Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	008118	A. BUILDING: _____ B. WING _____	01/24/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
TEXAS AMBULATORY SURGICAL CENTER	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 entrance conference was held with the facility Administrator on the afternoon of 01/22/18. The purpose and process of the licensure resurvey were discussed, and an opportunity given for questions. Continued licensure is recommended, with an approved plan of correction. An exit conference was held with the facility Administrator and Medical Director on the afternoon of 01/24/18. Preliminary findings of the survey were discussed, and an opportunity given for questions.	T 000	REVIEWED MAR 05 2018 BY: Wanda Wilson, RN	
T 121	135.4(h) ASC OPERATION (h) The governing body shall provide (in a manner consistent with state law and based on evidence of education, training, and current competence) for the initial appointment, reappointment, and assignment or curtailment of privileges and practice for nonphysician health care personnel and practitioners. This Requirement is not met as evidenced by: Based on review of available records and staff	T 121		

SOD - State Form
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

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T 121	Continued From page 1 interviews, the governing body failed to establish policies and procedures for overseeing and evaluating the clinical activities of certified registered nurse anesthetists. Findings were: Review of the facility policies and procedures revealed that the facility had no policy or procedure approved by the governing body to appoint or reappoint certified registered nurse anesthetists, to verify the qualifications of certified registered nurse anesthetists. Review of the credentialing record for Staff member #5, a certified registered nurse anesthetist, revealed that there was no documentation of this staff member being appointed or reappointed by the governing body at the facility. In an interview with staff member #8 on 01/24/18, they stated that the facility did not have a policy or procedure related to oversight of anesthesia services. The facility was unable to provide documentation of appointment or reappointment by the governing body for staff member #5 a certified registered nurse anesthetist.	T 121	The plan is to have the policy and procedure and to implement immediately. The administrator will provide the policy and procedure and the governing body will implement.The governing body will discuss the policy and procedure with the CRNA and it is effective immediately. The governing body will monitor to and oversee and evaluate the CRNA to insure the policies and procedures are being performed correctly. A policy has been implemented by the Governing Body and a form has been placed in the employee file of the CRNA staff member #5 indicating the appointment of staff member #5 CRNA to provide anesthesia services. The overseeing and evaluating of the clinical activities of the CRNA is included in the Policies and Procedures and is placed in the Policy and Procedure Book. Verification of licensing of CRNA is included. The credentialing record is placed in the employee personnel file.	01/26/18
T 125	135.4(l) ASC OPERATION (l) An ASC that performs abortions shall adopt, implement and enforce a policy to ensure compliance with Health and Safety Code, Chapters 245 and 171, Subchapters A and B (relating to Abortion and Informed Consent).	T 125		

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T 125	Continued From page 2 This Requirement is not met as evidenced by: Based on a review of clinical records and an interview with staff, the facility failed to adopt, implement and enforce a policy to ensure compliance with Health and Safety Code, Chapters 245 and 171, Subchapters A and B (relating to Abortion and Informed Consent). Findings were: HEALTH AND SAFETY CODE TITLE 2. HEALTH SUBTITLE H. PUBLIC HEALTH PROVISIONS CHAPTER 171. ABORTION SUBCHAPTER A. GENERAL PROVISIONS Sec. 171.0031.AAREQUIREMENTS OF PHYSICIAN; OFFENSE. (a)AAA physician performing or inducing an abortion: (1)AAmust, on the date the abortion is performed or induced, have active admitting privileges at a hospital that: (A)AAis located not further than 30 miles from the location at which the abortion is performed or induced; and (B)AAprovides obstetrical or gynecological health care services; and (2)AAshall provide the pregnant woman with: (A)AAa telephone number by which the pregnant woman may reach the physician, or other health care personnel employed by the physician or by the facility at which the abortion was performed or induced with access to the woman ' s relevant medical records, 24 hours a day to request assistance for any complications that arise from the performance or induction of the	T 125		

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T 125	Continued From page 3 abortion or ask health-related questions regarding the abortion; and (B)AAthe name and telephone number of the nearest hospital to the home of the pregnant woman at which an emergency arising from the abortion would be treated. (b)AAA physician who violates Subsection (a) commits an offense.AAAn offense under this section is a Class A misdemeanor punishable by a fine only, not to exceed $4,000. "4 of 4 patients who underwent a medication abortion (medication procedure patients #1 - #4) were not provided the name and telephone number of the nearest hospital to their home upon discharge. Sec.A171.012.AAVOLUNTARY AND INFORMED CONSENT. (a)AAConsent to an abortion is voluntary and informed only if: (1)AAthe physician who is to perform the abortion informs the pregnant woman on whom the abortion is to be performed of: (A)AAthe physician ' s name; (B)AAthe particular medical risks associated with the particular abortion procedure to be employed, including, when medically accurate: (i)AAthe risks of infection and hemorrhage; (ii)AAthe potential danger to a subsequent pregnancy and of infertility; and (iii)AAthe possibility of increased risk of breast cancer following an induced abortion and the natural protective effect of a completed pregnancy in avoiding breast	T 125	Administrator will be responsible for the plan of correction. The plan is to write the name and telephone number of the hospital nearest the patients home on the follow-up instruction sheet that is given to the patient and a copy will be placed in the patient chart. Staff meeting will be held to insure that all staff members know that this is mandatory and on chart check this will be checked and confirmed. A meeting was held with all employees and instructions were given that all patient charts for medical and surgical procedures must have the name and telephone number of a hospital closest to the patients home and the telephone number for the nurse is given to all patients.	1/26/18

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T 125	Continued From page 4	T 125		

cancer;
(C)AAthe probable gestational age of the unborn child at the time the abortion is to be performed; and
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(D)AAthe medical risks associated with carrying the child to term;
(2)AAthe physician who is to perform the abortion or the
physician ' s agent informs the pregnant woman that:
(A)AAmedical assistance benefits may be available
for prenatal care, childbirth, and neonatal care;
(B)AAthe father is liable for assistance in the support of the child without regard to whether the father has
offered to pay for the abortion; and
(C)AApublic and private agencies provide pregnancy prevention counseling and medical referrals for
obtaining pregnancy prevention medications or devices, including
emergency contraception for victims of rape or incest;
(3)AAthe physician who is to perform the abortion or the
physician ' s agent:
(A)AAprovidesAAthe pregnant woman with the printed materials described by Section 171.014; and
(B)AAinforms the pregnant woman that those materials:
(i)AAhave been provided by the Department of State Health Services;
(ii)AAare accessible on an Internet website sponsored by the department;
(iii)AAdescribe the unborn child and list agencies that offer alternatives to abortion; and
(iv)AAinclude a list of agencies that offer

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T 125	Continued From page 5 sonogram services at no cost to the pregnant woman; (4)AAbefore any sedative or anesthesia is administered to the pregnant woman and at least 24 hours before the abortion or at least two hours before the abortion if the pregnant woman waives this requirement by certifying that she currently lives 100 miles or more from the nearest abortion provider that is a facility licensed under Chapter 245 or a facility that performs more than 50 abortions in any 12-month period: "1 of 4 patients who underwent a 1-day procedure (1-day procedure patient #4) did not live 100 miles from the nearest abortion provider and did not qualify to undergo the 1-day procedure. Sec. 171.063.AADISTRIBUTION OF ABORTION-INDUCING DRUG. (a)AAA person may not knowingly give, sell, dispense, administer, provide, or prescribe an abortion-inducing drug to a pregnant woman for the purpose of inducing an abortion in the pregnant woman or enabling another person to induce an abortion in the pregnant woman unless: (1)AAthe person who gives, sells, dispenses, administers, provides, or prescribes the abortion-inducing drug is a physician; and (2)AAexcept as otherwise provided by Subsection (b), the provision, prescription, or administration of the	T 125	The plan is to prevent this error from occuring. The administrator is responsible for the plan of correction.The plan is going to be implemented with a staff meeting and tools to prevent this error from occuring. The administrator will monitor all 1 day patients to insure there is no error. A Texas map with all of the clinics in Texas marked for easy viewing and a list of all Texas abortion clinics with addresses and telephone numbers is implemented and a staff meeting held to instruct staff of the use of these tools. Administrator will double check all one day procedures to prevent any errors. Patients will be informed of their nearest clinic to their home and given the telephone number.	1/26/18

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T 125	Continued From page 6 abortion-inducing drug satisfies the protocol tested and authorized by the United States Food and Drug Administration as outlined in the final printed label of the abortion-inducing drug. (b)AAA person may provide, prescribe, or administer the abortion-inducing drug in the dosage amount prescribed by the clinical management guidelines defined by the American Congress of Obstetricians and Gynecologists Practice Bulletin as those guidelines existed on January 1, 2013. (c)AABefore the physician gives, sells, dispenses, administers, provides, or prescribes an abortion-inducing drug, the physician must examine the pregnant woman and document, in the woman ' s medical record, the gestational age and intrauterine location of the pregnancy. (d)AAThe physician who gives, sells, dispenses, administers, provides, or prescribes an abortion-inducing drug shall provide the pregnant woman with: (1)AAa copy of the final printed label of that abortion-inducing drug; and (2)AAa telephone number by which the pregnant woman may 24 reach the physician, or other health care personnel employed by the physician or by the facility at which the abortion was performed with access to the woman ' s relevant medical records, 24 hours a day to request assistance for any complications that	T 125		

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T 125	Continued From page 7 arise from the administration or use of the drug or ask health-related questions regarding the administration or use of the drug. (e)AAThe physician who gives, sells, dispenses, administers, provides, or prescribes the abortion-inducing drug, or the physician ' s agent, must schedule a follow-up visit for the woman to occur not more than 14 days after the administration or use of the drug.AAAt the follow-up visit, the physician must: (1)AAconfirm that the pregnancy is completely terminated; and (2)AAassess the degree of bleeding. "1 of 4 patients who underwent a medication abortion (medication procedure patient #2) was not scheduled for a follow-up appointment (within 14 days or otherwise) upon her discharge from the facility. The above was confirmed in an interview with staff #1 and staff #8 on the evening of 1-24-18. Based on a review of documentation and interview the facility failed to ensure that an ASC that performs abortions shall adopt, implement and enforce a policy to ensure compliance with Health and Safety Code, Chapters 245 and 171, Subchapters A and B (relating to Abortion and Informed Consent). Findings Included: The Texas Health and Safety Code, Chapter 171, Subchapter B. Informed Consent states in part, "Sec. 171.012. VOLUNTARY AND INFORMED CONSENT. (a) Consent to an abortion is	T 125	Administrator and Physician are responsible to insure a scheduled follow-up appointment is given to all patients upon her discharge. The administrator will check charts before the Physician see's the patient and the Physician will confirm when he speaks with patient. Staff meeting will be held to monitor and insure this is done. On the patient follow-up form the patient follow up appointment date and time will be documented and a copy will be placed in the patients chart. This will be confirmed by administrator and Physician when consulting patient for medical abortion procedure.	1/26/18

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T 125	Continued From page 8 voluntary and informed only if:(1) the physician who is to perform the abortion informs the pregnant woman on whom the abortion is to be performed of:(A) the physician's name." Review medical records revealed 11 of 19 surgical patients that had "Informed Consent for Abortion, Anesthesia, and Other Services" that included a statement that "I am [age] years old and consent to the performance upon me of pregnancy termination by [physician name]" that listed a physician name that was not the physician performing the abortion, per the health and safety code. * Surgical patient #1's informed consent listed staff member #2, however the procedure was completed by staff member #3. * Surgical patient #2's informed consent listed staff member #2, however the procedure was completed by staff member #3. * Surgical patient #5's informed consent had a blank space for the physician name that was not completed, the procedure was completed by staff member #1. * Surgical patient #6's informed consent listed staff member #2, however the procedure was completed by staff member #1. * Surgical patient #7's informed consent listed staff member #2, however the procedure was completed by staff member #1. * Surgical patient #8's informed consent listed staff member #2, however the procedure was completed by staff member #1. * Surgical patient #10's informed consent listed staff member #2, however the procedure was completed by staff member #1. * Surgical patient #14's informed consent listed staff member #2, however the procedure was completed by staff member #1. * Surgical patient #15's informed consent listed	T 125	Administrator will be responsible for the plan of correction. The plan is to omit forms with incorrect information and employee or Physician names pre-printed on the forms. The plan will be implemented with new, updated and corrected forms being made and used in all patient charts. Ongoing compliance will be to update and replace forms as needed. The forms used in the charts in question are all older forms that were used when other Physicians worked at this facility. The forms have are being replaced and updated with corrected information and Physician names where applicable. The old forms have been replaced both in english and spanish and the old forms disposed of. The new forms are being replaced in english and spanish.	2/28/18

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T 125	Continued From page 9 staff member #2, however the procedure was completed by staff member #1. * Surgical patient #17's informed consent listed staff member #2, however the procedure was completed by staff member #1. * Surgical patient #18's informed consent listed staff member #2, however the procedure was completed by staff member #1. In an interview on 01/23/18, staff members #1 and 8 confirmed the informed consent forms did not accurately reflect which physician performed the procedures. Staff members # 2 and 3 were previously employed at the facility, but currently were not employed at the facility. These staff member stated the from had been updated to reflect only staff member #1's name. Staff member #1 is the only physician working at the facility at the time of the survey. This surveyor noted that the 2018 informed consent forms only listed staff member #1 as the physician completing the procedure. [redacted]	T 125	Correction The informed consent forms have been replaced in both english and spanish and corrections are made. The staff members previously employed are no longer at the clinic and all forms are being updated and corrected. The informed consent form has been corrected and implemented into the patients charts. There is only one Physician working at the facility and this correction is done and implemented.	1/26/18

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[redacted]				
T 153	135.6(b)(6) ADMINISTRATION OF A LICENSED ASC (b) Personnel policies shall be established and implemented to facilitate attainment of the mission, goals, and objectives of the ASC. Personnel policies shall: (6) provide adequate orientation and training to familiarize all personnel with the ASC's policies, procedures, and facilities. This Requirement is not met as evidenced by: Based on a review of documentation and interview, the facility failed to ensure the enforcement of personnel policies to provide adequate orientation and training to	T 153		

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T 153	Continued From page 11 familiarize all personnel (including contracted employees) with the ASC's policies, procedures, and facilities. Findings included: A facility based policy entitled, "Employee Training and Orientation" stated in part, " Employee will receive orientation and training for the area they work and documentation will be placed in their employee file". Facility based job description for a Registered Nurse stated in part, "A RN will have at minimum certification in basic cardiac life support." The contact for between the facility agency providing agency nurses stated in part, "COMPETENCY ASSESSMENT FOR EACH ASSIGNMENT AND CLIENT ORIENTATION [Agency name] assesses and documents field staff competency needed to provide care, treatment, and services to the population served. CLIENT responsibilities for competency assessment including orientation to relevant unit, setting or program -specific policies and procedures; assessment for competency to the relevant unit, setting or program-specific policies and procedures; technical skills training and observation on unit specific medical equipment, and orientation to unit specific computer systems for documentation and medication administration." Review of facility based documentation for the calendar year 2017, seven agency nurses were used at the facility. The facility did not have personnel files for these agency nurses. The facility did not have documentation of the nurses	T 153	Administrator will be responsible for the plan. The plan is to keep employee files on all employees (staff and agency). The plan will be implemented with all employees (staff and agency) being trained and oriented to the work area they will work and an employee file being done for all agency employees that work at the facility. Ongoing compliance will be that ALL employees whether agency or staff will have an orientation and employee file before working at the facility. An employee file is made for all staff employees routinely and employees are trained and oriented to their work area. Agency nurses/staff will be oriented and trained prior to working at the facility and credentials, CPR, and ACLS (if app.) will be confirmed prior to working. An employee file will be made for all agency staff with credentialing in file before they work at the clinic.	1/28/18

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T 153	Continued From page 12 licensure and CPR training. There was no documented orientation to relevant unit, setting or program -specific policies and procedures; assessment for competency to the relevant unit, setting or program-specific policies and procedures, or technical skills training and observation on unit specific medical equipment per the facility contract with the agency providing the agency nurses. The above findings were confirmed on 01/24/18 in an interview with staff member #8.	T 153		
T 211	135.9(j)(5) MEDICAL RECORDS IN A LICENSED ASC (j) The (ASC) shall include the following in patients' medical records: (5) a preanesthesia evaluation by an individual qualified to administer anesthesia: This Requirement is not met as evidenced by: Based on a review of documentation and interview, the facility failed to ensure that patients' medical records contained a preanesthesia evaluation by an individual qualified to administer anesthesia. Findings included: Facility based Standard Operating Procedures titled, "Medical and Clinical Services" stated in part, "The person administering the anesthetic agent(s) examines the patient immediately prior to surgery to evaluate the risk of anesthesia."	T 211		

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T 211	Continued From page 13 Review of medical record revealed 8 of 19 surgical patients did not have an appropriate pre-anesthesia assessment completed prior to the procedure. A "Pre-Anesthesia Evaluation" form was on the back of all the anesthesia record. The "Pre-Anesthesia Evaluation" form included an area to notate pre-procedure vital signs, previous anesthesia/operation, family history of anesthesia complications, assessment of the patient's airway/teeth/neck and head, allergies, and system assessment. * Surgical patient #8 had a pre-anesthesia form completed by staff member #5 that only noted pre-procedure vitals, allergies, and stated "healthy" for the systems assessment. * Surgical patient #9 had a pre-anesthesia form completed by staff member #5 that was not completed. * Surgical patient #10 had a pre-anesthesia form completed by staff member #5 that only noted no allergies and stated "healthy" for the systems assessment. * Surgical patient #14 had a pre-anesthesia form completed by staff member #5 that only noted pre-procedure vitals, no allergies, and stated "healthy" for the systems assessment. * Surgical patient #15 had a pre-anesthesia form completed by staff member #5 that only noted no allergies and stated "healthy" for the systems assessment. * Surgical patient #16 had a pre-anesthesia form completed by staff member #5 that only noted no allergies and stated "healthy" for the systems assessment. * Surgical patient #17 had a pre-anesthesia form completed by staff member #5 that only noted no allergies and stated "healthy" for the systems assessment. * Surgical patient #18 had a pre-anesthesia form completed by staff member #5 that was not	T 211		

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T 211	Continued From page 14 completed. Due to the incomplete nature of these forms, it is not know if an effective pre-anesthesia evaluation was completes assessing all factors including: In an interview on 01/24/18 staff member # 1 and 8, confirmed the above forms were not completed effectively. These staff members stated that staff member #5 no longer is employed at the facility. That staff member expired in 2018. The Pre-Anesthesia form has since been updated and and another employee #4 is used as the primary anesthetist at the facility.	T 211	Administrator and governing body will be responsible for the plan. All patients will have a complete pre-op evaluation prior to procedure or anesthesia by CRNA. New forms are being made and implemented with complete pre-op anesthesia evaluation and patient information forms to assist CRNA in evaluation. Compliance monitoring will be done with chart checks done randomly. Everything will be documented in chart. Patients have always received pre-op evaluation. Documentation by prior CRNA"s no longer working at the facility do not show documentation of the pre-op evaluations. New forms implemented. All patients will have complete pre-op evaluation by CRNA prior to receiving anesthesia and put in patient chart.	1/26/18
T 218	135.9(j)(12) MEDICAL RECORDS IN A LICENSED ASC (j) The (ASC) shall include the following in patients' medical records: (12) evidence that the patient left the facility in the company of a responsible adult, unless the operating surgeon or advanced practice registered nurse, writes an order that the patient may leave the facility without the company of a responsible adult; and This Requirement is not met as evidenced by: Based on a review of clinical records, the facility failed to include evidence that all patients left the facility in the company of a responsible adult, unless the operating surgeon or advanced practice registered nurse, writes an order that the patient may leave the facility without the company of a responsible adult. Findings were: A review of clinical records revealed that 3 of 4	T 218	Administrator will be responsible for plan. The plan is proper orders written by Physician if no driver needed or confirmation of driver prior to procedure. Implementation of plan is training staff and proper documents and orders. Compliance is monitoring with chart checks and continued training of staff. Physician orders have been updated for patients that the Physician feels does not need a driver. The clinical records mentioned were all medical abortions and the doctor did not feel that they needed a driver due to no pain or anesthetic meds were given. We were unaware that an order had to be written for the patient to leave without a driver for medical abortions. Documents are updated and implemented.	1/25/18

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T 218	Continued From page 15 patients that underwent a medication procedure (medication procedure patients #1, #3 & #4) and 1 of 19 patients that underwent a surgical procedure (surgical procedure patient #1) did not leave the facility in the company of a responsible adult. The clinical record contained no order stating that these patients could leave without the company of a responsible adult. The above was confirmed in an interview with staff #1 and staff #8 on the evening of 1-24-18.	T 218	This surgical patient did not receive any pain or anesthetic medications for the procedure. Orders have been updated for Physician order for patients to leave the facility without a designated driver.	1/25/18
T 231	135.10(c) FACILITIES AND ENVIRONMENT IN A LIC ASC (c) Facilities shall be clean and properly maintained. This Requirement is not met as evidenced by: Based on tour and interview, the facility failed to ensure that the facilities were properly maintained. Findings included During a tour of the facility on 01/24/18 the following observations were made: * In a facility supply room, approximately 8 large external shipping containers were observed stored with patient care items. 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	T 231	Administrator responsible for the plan. The plan is to remove all cardboard /shipping containers from surgical area. External containers will be removed and supplies placed on shelves. Implemented by removing all cardboard, shipping, and external containers. On going compliance will be monitored with staff training, and removing items from shipping cartons before entering clean area. All supplies and cardboard boxes have been removed from all clean areas of the clinic. Supplies is removed from shipping cartons before being placed in storage area. Plastic bins have been placed on metal shelves in clean storage areas for supplies to be stored an labeled.	1/28/18

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T 231	Continued From page 16 to risk of environmental contamination)." Preventing Infection in Ambulatory Care, Winter 2011/2012; available: http://apic.org/Resource_/TinyMceFileManager/Education/Preventing-Inf-in-Amb-Care-Winter2012-FINAL.PDF. In an interview on 01/24/18 staff member #8 confirmed the above findings.	T 231		
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: Based on observation and an interview with staff, the ambulatory surgical center (ASC) failed to provide drugs and biologicals in a safe and effective manner in accordance with professional practices and in compliance with all state and federal laws and regulations. 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).	T 267		

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T 267	Continued From page 17 According to 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 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,	T 267		

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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.
(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

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T 267	Continued From page 19 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 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	T 267		

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T 267	Continued From page 20 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 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	T 267		

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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 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 biologicals;

(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

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T 267	Continued From page 22 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; (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	T 267		

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(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, 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;

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(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 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

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T 267	Continued From page 25 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. (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	T 267		

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(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 267	Continued From page 26 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 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.	T 267		

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T 267	Continued From page 27 (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 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	T 267		

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T 267	Continued From page 28 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 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	T 267		

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T 267	Continued From page 29 (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, 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	T 267		

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T 267	Continued From page 30 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 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.	T 267		

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T 267	Continued From page 31 (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 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	T 267		

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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;
(-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

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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 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

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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.
(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

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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 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

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T 267	Continued From page 36 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. (9) Drugs supplied for postoperative use. Drugs supplied to patients for postoperative use shall be supplied according to the following procedures. (A) Drugs may only be supplied to patients who have been admitted to the ASC. (B) Drugs may only be supplied in accordance with the system of control and accountability established for drugs supplied from the ambulatory surgical center; such system shall be developed and supervised by the pharmacist-in-charge or staff pharmacist designated by the pharmacist-in-charge. (C) Only drugs listed on the approved	T 267		

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T 267	Continued From page 37 postoperative drug list may be supplied; such list shall be developed by the pharmacist-in-charge and the medical staff and shall consist of drugs of the nature and type to meet the immediate postoperative needs of the ambulatory surgical center patient. (D) Drugs may only be supplied in prepackaged quantities not to exceed a 72-hour supply in suitable containers and appropriately prelabeled (including name, address, and phone number of the facility, and necessary auxiliary labels) by the pharmacy, provided, however that topicals and ophthalmics in original manufacturer's containers may be supplied in a quantity exceeding a 72-hour supply. (E) At the time of delivery of the drug, the practitioner shall complete the label, such that the prescription container bears a label with at least the following information: (i) date supplied; (ii) name of practitioner; (iii) name of patient; (iv) directions for use; (v) brand name and strength of the drug; or if no brand name, then the generic name of the drug dispensed, strength, and the name of the manufacturer or distributor of the drug; and (vi) unique identification number. (F) After the drug has been labeled, the practitioner or a licensed nurse under the supervision of the practitioner shall give the appropriately labeled, prepackaged medication to the patient. (G) A perpetual record of drugs which are supplied from the ASC shall be maintained which includes: (i) name, address, and phone number of the facility; (ii) date supplied; (iii) name of practitioner;	T 267		

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T 267	Continued From page 38 (iv) name of patient; (v) directions for use; (vi) brand name and strength of the drug; or if no brand name, then the generic name of the drug dispensed, strength, and the name of the manufacturer or distributor of the drug; and (vii) unique identification number. (H) The pharmacist-in-charge, or a pharmacist designated by the pharmacist-in-charge, shall review the records at least once in every calendar week that the pharmacy is open. (10) Drug regimen review. (A) A pharmacist shall evaluate medication orders and patient medication records for: (i) known allergies; (ii) rational therapy--contraindications; (iii) reasonable dose and route of administration; (iv) reasonable directions for use; (v) duplication of therapy; (vi) drug-drug interactions; (vii) drug-food interactions; (viii) drug-disease interactions; (ix) adverse drug reactions; (x) proper utilization, including overutilization or underutilization; and (xi) clinical laboratory or clinical monitoring methods to monitor and evaluate drug effectiveness, side effects, toxicity, or adverse effects, and appropriateness to continued use of the drug in its current regimen. (B) A retrospective, random drug regimen review as specified in the pharmacy's policies and procedures shall be conducted on a periodic basis to verify proper usage of drugs not to exceed 31 days between such reviews. (C) Any questions regarding the order must be resolved with the prescriber and a written notation of these discussions made and maintained. (e) Records. (1) Maintenance of records.	T 267		

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T 267	Continued From page 39 (A) Every inventory or other record required to be kept under the provisions of this section (relating to Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center) shall be: (i) kept by the pharmacy and be available, for at least two years from the date of such inventory or record, for inspecting and copying by the board or its representative, and other authorized local, state, or federal law enforcement agencies; and (ii) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format, the requested records must be provided in a mutually agreeable electronic format if specifically requested by the board or its representative. Failure to provide the records set out in this subsection, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act. (B) Records of controlled substances listed in Schedule II shall be maintained separately and readily retrievable from all other records of the pharmacy. (C) Records of controlled substances listed in Schedules III - V shall be maintained separately or readily retrievable from all other records of the pharmacy. For purposes of this subparagraph, readily retrievable means that the controlled substances shall be asterisked, red-lined, or in some other manner readily identifiable apart from all other items appearing on the record. (D) Records, except when specifically required to be maintained in original or hard-copy form, may be maintained in an alternative data retention system, such as a data processing or direct imaging system provided: (i) the records in the alternative data retention system contain all of the information required on the manual record; and	T 267		

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T 267	Continued From page 40 (ii) the alternative data retention system is capable of producing a hard copy of the record upon the request of the board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies. (E) Controlled substance records shall be maintained in a manner to establish receipt and distribution of all controlled substances. (F) An ASC pharmacy shall maintain a perpetual inventory of controlled substances listed in Schedule II - V which shall be verified for completeness and reconciled at least once in every calendar week that the pharmacy is open. (G) Distribution records for controlled substances, listed in Schedule II - V, shall include the following information: (i) patient's name; (ii) practitioner's name who order the drug; (iii) name of drug, dosage form, and strength; (iv) time and date of administration to patient and quantity administered; (v) signature or electronic signature of individual administering the controlled substance; (vi) returns to the pharmacy; and (vii) waste (waste is required to be witnessed and cosigned, manually or electronically, by another individual). (H) The record required by subparagraph (G) of this paragraph shall be maintained separately from patient records. (I) A pharmacist shall conduct an audit by randomly comparing the distribution records required by subparagraph (G) with the medication orders in the patient record on a periodic basis to verify proper administration of drugs not to exceed 30 days between such reviews. (2) Patient records. (A) Each medication order or set of orders issued together shall bear the following information: (i) patient name;	T 267		

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T 267	Continued From page 41 (ii) drug name, strength, and dosage form; (iii) directions for use; (iv) date; and (v) signature or electronic signature of the practitioner or that of his or her authorized agent, defined as a employee or consultant/full or part-time pharmacist of the ASC. (B) Medication orders shall be maintained with the medication administration record in the medical records of the patient. (3) General requirements for records maintained in a data processing system. (A) If an ASC pharmacy's data processing system is not in compliance with the board's requirements, the pharmacy must maintain a manual recordkeeping system. (B) The facility shall maintain a backup copy of information stored in the data processing system using disk, tape, or other electronic backup system and update this backup copy on a regular basis to assure that data is not lost due to system failure. (C) A pharmacy that changes or discontinues use of a data processing system must: (i) transfer the records to the new data processing system; or (ii) purge the records to a printout which contains: (I) all of the information required on the original document; or (II) for records of distribution and return for all controlled substances, the same information as required on the audit trail printout as specified in subparagraph (F) of this paragraph. The information on the printout shall be sorted and printed by drug name and list all distributions and returns chronologically. (D) Information purged from a data processing system must be maintained by the pharmacy for two years from the date of initial entry into the	T 267		

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T 267	Continued From page 42 data processing system. (E) The pharmacist-in-charge shall report to the board in writing any significant loss of information from the data processing system within 10 days of discovery of the loss. (F) The data processing system shall have the capacity to produce a hard-copy printout of an audit trail of drug distribution and return for any strength and dosage form of a drug (by either brand or generic name or both) during a specified time period. This printout shall contain the following information: (i) patient's name and room number or patient's facility identification number; (ii) prescribing or attending practitioner's name; (iii) name, strength, and dosage form of the drug product actually distributed; (iv) total quantity distributed from and returned to the pharmacy; (v) if not immediately retrievable via electronic image, the following shall also be included on the printout: (I) prescribing or attending practitioner's address; and (II) practitioner's DEA registration number, if the medication order is for a controlled substance. (G) An audit trail printout for each strength and dosage form of these drugs distributed during the preceding month shall be produced at least monthly and shall be maintained in a separate file at the facility. The information on this printout shall be sorted by drug name and list all distributions/returns for that drug chronologically. (H) The pharmacy may elect not to produce the monthly audit trail printout if the data processing system has a workable (electronic) data retention system which can produce an audit trail of drug distribution and returns for the preceding two years. The audit trail required in this clause shall be supplied by the pharmacy within 72 hours, if	T 267		

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T 267	Continued From page 43 requested by an authorized agent of the Texas State Board of Pharmacy, or other authorized local, state, or federal law enforcement or regulatory agencies. (I) In the event that an ASC pharmacy which uses a data processing system experiences system downtime, the pharmacy must have an auxiliary procedure which will ensure that all data is retained for on-line data entry as soon as the system is available for use again. (4) Distribution of controlled substances to another registrant. A pharmacy may distribute controlled substances to a practitioner, another pharmacy, or other registrant, without being registered to distribute, under the following conditions. (A) The registrant to whom the controlled substance is to be distributed is registered under the Controlled Substances Act to possess that controlled substance. (B) The total number of dosage units of controlled substances distributed by a pharmacy may not exceed 5.0% of all controlled substances dispensed by the pharmacy during the 12-month period in which the pharmacy is registered; if at any time it does exceed 5.0%, the pharmacy is required to obtain an additional registration to distribute controlled substances. (C) If the distribution is for a Schedule III, IV, or V controlled substance, a record shall be maintained which indicates: (i) the actual date of distribution; (ii) the name, strength, and quantity of controlled substances distributed; (iii) the name, address, and DEA registration number of the distributing pharmacy; and (iv) the name, address, and DEA registration number of the pharmacy, practitioner, or other registrant to whom the controlled substances are distributed.	T 267		

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T 267	Continued From page 44 (D) If the distribution is for a Schedule II controlled substance, the following is applicable. (i) The pharmacy, practitioner, or other registrant who is receiving the controlled substances shall issue Copy 1 and Copy 2 of a DEA order form (DEA 222) to the distributing pharmacy. (ii) The distributing pharmacy shall: (I) complete the area on the DEA order form (DEA 222) titled "To Be Filled in by Supplier"; (II) maintain Copy 1 of the DEA order form (DEA 222) at the pharmacy for two years; and (III) forward Copy 2 of the DEA order form (DEA 222) to the divisional office of the Drug Enforcement Administration. (5) Other records. Other records to be maintained by the pharmacy include: (A) a permanent log of the initials or identification codes which will identify each pharmacist by name. The initials or identification code shall be unique to ensure that each pharmacist can be identified, i.e., identical initials or identification codes cannot be used; (B) Copy 3 of DEA order form (DEA 222), which has been properly dated, initialed, and filed, and all copies of each unaccepted or defective order form and any attached statements or other documents and/or for each order filled using the DEA Controlled Substance Ordering System (CSOS), the original signed order and all linked records for that order; (C) a copy of the power of attorney to sign DEA 222 order forms (if applicable); (D) suppliers' invoices of dangerous drugs and controlled substances dated and initialed or signed by the person receiving the drugs; a pharmacist shall verify that the controlled drugs listed on the invoices were added to the pharmacy's perpetual inventory by clearly recording his/her initials and the date of review of the perpetual inventory;	T 267		

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T 267	Continued From page 45 (E) supplier's credit memos for controlled substances and dangerous drugs; (F) a copy of inventories required by §291.17 of this title (relating to Inventory Requirements) except that a perpetual inventory of controlled substances listed in Schedule II may be kept in a data processing system if the data processing system is capable of producing a copy of the perpetual inventory on-site; (G) reports of surrender or destruction of controlled substances and/or dangerous drugs to an appropriate state or federal agency; (H) records of distribution of controlled substances and/or dangerous drugs to other pharmacies, practitioners, or registrants; and (I) a copy of any notification required by the Texas Pharmacy Act or these rules, including, but not limited to, the following: (i) reports of theft or significant loss of controlled substances to DEA, DPS, and the board; (ii) notification of a change in pharmacist-in-charge of a pharmacy; and (iii) reports of a fire or other disaster which may affect the strength, purity, or labeling of drugs, medications, devices, or other materials used in the diagnosis or treatment of injury, illness, and disease. (6) Permission to maintain central records. Any pharmacy that uses a centralized recordkeeping system for invoices and financial data shall comply with the following procedures. (A) Controlled substance records. Invoices and financial data for controlled substances may be maintained at a central location provided the following conditions are met. (i) Prior to the initiation of central recordkeeping, the pharmacy submits written notification by registered or certified mail to the divisional director of the Drug Enforcement Administration as required by the Code of Federal Regulations,	T 267		

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T 267	Continued From page 46 Title 21, §1304(a), and submits a copy of this written notification to the Texas State Board of Pharmacy. Unless the registrant is informed by the divisional director of the Drug Enforcement Administration that permission to keep central records is denied, the pharmacy may maintain central records commencing 14 days after receipt of notification by the divisional director. (ii) The pharmacy maintains a copy of the notification required in this subparagraph. (iii) The records to be maintained at the central record location shall not include executed DEA order forms, prescription drug orders, or controlled substance inventories, which shall be maintained at the pharmacy. (B) Dangerous drug records. Invoices and financial data for dangerous drugs may be maintained at a central location. (C) Access to records. If the records are kept in any form requiring special equipment to render the records easily readable, the pharmacy shall provide access to such equipment with the records. (D) Delivery of records. The pharmacy agrees to deliver all or any part of such records to the pharmacy location within two business days of written request of a board agent or any other authorized official. Source Note: The provisions of this §291.76 adopted to be effective October 7, 1986, 11 TexReg 4034; amended to be effective July 29, 1987, 12 TexReg 2337; amended to be effective September 14, 1988, 13 TexReg 4323; amended to be effective September 5, 1990, 15 TexReg 4810; amended to be effective September 27, 1991, 16 TexReg 5071; amended to be effective January 29, 1992, 17 TexReg 324; amended to	T 267		

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T 267	Continued From page 47 be effective September 30, 1993, 18 TexReg 6460; amended to be effective August 31, 2000, 25 TexReg 8406; amended to be effective March 4, 2004, 29 TexReg 2000; amended to be effective June 6, 2004, 29 TexReg 5376; amendedtobe effective December 3, 2006, 31 TexReg 9611; amended to be effective September 18, 2007, 32 TexReg 6333; amended to be effective September 20, 2009, 34 TexReg 6323; amended to be effective March 10, 2011, 36 TexReg 1528; amended to be effective December 10, 2013, 38 TexReg 8847; amended to be effective September 11, 2014, 39 TexReg 7119; amended to be effective December 6, 2015, 40 TexReg 8766; amended to be effective September 11, 2016, 41 TexReg 6708 Findings were: During a review of clinical records, a tour of the facility and an interview with staff, the facility was found to possess the following medications: "Epinephrine "Flumazenil "Naloxone "Nitrostat "Verapamil "Esmolol Hcl "Ephedrine "Dyphenhydramine "Lidocaine "Atropine "Amiodarone "Metoprolol "Ondansetron "Solumedrol "Ketorolac "Dexamethasone "Ventolin "Succinylcholine	T 267	Administrator and governing body will be responsible for the paln. Plan is to receive license from Texas State Board of Pharmacy for ASC. Implementing plan with application to Texas State Board of Pharmacy for license. Ongoing compliance will be license renewals and the pharmacist on staff. This facility has applied for an application for an free standing ASC Pharmacy License Class C with the Texas Board of Pharmacy. Requested documents and application sent in. The application is pending at this time. Ativan, Ketamine and Propofol are scheduled drugs that are controlled and locked up by the Physician and distributed by the Physician. They are given only under Physician supervision. Metronidazole, Ondanestrone, 1% Lidocaine, Phenergan, Misoprostol, Naproxen, and Nubain are floor medications that we give our patients at the clinic. The rest of the medications on this list are all crash cart medications and are locked up in the emergency crash cart. These medications will only be used at the direction of the Physician in an emergency situation. The medications are checked monthly by the nurse for expiration dates and replaced as needed.	Pending Application

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T 267	Continued From page 48 "Propofol "Phenergan "Metronidazole "Naproxen "Misoprostol "Nubain "Ativan (Schedule IV medication) "Ketamine (Schedule III medication" In an interview with staff #1 on 1-24-18, staff #1 was asked if the facility was licensed as required by the Texas State Board of Pharmacy and in compliance with 22 Texas Administrative Code, §291.76 (relating to Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center). Staff #1 stated that the facility was not licensed as required. When asked why the facility was not licensed as required, staff #1 stated that [staff #1] did not think it was necessary. The above was confirmed in an interview with the Medical Director and Clinic Administrator the afternoon of 1-24-18.	T 267	Staff # 1 does not have a Pharmacy License and was never told he needed one. He is the only Physician at the facility and monitors all the medications, The physician locks up all scheduled drugs and they are given on as an needed patient to patient basis. A Pharmacy License has been applied for and the application is pending at this time.	Pending
T 420	135.52 SUBCHAPTER C. PHYSICAL PLANT AND CONSTRUCTION 135.52 Construction Requirements for a New Ambulatory Surgical Center.	T 420		

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T 420	Continued From page 49 This Requirement is not met as evidenced by: The Texas Administrative Code 135.52 Construction Requirements for a New Ambulatory Surgical Center states in part, "135.52(i) General electrical requirements. This paragraph contains common electrical and essential emergency system requirements. (13) NURSES CALLING SYSTEM. (A) A nurse emergency calling system shall be installed in all toilets used by patients to summon nursing staff in an emergency. Activation of the system shall sound an audible signal which repeats every five seconds at a staffed location, and shall activate a distinct visible signal outside of toilet room where the call originated. The visible and audible signals shall be cancelable only at the patient calling station. Activation of the system shall also activate distinct visible signals in the clean workroom, in the soiled workroom, and if provided, in the nourishment station." Findings included: * During a observation of the facility on 01/22/18, 01/23/18, and 01/24/18 it was observed that the cord to the emergency calling system of the bathroom in the holding area was wrapped around the handicapped bar, rendering the call system ineffective in the event of an emergency. * During a tour of the facility on 01/24/18 it was observed only 1 of 4 patient used toilets had nurse emergency calling systems in place. The above findings were confirmed in an interview with member 8 on 01/24/18.	T 420	Administrator will be responsible for the plan. The plan is to nurse emergency call system in all toilets used by patients to summon nursing staff in an emergency. Implemented by placing Emergency call alarms in patient bathrooms. Ongoing compliance is checking systems to ensure they are working properly. This is corrected and staff trained on use. Call lights with emergency alarms are placed in the patient bathrooms to insure patients have a means of calling for help in an emergency situation. Emergency call systems are placed in all patient bathrooms. Patients are instructed not to wrap cords around handicap bars. This is checked frequently by staff when cleaning the bathrooms.	2/28/18 2/28/18