ID #51) stated that she was unaware the blades had to be sterilized. Observation of the Emergency Crash Cart on 03/10/2020 at 1145 along with the Facility Administrator Employee (ID # 51) the following was observed: Seven (7) - 21 gauge 1 ¼ inch Excel Safety catheter. Lot # 131112 Expired 10-2018. Four (4) - 22-gauge 1-inch Excel safety catheter. Lot @ 140405 Expired 03-2019. One (1) Open vial of multi-dose Naloxone HCL Injection 4 mg/10 ml vial. Open date labeled as 01/24/2020. Facility Administrator (ID # 51) on 03/10/2020 at 1150 confirmed that she was responsible for	T 228		

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T 228	Continued From page 9 checking the crash cart and must have missed the expired items and it was only checked when she was working. Observation of the pharmacy on 03/10/2020 at 1245 along with the Facility Administrator Employee (ID # 51) the following was observed: Seventeen (17) - 21-gauge ¾ inch safety winged infusion set Lot # 1608308, Expired 07/2019. Items observed stored underneath the pharmacy sink revealed: Three (3) cases containing 25 vials of 50 ml 2% Lidocaine in each case stored in a cabinet underneath the sink in the original card board packing boxes. Three (3) cases containing 25 vials of 50 ml 1% Lidocaine in each case stored in a cabinet underneath the sink. There were aproximately 50 mini spike dispensing pins in a clear plastic bag stored in a cabinet underneath the sink. The Facility Administrator (ID # 51) on 03/10/2020 at 1300 confirmed that she was responsible for checking the drugs and supplies along with the pharmacist and stated that she was unaware that items should not be stored under the sink.	T 228		
T 231	135.10(c) FACILITIES AND ENVIRONMENT IN A LIC ASC (c) Facilities shall be clean and properly maintained.	T 231		

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T 231	Continued From page 10 This Requirement is not met as evidenced by: Based on observation and interview, the facility failed to ensure the facilities were properly maintained. Findings included: Record review of guidelines from APIC "Preventing Infection in Ambulatory Care, Winter 2011/2012: http://apic.org/Resource_/TinyMceFileManager/Education/Preventing-Inf-in-Amb-Care-Winter2012-FINAL.PDF. External shipping containers are exposed to a number of environmental contaminants en route to their final destination and are considered dirty items. According to APIC: "Supplies must be: Removed from shipping cartons or cardboard boxes before storage to prevent contamination with soil/debris that may be on cartons ...Do not leave outer shipping boxes in clinical areas (due to risk of environmental contamination)." Observation during a tour on 3/10/2020 along with the Facility Administrator Employee (ID # 51) of the Operation Room #2's supply room two (2) cases of Propofol with 25 vials of 500 mg/50ml of Propofol vials in each case. Medication was stored directly on the floor in the orginial cardboard boxes. Interview with the Facility Administrator (ID #51) confirmed on 3/10/2020 at 1230 the medications stored on the floor in the orginal containers and stated she was unaware the the containers could not be stored in their card board boxes and stored on the floor.	T 231		

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T 252	Continued From page 11	T 252		
T 252	135.11(b)(5) ANESTHESIA & SURGICAL SVCS IN A LIC ASC (5) An appropriate history, physical examination, and pertinent preoperative diagnostic studies shall be incorporated into the patient's medical record prior to surgery. This Requirement is not met as evidenced by: Based on record review and interview the facility failed to ensure the patient had an appropriate history and physical examination and pertient preoperative diagnostic studies prior to an abortion in ten patient records out of 23 patient records (patient ID # 2,4,5,6,7,15,16,17,18,22). Findings Included: Record review of facility policy on 03/12/2020 (no date) "Medical Staff Rules and Regulations", stated General Conduct of Care: (5) The attending physician will obtain and document a preoperative history, physical exam. (14) The record should include ... medical history, physical examination ... Record review of ten (10) patient medical records (patient #2,4,5,6,7,15,16,17,18,22) out of 23 revealed the physical exam embedded with the operative report with no documentation of allergies or history and physical. The physical exam was documented by the physician (ID# 54) as WNL (within normal limits) in seven of the ten patients (#2,4,5,6,7,15). Four patients (ID #16, 17, 18, 22) of the ten patients did not have the physical exam completed. Interview on 03/11/20120 at 1420 with the physician (Staff ID #54) who pointed to the	T 252		

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T 252	Continued From page 12 physical examination on the operative report sheet and stated, "this is my physical exam and if anything is different I note it on the sheet, right there".	T 252		
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 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,	T 259		

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T 259	Continued From page 13 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 record review, observation and interview, the facility failed to ensure all standards and polices related to decontamination and sterilization were implemented and enforced, 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. Findings included; Record review of the facility policy Biological Indicators" (no date) stated: A log shall be maintained with the load identifications, biological indicator results, and identification of the contents of the load. Record review of facility policy "Sterilization Procedure, Instruments", updated 06/2012,	T 259		

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T 259	Continued From page 14 stated: rinse the instructions in clean water then rinse in a container filled with surgical milk. Record review of the autoclave log dated 02/01/20 -03/07/20 did not list the results of the biological indicators. The results of the Sterilizer Inspection log dated for March dated 03/05/20, 03/06/20 and 03/07/20 and February revealed the letters "N" normal for the test and the letter "P" for controls. Interview on 03/11/2020 at 1030 with Staff (ID#53) revealed the following: she pointed to a measuring cup and stated we put this much milk and this much water and we want to cover the instrument. She went on to say we use these pans to clean the instruments and demonstrated how the instruments were sterilized and documented on the inspection log. She also validated the results on the autoclave log.	T 259		
T 267	135.12(a) PHARMACEUTICAL SERVICES IN A LIC ASC Pharmaceutical Services. (a) The ambulatory surgical center (ASC) shall provide drugs and biologicals in a safe and effective manner in accordance with professional practices and shall be in compliance with all state and federal laws and regulations. The ASC shall be licensed as required by the Texas State Board of Pharmacy and comply with 22 Texas Administrative Code, §291.76 (relating to Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center). This Requirement is not met as evidenced by:	T 267		

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T 267	Continued From page 15 Based on observation and an interview with staff, the ambulatory surgical center (ASC) failed to provide drugs and biological's in a safe and effective manner in accordance with professional practices and in compliance with all state and federal laws and regulations. Findings Included: Review on 3/12/2020 at 1400 of the facility's current policy and procedure titled "Policy & Procedures for Drug Storage". Purpose: To outline the scope of services and guidelines of drug storage. Policies and procedures related to all aspects of drugs, to assure optimum clinical results, accountability and minimum potential harm. Policy: Monthly Consultant Pharmacist Duties: a. Reconcile all controlled substance in all locations of the surgical center. b. Review all controlled substance records for accuracy, completeness and accountability. c. Balance all controlled substance inventories. d. Reconcile all invoices with perpetual drug invoices and maintain records and invoices in the clinic manager (ID # 51) office. e. Randomly audit charts as it relates to medication administered. f. Inspect drug storage area for clean, proper storage and temperatures. g. Conduct assurance checks for DEA license and registration. h. Review and update system for removal of recalls and expired drugs. i. The pharmacy Consultant will be available by phone daily Monday-Friday. Drug Storage: 1. Drug administration and storage areas shall be well lighted and located where	T 267		

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T 267	Continued From page 16 personnel preparing drugs for administration will not be interrupted. 2. Drugs shall be stored under the proper conditions (refrigerator, light protected, etc). 3. Drugs shall be stored under proper conditions of sanitation temperature, light, moisture and ventilation. 4. Store drugs in an orderly manner to minimize errors. 5. Keep storage areas clean, decluttered, free from trash, insects and rodents. Refrigeration/Freezer Monitoring: The Aaron's Women's Clinic will monitor and document refrigerator and freezer temperatures daily. 1. Each day the temperature will be recorded. 2. Adjust the temperature if necessary. 3. Contact maintenance if temperature is not corrected. 4. Temperature records wil be kept for 3 years. The ASC was not licensed as required by the Texas State Board of Pharmacy and did not comply with 22 Texas Administrative Code, §291.76 (relating to Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center). The facility has not adopted or implemented a nationally recognized infection control guidelines and the medical director did not have a current DEA license in his employee file. Record review on 03/16/2020 of the Department of Health & Human Services Letter dated June 15, 2012, Ref: S&C: 12-35-ALL..... Medications in single dose vials (SDV) typically lack antimicrobial preservatives. According to the Center for Disease Control and Prevention (CDC), ongoing outbreaks provide evidence that medications from SDVs can become contaminated and serve as a source of infection when they are used	T 267		

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T 267	Continued From page 17 inappropriately.....Providers and suppliers expected to comply with nationally recognized standards of infection control practices. Such standards apply to areas such as environmental infection control (cleaning of patient/resident rooms, ORs, etc)., hand hygiene of health care personnel, personal protective equipment, medication injection practices, sterilization of critical equipment and high-level disinfection of semi-critical equipment, patient isolation precautions, etc. Among these standard practices is the expectation that medications labeled as single dose vial (SDVs) must not be used for multiple patients, due to the risk of spreading infections diseases. Medications labeled as single-use or single dose by manufacturers typically lack antimicrobial preservatives and once a SDV is entered, the contents can support the growth of microorganisms. The risk of infections transmissions associated with using SDVs for multiple patients is well documented, with evidence accumulated from the investigation of multiple outbreaks. Record review of the 22 Texas Administrative Code, §291.76 (relating to Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center); Texas Administrative Code (Last Updated: January 11,2017) TITLE 22. EXAMINING BOARDS PART 15. TEXAS STATE BOARD OF PHARMACY CHAPTER 291. PHARMACIES SUBCHAPTER D. INSTITUTIONAL PHARMACY (CLASS C) SECTION 291.76. Class C Pharmacies Located	T 267		

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T 267	Continued From page 18 in a Freestanding Ambulatory Surgical Center Latest version. (a) Purpose. The purpose of this section is to provide standards in the conduct, practice activities, and operation of a pharmacy located in a freestanding ambulatory surgical center that is licensed by the Texas Department of State Health Services. Class C pharmacies located in a freestanding ambulatory surgical center shall comply with this section, in lieu of §§291.71 - 291.75 of this title (relating to Purpose; Definitions; Personnel; Operational Standards; and Records). (b) Definitions. The following words and terms, when used in these sections, shall have the following meanings, unless the context clearly indicates otherwise. (1) Act--The Texas Pharmacy Act, Occupations Code, Subtitle J, as amended. (2) Administer--The direct application of a prescription drug by injection, inhalation, ingestion, or any other means to the body of a patient by: (A) a practitioner, an authorized agent under his supervision, or other person authorized by law; or (B) the patient at the direction of a practitioner. (3) Ambulatory surgical center (ASC)--A freestanding facility that is licensed by the Texas Department of State Health Services that primarily provides surgical services to patients who do not require overnight hospitalization or extensive recovery, convalescent time or observation. The planned total length of stay for an ASC patient shall not exceed 23 hours. Patient stays of greater than 23 hours shall be the result of an unanticipated medical condition and shall occur infrequently. The 23-hour period begins with the induction of anesthesia.	T 267		

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T 267	Continued From page 19 (4) Automated medication supply system--A mechanical system that performs operations or activities relative to the storage and distribution of medications for administration and which collects, controls, and maintains all transaction information. (5) Board--The Texas State Board of Pharmacy. (6) Consultant pharmacist--A pharmacist retained by a facility on a routine basis to consult with the ASC in areas that pertain to the practice of pharmacy. (7) Controlled substance--A drug, immediate precursor, or other substance listed in Schedules I - V or Penalty Groups 1 - 4 of the Texas Controlled Substances Act, as amended, or a drug immediate precursor, or other substance included in Schedule I - V of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended (Public Law 91-513). (8) Dispense--Preparing, packaging, compounding, or labeling for delivery a prescription drug or device in the course of professional practice to an ultimate user or his agent by or pursuant to the lawful order of a practitioner. (9) Distribute--The delivery of a prescription drug or device other than by administering or dispensing. (10) Downtime--Period of time during which a data processing system is not operable. (11) Electronic signature--A unique security code or other identifier which specifically identifies the person entering information into a data processing system. A facility which utilizes electronic signatures must: (A) maintain a permanent list of the unique security codes assigned to persons authorized to use the data processing system; and (B) have an ongoing security program which is	T 267		

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T 267	Continued From page 20 capable of identifying misuse and/or unauthorized use of electronic signatures. (12) Floor stock--Prescription drugs or devices not labeled for a specific patient and maintained at a nursing station or other ASC department (excluding the pharmacy) for the purpose of administration to a patient of the ASC. (13) Formulary--List of drugs approved for use in the ASC by an appropriate committee of the ambulatory surgical center. (14) Hard copy--A physical document that is readable without the use of a special device (i.e., data processing system, computer, etc.). (15) Investigational new drug--New drug intended for investigational use by experts qualified to evaluate the safety and effectiveness of the drug as authorized by the federal Food and Drug Administration. (16) Medication order--An order from a practitioner or his authorized agent for administration of a drug or device. (17) Pharmacist-in-charge--Pharmacist designated on a pharmacy license as the pharmacist who has the authority or responsibility for a pharmacy's compliance with laws and rules pertaining to the practice of pharmacy. (18) Pharmacy--Area or areas in a facility, separate from patient care areas, where drugs are stored, bulk compounded, delivered, compounded, dispensed, and/or distributed to other areas or departments of the ASC, or dispensed to an ultimate user or his or her agent. (19) Prescription drug-- (A) A substance for which federal or state law requires a prescription before it may be legally dispensed to the public; (B) A drug or device that under federal law is required, prior to being dispensed or delivered, to be labeled with either of the following statements: (i) Caution: federal law prohibits dispensing	T 267		

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T 267	Continued From page 21 without prescription or "Rx only" or another legend that complies with federal law; or (ii) Caution: federal law restricts this drug to use by or on order of a licensed veterinarian; or (C) A drug or device that is required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by a practitioner only. (20) Prescription drug order-- (A) An order from a practitioner or his authorized agent to a pharmacist for a drug or device to be dispensed; or (B) An order pursuant to Subtitle B, Chapter 157, Occupations Code. (21) Full-time pharmacist--A pharmacist who works in a pharmacy from 30 to 40 hours per week or if the pharmacy is open less than 60 hours per week, one-half of the time the pharmacy is open. (22) Part-time pharmacist--A pharmacist who works less than full-time. (23) Pharmacy technician--An individual who is registered with the board as a pharmacy technician and whose responsibility in a pharmacy is to provide technical services that do not require professional judgment regarding preparing and distributing drugs and who works under the direct supervision of and is responsible to a pharmacist. (24) Pharmacy technician trainee--An individual who is registered with the board as a pharmacy technician trainee and is authorized to participate in a pharmacy's technician training program. (25) Texas Controlled Substances Act--The Texas Controlled Substances Act, the Health and Safety Code, Chapter 481, as amended. (c) Personnel. (1) Pharmacist-in-charge. (A) General. Each ambulatory surgical center shall have one pharmacist-in-charge who is	T 267		

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T 267	Continued From page 22 employed or under contract, at least on a consulting or part-time basis, but may be employed on a full-time basis. (B) Responsibilities. The pharmacist-in-charge shall have the responsibility for, at a minimum, the following: (i) establishing specifications for procurement and storage of all materials, including drugs, chemicals, and biological's; (ii) participating in the development of a formulary for the ASC, subject to approval of the appropriate committee of the ASC; (iii) distributing drugs to be administered to patients pursuant to the practitioner's medication order; (iv) filling and labeling all containers from which drugs are to be distributed or dispensed; (v) maintaining and making available a sufficient inventory of antidotes and other emergency drugs, both in the pharmacy and patient care areas, as well as current antidote information, telephone numbers of regional poison control center and other emergency assistance organizations, and such other materials and information as may be deemed necessary by the appropriate committee of the ASC; (vi) maintaining records of all transactions of the ASC pharmacy as may be required by applicable state and federal law, and as may be necessary to maintain accurate control over and accountability for all pharmaceutical materials; (vii) participating in those aspects of the ASC's patient care evaluation program which relate to pharmaceutical material utilization and effectiveness; (viii) participating in teaching and/or research programs in the ASC; (ix) implementing the policies and decisions of the appropriate committee(s) relating to pharmaceutical services of the ASC;	T 267		

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T 267	Continued From page 23 (x) providing effective and efficient messenger and delivery service to connect the ASC pharmacy with appropriate areas of the ASC on a regular basis throughout the normal workday of the ASC; (xi) labeling, storing, and distributing investigational new drugs, including maintaining information in the pharmacy and nursing station where such drugs are being administered, concerning the dosage form, route of administration, strength, actions, uses, side effects, adverse effects, interactions, and symptoms of toxicity of investigational new drugs; (xii) meeting all inspection and other requirements of the Texas Pharmacy Act and this subsection; and (xiii) maintaining records in a data processing system such that the data processing system is in compliance with the requirements for a Class C (institutional) pharmacy located in a freestanding ASC. (2) Consultant pharmacist. (A) The consultant pharmacist may be the pharmacist-in-charge. (B) A written contract shall exist between the ASC and any consultant pharmacist, and a copy of the written contract shall be made available to the board upon request. (3) Pharmacists. (A) General. (i) The pharmacist-in-charge shall be assisted by a sufficient number of additional licensed pharmacists as may be required to operate the ASC pharmacy competently, safely, and adequately to meet the needs of the patients of the facility. (ii) All pharmacists shall assist the pharmacist-in-charge in meeting the responsibilities as outlined in paragraph (1)(B) of this subsection and in ordering, administering,	T 267		

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T 267	Continued From page 24 and accounting for pharmaceutical materials. (iii) All pharmacists shall be responsible for any delegated act performed by pharmacy technicians or pharmacy technician trainees under his or her supervision. (iv) All pharmacists while on duty shall be responsible for complying with all state and federal laws or rules governing the practice of pharmacy. (B) Duties. Duties of the pharmacist-in-charge and all other pharmacists shall include, but need not be limited to, the following: (i) receiving and interpreting prescription drug orders and oral medication orders and reducing these orders to writing either manually or electronically; (ii) selecting prescription drugs and/or devices and/or suppliers; and (iii) interpreting patient profiles. (C) Special requirements for compounding non-sterile preparations. All pharmacists engaged in compounding non-sterile preparations shall meet the training requirements specified in §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations). (4) Pharmacy technicians and pharmacy technician trainees. (A) General. All pharmacy technicians and pharmacy technician trainees shall meet the training requirements specified in §297.6 of this title (relating to Pharmacy Technician and Pharmacy Technician Trainee Training). (B) Duties. Pharmacy technicians and pharmacy technician trainees may not perform any of the duties listed in paragraph (3)(B) of this subsection. Duties may include, but need not be limited to, the following functions, under the direct supervision of a pharmacist: (i) prepacking and labeling unit and multiple dose packages, provided a pharmacist supervises and	T 267		

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T 267	Continued From page 25 conducts a final check and affixes his or her name, initials, electronic signature to the appropriate quality control records prior to distribution; (ii) preparing, packaging, compounding, or labeling prescription drugs pursuant to medication orders, provided a pharmacist supervises and checks the preparation; (iii) compounding non-sterile preparations pursuant to medication orders provided the pharmacy technicians or pharmacy technician trainees have completed the training specified in §291.131 of this title; (iv) bulk compounding, provided a pharmacist supervises and conducts in-process and final checks and affixes his or her name, initials, or electronic signature to the appropriate quality control records prior to distribution; (v) distributing routine orders for stock supplies to patient care areas; (vi) entering medication order and drug distribution information into a data processing system, provided judgmental decisions are not required and a pharmacist checks the accuracy of the information entered into the system prior to releasing the order or in compliance with the absence of pharmacist requirements contained in subsection (d)(6)(E) and (F) of this section; (vii) maintaining inventories of drug supplies; (viii) maintaining pharmacy records; and (ix) loading drugs into an automated medication supply system. For the purpose of this clause, direct supervision may be accomplished by physically present supervision or electronic monitoring by a pharmacist. (C) Procedures. (i) Pharmacy technicians and pharmacy technician trainees shall handle medication orders in accordance with standard written procedures and guidelines.	T 267		

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T 267	Continued From page 26 (ii) Pharmacy technicians and pharmacy technician trainees shall handle prescription drug orders in the same manner as pharmacy technicians or pharmacy technician trainees working in a Class A pharmacy. (D) Special requirements for compounding non-sterile preparations. All pharmacy technicians and pharmacy technician trainees engaged in compounding non-sterile preparations shall meet the training requirements specified in §291.131 of this title. (5) Owner. The owner of an ASC pharmacy shall have responsibility for all administrative and operational functions of the pharmacy. The pharmacist-in-charge may advise the owner on administrative and operational concerns. The owner shall have responsibility for, at a minimum, the following, and if the owner is not a Texas licensed pharmacist, the owner shall consult with the pharmacist-in-charge or another Texas licensed pharmacist: (A) establishing policies for procurement of prescription drugs and devices and other products dispensed from the ASC pharmacy; (B) establishing and maintaining effective controls against the theft or diversion of prescription drugs; (C) if the pharmacy uses an automated medication supply system, reviewing and approving all policies and procedures for system operation, safety, security, accuracy and access, patient confidentiality, prevention of unauthorized access, and malfunction; (D) providing the pharmacy with the necessary equipment and resources commensurate with its level and type of practice; and (E) establishing policies and procedures regarding maintenance, storage, and retrieval of records in a data processing system such that the system is in compliance with state and federal	T 267		

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T 267	Continued From page 27 requirements. (6) Identification of pharmacy personnel. All pharmacy personnel shall be identified as follows: (A) Pharmacy technicians. All pharmacy technicians shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacy technician. (B) Pharmacy technician trainees. All pharmacy technician trainees shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacy technician trainee. (C) Pharmacist interns. All pharmacist interns shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacist intern. (D) Pharmacists. All pharmacists shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacist. (d) Operational standards. (1) Licensing requirements. (A) An ASC pharmacy shall register annually or biennially with the board on a pharmacy license application provided by the board, following the procedures specified in §291.1 of this title (relating to Pharmacy License Application). (B) An ASC pharmacy which changes ownership shall notify the board within 10 days of the change of ownership and apply for a new and separate license as specified in §291.3 of this title (relating to Required Notifications). (C) An ASC pharmacy which changes location and/or name shall notify the board of the change within 10 days and file for an amended license as specified in §291.3 of this title. (D) An ASC pharmacy owned by a partnership or corporation which changes managing officers shall notify the board in writing of the names of the new managing officers within 10 days of the change, following the procedures in §291.3 of this	T 267		

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T 267	Continued From page 28 title. (E) An ASC pharmacy shall notify the board in writing within 10 days of closing, following the procedures in §291.5 of this title (relating to Closing a Pharmacy). (F) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged for issuance and renewal of a license and the issuance of an amended license. (G) A separate license is required for each principal place of business and only one pharmacy license may be issued to a specific location. (H) An ASC pharmacy, licensed under the Act, §560.051(a)(3), concerning institutional pharmacy (Class C), which also operates another type of pharmacy which would otherwise be required to be licensed under the Act, §560.051(a)(1), concerning community pharmacy (Class A), or the Act, §560.051(a)(2), concerning nuclear pharmacy (Class B), is not required to secure a license for the other type of pharmacy; provided, however, such license is required to comply with the provisions of §291.31 of this title (relating to Definitions), §291.32 of this title (relating to Personnel), §291.33 of this title (relating to Operational Standards), §291.34 of this title (relating to Records), and §291.35 of this title (relating to Official Prescription Records), or §291.51 of this title (relating to Purpose), §291.52 of this title (relating to Definitions), §291.53 of this title (relating to Personnel), §291.54 of this title (relating to Operational Standards), and §291.55 of this title (relating to Records), contained in Nuclear Pharmacy (Class B), to the extent such sections are applicable to the operation of the pharmacy. (I) An ASC pharmacy engaged in the compounding of non-sterile preparations shall comply with the provisions of §291.131 of this	T 267		

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T 267	Continued From page 29 title. (J) ASC pharmacy personnel shall not compound sterile preparations unless the pharmacy has applied for and obtained a Class C-S pharmacy license. (K) An ASC pharmacy engaged in the provision of remote pharmacy services, including storage and dispensing of prescription drugs, shall comply with the provisions of §291.121 of this title (relating to Remote Pharmacy Services). (L) An ASC pharmacy engaged in centralized prescription dispensing and/or prescription drug or medication order processing shall comply with the provisions of §291.123 of this title (relating to Centralized Prescription Drug or Medication Order Processing) and/or §291.125 of this title (relating to Centralized Prescription Dispensing). (2) Environment. (A) General requirements. (i) Each ambulatory surgical center shall have a designated work area separate from patient areas, and which shall have space adequate for the size and scope of pharmaceutical services and shall have adequate space and security for the storage of drugs. (ii) The ASC pharmacy shall be arranged in an orderly fashion and shall be kept clean. All required equipment shall be clean and in good operating condition. (B) Special requirements. (i) The ASC pharmacy shall have locked storage for Schedule II controlled substances and other controlled drugs requiring additional security. (ii) The ASC pharmacy shall have a designated area for the storage of poisons and externals separate from drug storage areas. (C) Security. (i) The pharmacy and storage areas for prescription drugs and/or devices shall be enclosed and capable of being locked by key,	T 267		

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T 267	Continued From page 30 combination, or other mechanical or electronic means, so as to prohibit access by unauthorized individuals. Only individuals authorized by the pharmacist-in-charge may enter the pharmacy or have access to storage areas for prescription drugs and/or devices. (ii) The pharmacist-in-charge shall consult with ASC personnel with respect to security of the drug storage areas, including provisions for adequate safeguards against theft or diversion of dangerous drugs and controlled substances, and to security of records for such drugs. (iii) The pharmacy shall have locked storage for Schedule II controlled substances and other drugs requiring additional security. (3) Equipment and supplies. Ambulatory surgical centers supplying drugs for postoperative use shall have the following equipment and supplies: (A) data processing system including a printer or comparable equipment; (B) adequate supply of child-resistant, moisture-proof, and light-proof containers; and (C) adequate supply of prescription labels and other applicable identification labels. (4) Library. A reference library shall be maintained that includes the following in hard-copy or electronic format and that pharmacy personnel shall be capable of accessing at all times: (A) current copies of the following: (i) Texas Pharmacy Act and rules; (ii) Texas Dangerous Drug Act and rules; (iii) Texas Controlled Substances Act and rules; (iv) Federal Controlled Substances Act and rules or official publication describing the requirements of the Federal Controlled Substances Act and rules; (B) at least one current or updated general drug information reference which is required to contain drug interaction information including information needed to determine severity or significance of	T 267		

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T 267	Continued From page 31 the interaction and appropriate recommendations or actions to be taken; and (C) basic antidote information and the telephone number of the nearest regional poison control center. (5) Drugs. (A) Procurement, preparation, and storage. (i) The pharmacist-in-charge shall have the responsibility for the procurement and storage of drugs, but may receive input from other appropriate staff of the facility, relative to such responsibility. (ii) The pharmacist-in-charge shall have the responsibility for determining specifications of all drugs procured by the facility. (iii) ASC pharmacies may not sell, purchase, trade, or possess prescription drug samples, unless the pharmacy meets the requirements as specified in §291.16 of this title (relating to Samples). (iv) All drugs shall be stored at the proper temperatures, as defined in the USP/NF and in §291.15 of this title (relating to Storage of Drugs). (v) Any drug bearing an expiration date may not be dispensed or distributed beyond the expiration date of the drug. (vi) Outdated drugs shall be removed from dispensing stock and shall be quarantined together until such drugs are disposed of. (B) Formulary. (i) A formulary may be developed by an appropriate committee of the ASC. (ii) The pharmacist-in-charge or consultant pharmacist shall be a full voting member of any committee which involves pharmaceutical services. (iii) A practitioner may grant approval for pharmacists at the ASC to interchange, in accordance with the facility's formulary, for the drugs on the practitioner's medication orders	T 267		

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T 267	Continued From page 32 provided: (I) a formulary has been developed; (II) the formulary has been approved by the medical staff of the ASC; (III) there is a reasonable method for the practitioner to override any interchange; and (IV) the practitioner authorizes pharmacist in the ASC to interchange on his/her medication orders in accordance with the facility's formulary through his/her written agreement to abide by the policies and procedures of the medical staff and facility. (C) Prepackaging and loading drugs into automated medication supply system. (i) Prepackaging of drugs. (I) Drugs may be prepackaged in quantities suitable for distribution to other Class C pharmacies under common ownership or for internal distribution only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist. (II) The label of a prepackaged unit shall indicate: (-a-) brand name and strength of the drug; or if no brand name, then the generic name, strength, and name of the manufacturer or distributor; (-b-) facility's lot number; (-c-) expiration date; (-d-) quantity of the drug, if quantity is greater than one; and (-e-) if the drug is distributed to another Class C pharmacy, name of the facility responsible for prepackaging the drug. (III) Records of prepackaging shall be maintained to show: (-a-) the name of the drug, strength, and dosage form; (-b-) facility's lot number; (-c-) manufacturer or distributor; (-d-) manufacturer's lot number; (-e-) expiration date;	T 267		

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T 267	Continued From page 33 (-f-) quantity per prepackaged unit; (-g-) number of prepackaged units; (-h-) date packaged; (-i-) name, initials, or electronic signature of the prepacker; (-j-) signature or electronic signature of the responsible pharmacist; and (-k-) if the drug is distributed to another Class C pharmacy, name of the facility receiving the prepackaged drug. (IV) Stock packages, repackaged units, and control records shall be quarantined together until checked/released by the pharmacist. (ii) Loading bulk unit of use drugs into automated medication supply systems. Automated medication supply systems may be loaded with bulk unit of use drugs only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist. For the purpose of this clause, direct supervision may be accomplished by physically present supervision or electronic monitoring by a pharmacist. In order for the pharmacist to electronically monitor, the medication supply system must allow for bar code scanning to verify the loading of drugs, and a record of the loading must be maintained by the system and accessible for electronic review by the pharmacist. (6) Medication orders. (A) Drugs may be administered to patients in ASCs only on the order of a practitioner. No change in the order for drugs may be made without the approval of a practitioner except as authorized by the practitioner in compliance with paragraph (5)(B) of this subsection. (B) Drugs may be distributed only pursuant to the practitioner's medication order. (C) ASC pharmacies shall be exempt from the labeling provisions and patient notification	T 267		

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T 267	Continued From page 34 requirements of §562.006 and §562.009 of the Act, as respects drugs distributed pursuant to medication orders. (D) In ASCs with a full-time pharmacist, if a practitioner orders a drug for administration to a bona fide patient of the facility when the pharmacy is closed, the following is applicable. (i) Prescription drugs and devices only in sufficient quantities for immediate therapeutic needs of a patient may be removed from the ASC pharmacy. (ii) Only a designated licensed nurse or practitioner may remove such drugs and devices. (iii) A record shall be made at the time of withdrawal by the authorized person removing the drugs and devices. The record shall contain the following information: (I) name of the patient; (II) name of device or drug, strength, and dosage form; (III) dose prescribed; (IV) quantity taken; (V) time and date; and (VI) signature or electronic signature of person making withdrawal. (iv) The medication order in the patient's chart may substitute for such record, provided the medication order meets all the requirements of clause (iii) of this subparagraph. (v) The pharmacist shall verify the withdrawal as soon as practical, but in no event more than 72 hours from the time of such withdrawal. (E) In ASCs with a part-time or consultant pharmacist, if a practitioner orders a drug for administration to a bona fide patient of the ASC when the pharmacist is not on duty, or when the pharmacy is closed, the following is applicable. (i) Prescription drugs and devices only in sufficient quantities for therapeutic needs may be removed from the ASC pharmacy.	T 267		

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T 267	Continued From page 35 (ii) Only a designated licensed nurse or practitioner may remove such drugs and devices. (iii) A record shall be made at the time of withdrawal by the authorized person removing the drugs and devices; the record shall meet the same requirements as specified in subparagraph (D) of this paragraph. (iv) The pharmacist shall conduct an audit of patient's medical record according to the schedule set out in the policy and procedures at a reasonable interval, but such interval must occur at least once in every calendar week that the pharmacy is open. (7) Floor stock. In facilities using a floor stock method of drug distribution, the following is applicable for removing drugs or devices in the absence of a pharmacist. (A) Prescription drugs and devices may be removed from the pharmacy only in the original manufacturer's container or prepackaged container. (B) Only a designated licensed nurse or practitioner may remove such drugs and devices. (C) A record shall be made at the time of withdrawal by the authorized person removing the drug or device; the record shall contain the following information: (i) name of the drug, strength, and dosage form; (ii) quantity removed; (iii) location of floor stock; (iv) date and time; and (v) signature or electronic signature of person making the withdrawal. (D) A pharmacist shall verify the withdrawal according to the following schedule. (i) In facilities with a full-time pharmacist, the withdrawal shall be verified as soon as practical, but in no event more than 72 hours from the time of such withdrawal. (ii) In facilities with a part-time or consultant	T 267		

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T 267	Continued From page 36 pharmacist, the withdrawal shall be verified after a reasonable interval, but such interval must occur at least once in every calendar week that the pharmacy is open. (iii) The medication order in the patient's chart may substitute for the record required in subparagraph (C) of this paragraph, provided the medication order meets all the requirements of subparagraph (C) of this paragraph. (8) Policies and procedures. Written policies and procedures for a drug distribution system, appropriate for the ambulatory surgical center, shall be developed and implemented by the pharmacist-in-charge with the advice of the appropriate committee. The written policies and procedures for the drug distribution system shall include, but not be limited to, procedures regarding the following: (A) controlled substances; (B) investigational drugs; (C) prepackaging and manufacturing; (D) medication errors; (E) orders of physician or other practitioner; (F) floor stocks; (G) adverse drug reactions; (H) drugs brought into the facility by the patient; (I) self-administration; (J) emergency drug tray; (K) formulary, if applicable; (L) drug storage areas; (M) drug samples; (N) drug product defect reports; (O) drug recalls; (P) outdated drugs; (Q) preparation and distribution of IV admixtures; (R) procedures for supplying drugs for postoperative use, if applicable; (S) use of automated medication supply systems; (T) use of data processing systems; and (U) drug regimen review.	T 267		

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T 267	Continued From page 37 (V) Drugs supplied for postoperative use. Drugs supplied to patients for postoperative use shall be supplied according to the following procedures. Observation 3/12/2020 at 1130 along with Faculty Administrator, Employee (ID #51) of the Pharmacy Room a revealed refrigerator log for January 1, 2020 to March 5, 2020. Log failed to have daily refrigerator temperatures documented and no documentation of freezer. Office is open Monday - Saturday 0800 to 1600. Further observation with Employee (ID #51) revealed Narcotic & Control Drug Accountability for Stadol Injection and Propofol 500 mg/50ml. Observation of medication storage area revealed Stadol vial for injection revealed labeled as 1 mg/ml and labeled as Single-dose fliptop vials with instruction for intramuscularly or intravenous use. Discard unused portion. Each individual vial of Stadol was also observed to be labeled "Single-dose". Further observation revealed vials of Propofol Injectable Emulsion, USP, 500 mg/50 ml. Vial labeled for "Single Patient Use Only" for intravenous administration. Record review of Narcotic & Control Drug Accountability Log for February and March 2020 documents both Stadol and Propofol "Single-dose" vials were used on multiple patients. On 3/12/2020 at 1100 the Pharmacist, Employee (ID #56) records were reviewed, her personal file contained no signed contract with the ambulatory surgery center for the Pharmacist or a signed job description.	T 267		

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T 267	Continued From page 38 Interview with the facility's Pharmacist, Employee (ID #56) on 3/12/2020 at 1300 revealed that she was the pharmacist for the facility and had started in November 2019. Interview with Employee (ID#56) stated she was not aware the ambulatory surgery center was required to have a license. Employee (ID #56) stated she was told she need to come in monthly and conduct audits with medical records for medications that were given and to confirm what was left in storage was correct and the count was right. She goes on to say that she had not given any inservice or training the the facility's staff and further stated she did not have a written contract with the facility, just a verbal agreement and had nothing written about her job responsibilities as pharmacist for the ambulatory surgery center. Further interview with Pharmacist, Employee (ID #56) stated she was unaware the facility was using single dose vials and thought they were multi dose vials for the Stadol (Butorphanol Tartrate) and Propofol. Stadol (Butorphanol injection) is used to relieve moderate to severe pain and decrease awareness of pain before or during surgery. Butorphanol is in a class of medications called opioid agonist-antagonists. It works by changing the way the body senses pain. Propofol, is a short-acting medication that results in a decreased level of consciousness and lack of memory for events. Its uses include the starting and maintenance of general anesthesia, sedation for mechanically ventilated adults, and procedural sedation. It is also used for status epileptics if other medications have not worked. It is given by injection into a vein. Maximum effect takes about	T 267		

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T 267	Continued From page 39 two minutes to occur and it typically lasts five to ten minutes. Interview on 03/12/2020 at 1130 with Facility Administrator, Employee (ID #51) confirmed the facility used the same vials of Stadol and Propofol on multiple patients. Interview with Employee (ID #51) stated that she was unaware the vials were labeled for single use only. Employee (ID #51) stated the facility medical director, Employee (ID #54) would give the CRNA (Certified Registered Nurse Anesthetist) one vial of the 500 mg/50 ml, 10 mg/ml of Propofol to use on multiple patients. She confirmed the facility was using the 1 vial of Stadol (Butorphanol Tartrate) single dose that contained 1 mg/ml on separate patients. Further interview with Employee (ID#51) confirmed she was the only one that checked the refrigerator temperature was only checked when she was at the facility on Thursday, Friday and Saturday. Record review of the temperature log for January - March, 2020, revealed the following: January 1 - 6 - no temperature documented January 7,8,9 - temperature documented January 13 - 15 - no temperature documented January 16 - 18 - temperature documented January 19 - 22 - no temperature documented January 23 - 25 - temperature documented January 26 - 29 - no temperature documented January 30, 31 - temperature documented February - temperature documented on Thursday, Friday and Saturdays only during the month of February. March 5 - temperature documented. No further	T 267		

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T 267	Continued From page 40 documentation noted for March 2020.	T 267		
T 268	135.12(b) PHARMACEUTICAL SERVICES IN A LIC ASC (b) Pharmaceutical services may be made available by the ASC through a contractual agreement and shall be provided in accordance with the same ethical and professional practices and legal requirements that would be required if such services were provided directly by the ASC. This Requirement is not met as evidenced by: Based on observation, interview and record review the facility failed to ensure a current contract with the consulting pharmacist was maintained. Review of the Texas Administrative Code, Rule 291.76, Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center, (2) Consultant pharmacist. (B) A written contract shall exist between the ambulatory surgical center (ASC) and any consultant pharmacist, and a copy of the written contract shall be made available to the board upon request. Findings Included: On 3/12/2020 at 1300 review of the Pharmacist, Employee (ID #56) personnel file revealed no signed job description or contract. Interview on 3/12/2020 at 1300 with Pharmacist, Employee (ID #56) revealed she had no written or signed contract with the Ambulatory Surgery Center. Employee (ID #56) stated it was just a	T 268		

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	008118		03/12/2020

NAME OF PROVIDER OR SUPPLIER
TEXAS AMBULATORY SURGICAL CENTER

STREET ADDRESS, CITY, STATE, ZIP CODE
2505 NORTH SHEPHERD
HOUSTON, TX 77008

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T 268	Continued From page 41 verbal agreement and had not signed a contract.	T 268		
T 303	135.15(a)(4) NURSING SERVICES IN A LICENSED ASC (a) Nursing services. (4) An RN qualified, at a minimum, with current certification in basic cardiac life support shall be on duty and on the premises at all times whenever patients are present in the facility. This Requirement is not met as evidenced by: Based on observation, record review and interview the facility failed to ensure a qualified registered nurse (RN) with basic life support was on the premises at all times whenever patients are present in the facility. The facility employs one RN who works Thursday through Saturday. Findings Included: Observation and record review on 03/09/2020-03/11/2020 revealed: Patients were in the clinic on 03/09/2020-03/11/2020 for sonogram and information on the clinic services. Record review on 03/12/2020 at 1300 of the Registered Nurse (RN) (staff ID #57) employee file revealed no current certification for basic cardiac life support was documented in the employee file. Record review of the Texas Ambulatory Surgical Center on 03/1132/2020 website revealed the	T 303		

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T 303	Continued From page 42 center was open from 0800 to 1700 daily except Sunday's. Interview on 03/12/2020 at 1300 with the administrator (ID #51) who stated the RN and the Certified Registered Nurse Anesthetists (CRNA) both work on Thursday through Saturday only. Interview on 03/12/2020 at 1600 with the physician (ID #54) who stated we just have the RN here on Thursday, Friday and Saturday when we have procedures. On Monday, Tuesday and Wednesday this ASC is a clinic and we do not need an RN on those days.	T 303		
T 359	135.27(d)(1-4) PATIENT SAFETY PROGRAM (d) Management. The ASC shall designate one or more individuals, or an interdisciplinary group, qualified by training or experience to be responsible for the management of the patient safety program. These responsibilities shall include: (1) coordinating all patient safety activities; (2) facilitating assessment and appropriate response to reported events; (3) monitoring the root cause analysis and resulting action plans; and (4) serving as liaison among ASC departments and committees to ensure facility-wide integration of the PSP. This Requirement is not met as evidenced by: Based on record review and interview the facility failed to coordinate patient safety activities and response to events resulting in actions plans to ensure facility-wide integration of the Patient safety plan within the facility.	T 359		

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T 359	Continued From page 43 Findings Included: Record review of the facility policy Patient Safety Program, dated January 30, 2008 that addressed all elements of the program. There was no indication of any training or data related to the elements of the program. Interview on 03/12/2020 at 1530 with the Facility Administrator employee (ID #51) who stated she audits but does not write anything down. When asked about the patient who had the drug reaction, she could not produce the name and did not follow-up. Interview with the pharmacist (ID#56) on 03/12/2020 at 1500 who stated there was a patient that had a drug reaction.	T 359		
T 397	135.43(c)(1) (A-B) HANDLING AND STORAGE OF GASES, ANESTHETICS, A (c) Flammable and nonflammable gases and liquids. Flammability of liquids and gasesshall be determined by National Fire Protection Association 329, Handling Releases of Flammable and Combustible Liquids and Gases, 2002 Edition. All documents published by National Fire Protection Association (NFPA) as referenced in this section may be obtained by writing or calling the NFPA at the following address or telephone number: National Fire Protection Association, 1 Batterymarch Park, Quincy, Massachusetts 02269-9101 or (800) 344-3555. (1) Nonflammable gases (examples include, but are not limited to, oxygen and	T 397		

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T 397	Continued From page 44 nitrous oxide) shall be stored and distributed in accordance with Chapter 5 of the National Fire Protection Association 99, Standard for Health Care Facilities, 2002 Edition (NFPA 99). (A) Medical gases and liquefied medical gases shall be handled inaccordance with the requirements of NFPA 99, Chapter 9. (B) Oxygen shall be administered in accordance with NFPA 99, §9.6. This Requirement is not met as evidenced by: Based on observation, and interview, the facility failed to safely store medical gases in accordance with National Fire Protection Association (NFPA) 99, Standard for Health Care Facilities. Findings include: A review on 03/11/2020 at 3:00 p.m. of the National Fire Protection Act 99, Chapter 5, 5.1.3.3.2 revealed, "Design and Construction. Location for central supply systems and the storage of positive-pressure gasses shall meet the following requirements. (7) They shall be provided with racks, chains, or other fastening to secure all cylinders from falling, whether connected, unconnected, full, or empty." Observation of the Operation Rooms (OR) (#1) on 03/10/2020 1230. along with the outside gas storage area the Facility Administrator Employee (ID #51) the following was observed: OR (#1) supply room revealed one (1) medium size oxygen cylinder was observed stored on the floor and upright and not secured in a rack. Facility outside gas storage area revealed three (3) large gas cylinders that were not secured in a	T 397		

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T 397	Continued From page 45 cart or by a chain. Interview on 03/11/2020 at 1230 with the Facility Administrator, Employee (ID #51) confirmed on the gas cylinders were not secured and should of been.	T 397		

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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 unannounced re-licensure survey of this ambulatory surgery center was conducted. This process was to determine the center's compliance with the State Licensing Regulations under Title 25 Texas Administrative Code (TAC), Chapter 135 (Ambulatory Surgical Centers), Subchapter A (Operating Requirements for Ambulatory Surgical Centers). An entrance conference was held on the morning of 03-10-2020 with key administrative personnel. The purpose, scope, and process of the visit was explained and an opportunity for questions and discussion was provided. An exit conference was held on the afternoon of 03-12-2020 with key administrative personnel. Findings of the survey were discussed and an opportunity for questions and discussion was provided.	T 000		
T 181	135.8(e) QUALITY ASSURANCE IN A LICENSED ASC (e) Problem identification and resolution activities shall be conducted as part of an ongoing, organized quality assurance program in which all practitioners in all clinical disciplines have an opportunity to participate. A variety of	T 181		

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T 252	Continued From page 11	T 252	T-252	
T 252	135.11(b)(5) ANESTHESIA & SURGICAL SVCS IN A LIC ASC (5) An appropriate history, physical examination, and pertinent preoperative diagnostic studies shall be incorporated into the patient's medical record prior to surgery. This Requirement is not met as evidenced by: Based on record review and interview the facility failed to ensure the patient had an appropriate history and physical examination and pertient preoperative diagnostic studies prior to an abortion in ten patient records out of 23 patient records (patient ID # 2,4,5,6,7,15,16,17,18,22). Findings Included: Record review of facility policy on 03/12/2020 (no date) "Medical Staff Rules and Regulations", stated General Conduct of Care: (5) The attending physician will obtain and document a preoperative history, physical exam. (14) The record should include ... medical history, physical examination ... Record review of ten (10) patient medical records (patient #2,4,5,6,7,15,16,17,18,22) out of 23 revealed the physical exam embedded with the operative report with no documentation of allergies or history and physical. The physical exam was documented by the physician (ID# 54) as WNL (within normal limits) in seven of the ten patients (#2,4,5,6,7,15). Four patients (ID #16, 17, 18, 22) of the ten patients did not have the physical exam completed. Interview on 03/11/20120 at 1420 with the physician (Staff ID #54) who pointed to the	T 252	Physician # 54 has implemented a new H&P form to replace the H&P that he has used for many years. He has always done a pre-op H&P on every patient prior to their abortion procedure. The new H&P will be implemented when clinic opens. Admin and Physician are responsible to insure Pre-op H&P is on Every Chart. H&P's have been done on all patients prior to the abortion procedures. The form used will be replaced. All of the medical records listed did have an H&P in their record completed by physician #54 on the H&P form is being replaced. The Physician is responsible to see that every patient has a pre-op exam and H&P. See attachment: New H&P Form	Form 3-15-20 3-15-20

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T 259	Continued From page 14 stated: rinse the instructions in clean water then rinse in a container filled with surgical milk. Record review of the autoclave log dated 02/01/20 -03/07/20 did not list the results of the biological indicators. The results of the Sterilizer Inspection log dated for March dated 03/05/20, 03/06/20 and 03/07/20 and February revealed the letters "N" normal for the test and the letter "P" for controls. Interview on 03/11/2020 at 1030 with Staff (ID#53) revealed the following: she pointed to a measuring cup and stated we put this much milk and this much water and we want to cover the instrument. She went on to say we use these pans to clean the instruments and demonstrated how the instruments were sterilized and documented on the inspection log. She also validated the results on the autoclave log.	T 259	T-259 Updated logs will be implemented for Sterilizer and biological indicator logs. Logs completed and implemented on re-opening. all employees that work Sterilization are responsible. See attachments : Logs	4-2-20
T 267	135.12(a) PHARMACEUTICAL SERVICES IN A LIC ASC Pharmaceutical Services. (a) The ambulatory surgical center (ASC) shall provide drugs and biologicals in a safe and effective manner in accordance with professional practices and shall be in compliance with all state and federal laws and regulations. The ASC shall be licensed as required by the Texas State Board of Pharmacy and comply with 22 Texas Administrative Code, §291.76 (relating to Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center). This Requirement is not met as evidenced by:	T 267	T-267 Pharmacy License Application is pending. Pharmacist and Physician are applying for Pharmacy License.They are Responsible for this task.	unknown