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
	130061	A. BUILDING: _____ B. WING _____	C 12/10/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD CENTER FOR CHOICE ASC	4600 GULF FREEWAY, SUITE 300 HOUSTON, TX 77023

(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	25 TAC 135 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 relicensure 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). In addition, a complaint investigations survey was conducted. TX 00220862 was unsubstantiated An entrance conference was held on the morning of 12-09-15 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 12-10-15 with key administrative personnel. Findings of the survey were discussed and an opportunity for questions and discussion was provided.	T 000	[Tag 228] The facility has policies on hand hygiene and all employees are trained upon hire and annually on those policies. There are also ad hoc trainings throughout the year if there is ever a concern of poor hand hygiene. In an effort to make it convenient to maintain proper hand hygiene, the facility has alcohol based sanitizer dispensers strategically located throughout the floor and within the requirements of the Life Safety Codes. Additionally, prior to each business day, the Facilities Assistant conducts a walk through to ensure that there is adequate soap and sanitizer available at every dispenser. To address the systemic concern of hand hygiene, there will be an increase in hand hygiene trainings and exercises effective January 27th, 2016. The Director of Nursing and Infection Preventionist will increase the frequency of trainings to quarterly from annually. The facility Administrator conducted a hand hygiene exercise with all staff December 14th, 2015. She will add signage of when hand hygiene must occur (downloaded from WHO) to all clinical areas by January 15th, 2016 as a reminder to all staff. Effective January 27th, 2016, there will be an enhanced quality assurance program implemented to ensure ongoing compliance with proper hand hygiene. The Infection Preventionist will conduct monthly observations of staff. Any breaches in hand hygiene will be addressed immediately by the Infection Preventionist and shared with the appropriate manager and Administrator. All observations and findings will be reported to the QAPI quarterly and then to the Governing Body by the Quality representative. Recv'd JAN 05 2016 HFC - Houston	January 27th, 2016
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	T 228		

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T 228	Continued From page 1 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 ensure adequate surveillance techniques, that minimize sources and transmission of infections. The facility failed to ensure: * Staff utilized appropriate hand hygiene when providing patient care. * Staff could verbalize proper concentration of enzymatic detergent used to wash surgical instruments. Surgical assistant (SA) # 8 did not have documented training/competency in sterile processing. *Contaminated "sterilized" packaged instruments were not available for use in surgery. * Proper testing / use of biological indicator for the autoclave on 12-07-15. * Metal equipment located in the operating room (OR) was able to be disinfected; did not not contain rust. * Staff cleansed IV medication port prior to injecting medications per facility policy. Findings include:	T 228	[Tag 228] All staff are trained upon hire and annually on infection prevention practices, including sterile processing. Surgical assistants are trained on proper usage of the enzymatic detergent and high level disinfectant as part of their orientation to sterile processing. An in-service will be conducted by the Surgical Assistant Supervisor by January 9th, 2016 to review proper usage/concentration of the enzymatic detergent and high level disinfectant. The enzymatic detergent instructions will be printed, laminated, and posted in the lab as a quick reference by January 9th, 2016. In order to ensure ongoing competency, surgical assistants will be tested annually on proper concentration of enzymatic detergent to water and on other sterile processing subjects. This written exam will be finalized by January 25th, 2016. To enhance compliance and to reduce the potential for human error of not measuring correctly, the Administrator has scheduled for the manufacturer to come the week of January 4th, 2016 to install the manufacturer's measuring device for their enzymatic detergent (Steris Acu-slnQ Enzymatic Dosing System). Once installation is complete, an in-service will be held by the manufacturer's representative. Surgical Assistant #8 will retake the affiliate online courses on "Infection Prevention" by January 15th, 2016 to document her training. All personnel files will be reviewed January 8th, 2016 by the Director of Nursing, Patient Care Manager, Business/Administrative Manager, and Surgical Assistant Supervisor to ensure all required trainings/competencies are documented. If there are any discrepancies found, then they will be addressed and reported to the Administrator immediately. This file review will now be scheduled every 6 months to ensure all files are up to date.	January 25th, 2016

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T 228	Continued From page 2 Hand Hygiene: Observation of suction abortion procedure (Patient # 1) on 12-09-15 at 10:45 a.m. revealed Physician # 6 and Surgical Assistant (SA) # 4 failed to sanitize their hands prior to donning gloves before the procedure. Further observation revealed after the procedure, SA # 4 bundled the contaminated surgical instruments. She failed to perform hand hygiene after removing her contaminated gloves and donning a new pair of gloves. SA # 4 proceeded to document in the patient record. Interview on 12-10-15 at 11:50 a.m. with Director of Nurses (DON) # 5 she stated " all staff should sanitize their hands before and after glove use." Enzymatic Detergent / Sterile Processing Competency : Observation on 12-09-15 at 11:10 a.m. in the "Products of Conception Lab" revealed SA # 7 washing dirty surgical instruments in the sink. Interview at the time of observation, SA # 7 said the instruments were cleaned with an enzyme cleaner mixed with water. When asked the concentration, SA # 7 said "it is 5 pumps of detergent and we fill it with water to the line in the sink." SA # 7 said there was "no actual marked line in the sink, just over time, a water line had developed..." SA # 7 was unsure how many gallons of water was presently in the sink. Asked how many ounces of enzymatic detergent per pump, SA # 7 said she was unsure "but we have always done 5 pumps." She went on to say to say no one used any type of measuring device for the detergent.	T 228	[Tag 228] The facility has a policy to inspect all instruments immediately prior to any procedure as part of the time out process to ensure contaminated "sterilized" packaged instruments are not used. The cited deficiencies were on packages that were in the clean utility room racks and not in current use. After the surveyor brought the attention of the spots to staff, the packages were immediately pulled from the rack. The Surgical Assistant Supervisor examined the packages in greater detail and was able to determine that the markings on the packages matched the markings on the autoclave tray used during sterilization. As of December 29th, 2015, a replacement tray had been ordered by the Surgical Assistant Supervisor. A quality improvement audit was conducted by the Administrator December 18th, 2015 to determine the causes of the markings on the autoclave tray. It was determined that the markings on the tray were small spots of rust caused by condensation on the tray because the dry cycle did not completely empty out all of the moisture in the autoclave chamber. After contacting the autoclave manufacturer, it was determined that the dry cycle could be increased by 10 minutes. A test load was ran with the updated dry cycle time of 40 minutes and the chamber and test packages were completely dry. This information was immediately shared and process was trained with the Surgical Assistants the same day. The "Autoclave Sterilization Log" will be updated by January 8th, 2016 by the Administrator to include a section for the Surgical Assistant to sign off that they have inspected the instruments at the end of the sterilization run. The Surgical Assistant Supervisor will conduct an in-service January 13th, 2016 on the sterilization processes, updated documentation requirement and the importance of inspecting instruments prior to storing on the "ready for use" racks in the utility room. To ensure ongoing compliance of the new system, a quality assurance audit will be implemented January 18th, 2016. The Surgical Assistant Supervisor will conduct random checks of packaged instruments to ensure their integrity and of the "Autoclave Sterilization	January 18th, 2016

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T 228	Continued From page 3 SA # 7 removed the bottle of ReVital Ox Enzymatic Detergent from under the sink. Review of the manufacture label on the bottle of ReVital Ox Enzymatic Detergent read:" Manual cleaning: dilute 1/8 to 1/2 fluid ounce per gallon of warm water...soak a minimum of 1 to 5 minutes.." Review of the entire label failed to reveal manufacturer instruction directing a number of "pumps" of detergent to use per gallon . Sterile processing competency: On 12-10-15, surveyor reviewed the personnel / training records of three (3) surgical assistants (SA) who worked in sterile processing. Review of the file of SA # 8 failed to reveal documented training or competency in sterile processing. Interview on 12-10-15 at 1:10 p.m. with HR Director #21, she stated she was unable to locate documented training or competency in sterile processing for SA # 8. Contaminated Packaged Sterile Instruments Observation on 12-09-15 at 11:40 a.m in the clean side of instrument processing area revealed two (2) packages of "2431 Dilators" dated as sterilized on 12-07-15. Both of the packages had a line of brown dots (dime- sized) on the back of the package. Interview with SA # 8 at time of observation she stated because of the discoloration on the back of the packages, the instruments were not considered sterilized. She went on to say they	T 228	[Tag 228 - Continued from page 3] Log" weekly. Any instruments that are questionable will be pulled from use and reprocessed. If there are any noted deficiencies, they will be addressed immediately and appropriate corrective action taken by the Surgical Assistant Supervisor. Reports will be compiled and submitted to the Administrator monthly. These monthly reports and data will be developed into a quality study to be reported to the QAPI quarterly to ensure ongoing compliance and then to the Governing Body. [Tag 228] The facility has a policy to use a biological indicator daily as quality assurance for the autoclave. Staff are trained to test two indicators daily – one as the test indicator in the autoclave and another indicator from the same lot number as the control. Each indicator is labeled with the date and initials of the surgical assistant running the autoclave load. The lot number and expiration date of the biological indicators are preprinted by the manufacturer. After evaluating potential causes of why the test biological indicator from 12-07-15 was not legible and conducting a quality assurance study December 30, 2015, it was confirmed that the handwritten information on it was written with an inappropriate marker/pen and smeared over the preprinted lot number. Since quality control for sterilization processes is so imperative to maintaining the highest standard of patient safety, the Administrator will update the facility policy, "Autoclave Quality Control," by January 8th, 2016 to include that if a biological indicator's information is not legible then another biological indicator must be tested that same day to ensure the autoclave is functioning properly. The Surgical Assistant Supervisor will conduct an in-service January 13th, 2016 to review the updated policy with all Surgical Assistants. A quality assurance study will be implemented by January 18th, 2016 to ensure continued compliance with quality control indicators by the Surgical Assistant	January 18th, 2016

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T 228	Continued From page 4 should not have been stored with the sterile, ready- to- use instruments. Proper testing / use of biological indicators for the autoclave: Observation on 12-09-15 at 11:40 a.m. in the clean side of instrument processing area revealed one counter top steam sterilizer. Interview at this same time with SA # 8, she explained the processes related to the use of the autoclave. SA # 8 said a steam indicator (dated) was placed in each load. Biological indicators (BI)were run at least once a day. Further observation revealed a BI incubator with a test and a control BI in place. SA # 8 stated the test and control BI had to be the same lot number. Further observation in the BI incubator revealed the lot number on the test BI was illegible; the control BI lot number was legible and dated 12-07-15. SA # 8 said if the lot numbers could not be verified as being the same, the BI test was not valid. Rust on Equipment in OR Observation on 12-09-15 at 10:45 a.m. in the Operating Room revealed a metal stand that contained a suction machine. The metal stand had rust on the top and bottom. Interview at the time of observation with DON # 5 she acknowledged the stand could not be disinfected due to the presence of rust. Hand Hygiene	T 228	[Tag 228 - Continued from page 4] Supervisor. She will conduct random checks of quality indicators weekly by inspecting biological indicators in the incubator, autoclave print outs, and the autoclave logs. If there are any noted deficiencies, they will be addressed immediately and appropriate corrective action taken by the Surgical Assistant Supervisor. Reports will be compiled and submitted to the Administrator monthly. These monthly reports will then be reported to the QAPI quarterly to ensure ongoing compliance and then to the Governing Body. [Tag 228] Rust on certain parts of metal equipment in the OR were caused by the facility's bleach product used to disinfect equipment. Facility Administrator has researched and found a hospital grade disinfectant with a rust inhibitor for use to prevent rusting from occurring again. Since rust cannot be removed and does not allow equipment to be properly disinfected, replacement parts for the rusted areas have been ordered as of December 28, 2015 and will be replaced immediately upon arrival by the Facilities Assistant. To enhance compliance and improve communications between front line staff and management, Administrator will expand online Quality Improvement reporting system to include equipment issues. All staff will be informed January 7th, 2016 by Administrator that if they see any equipment malfunctions or any equipment that cannot be properly disinfected, they should report it immediately to their supervisor or through the online reporting system to ensure appropriate action is taken. To ensure compliance with 135.10(a)(2), effective January 11th, 2016, Administrator and Facilities Assistant will begin conducting a quarterly inspection of all equipment to ensure they can be properly disinfected. If any equipment is found to be out of compliance, it will be immediately pulled out of use and service or replacement requested. All equipment issues will continue to be reported to the QAPI quarterly and then to the Governing Body.	January 11th, 2016

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T 228	Continued From page 5 Observation made on 12/10/2015 at 10:01 a.m. at Procedure Room #1, Physician #17 performed a suction abortion procedure to Patient #6, after the procedure she removed her pair of gloves and grabbed a pen coming from her pocket and documented on the patient's chart. Interview made with the Physician #17 on 12/10/2015 at 10:10 a.m., outside the Procedure Room, the Surveyor told her that she did not immediately perform hand hygiene after removing her contaminated gloves, she said "Yes, I should do that, but because maybe sometimes if people are watching you, it is kind of overwhelming." Record review of facility policy titled "Standard Precautions, Hand Hygiene, Personal Protective Equipment (PPE) ,undated" read :"...Hand hygiene is the #1 protection against transmission of communicable diseases...wash hands even prior to donning gloves...perform hand hygiene after removal of PPE..." Heparin Lock Observation made on 12/10/2015 at 09:55 a.m. at Procedure Room #1, while talking with Patient #6, Registered Nurse #19 aspirated 2 IV medications and immediately injected it to her right antecubital Peripheral Intravenous blue heparin lock without disinfecting the port. Interview made with the Facility's Director of Nursing on 12/10/2015 at 09:56 a.m., the Surveyor notified her about the procedure that Registered Nurse #19 did not wipe the port of the	T 228	[Tag 228] It is the policy of the facility that staff disinfect IV ports prior to accessing. Policies for safe injection practices are reviewed with all licensed staff upon hire and annually. After the surveyor addressed the issue with the Director of Nursing, she reminded Registered Nurse #19 on the importance of always disinfecting the IV ports. Since the cited deficiency has potential impact on all patients, the Director of Nursing will review and retrain all licensed staff on the facility's policy on "Safe Injection, Infusion, and Medication Vial Practices" and review the C DC's "One and Only" videos on January 12th, 2016. To enhance compliance, the CDC's "One and Only" videos will become part of any new licensed staff's orientation due to the importance of safe injection practices to all patients' safety. To ensure ongoing compliance of safe injection practices, a quality assurance program will begin January 19th, 2016. The Director of Nursing and/or the Infection Preventionist will begin systematically monitoring for compliance by conducting quarterly observations of each licensed staff to ensure safe injection practices are being applied. Any deficiencies will be addressed immediately and will be brought to the quarterly QAPI meeting for further review and forwarded to the Governing Body.	January 19th, 2016

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T 228	Continued From page 6 blue heparin lock, the Surveyor verified the medications, and she said "Yes, I saw it, she did not wipe it. She should have cleaned the port before injecting the medicines, those are Versed and Fentanyl." Record review of facility policy titled "Safe Injection, Infusion and Medication Vial Practices", undated, read: "...Aseptic technique: A. parenteral medications should be accessed in an aseptic manner ...IV solutions...E. Disinfect IV ports using friction with 70% alcohol. Allow to dry prior to accessing..."	T 228	[Tag 241] The facility requires all registered nurses to be privileged by the Director of Sedation & Anesthesia services prior to being allowed to administer moderate sedation to patients. New registered nurses hired are mentored and trained with more experienced nurses. In order to improve training, there will be an addition of structured didactic training through AORN's online course: Administering Moderate Sedation in the ASC. The facility Administrator submitted registration December 12th, 2015 for current registered nurses for the online course and all future hires will now be required to complete this didactic training prior to any hands on training with administering moderate sedation. To ensure documented competencies, a formal competency tool for moderate sedation will be implemented by January 25th, 2016. If the registered nurse cannot demonstrate competency, then they will be retrained by the Director of Nursing before continuing patient care. The process for annually privileging of registered nurses to provide moderate sedation will now require documented competency. The documented competency must be submitted to the Director of Sedation & Anesthesia Services or privileges will not be granted. Annual privileging and competency of registered nurses providing moderate sedation will be reviewed and approved by the Medical Executive Committee to ensure compliance and will have oversight by the Governing Body.	January 25th, 2016
T 241	135.11(a)(4) ANESTHESIA & SURGICAL SVCS IN A LIC ASC 4) Only personnel who have been approved by the facility to provide anesthesia services shall administer anesthesia. All approvals or delegations of anesthesia services as authorized by law shall be documented and include the training, experience, and qualifications of the person who provided the service. A qualified registered nurse (RN) who is not a certified registered nurse anesthetist (CRNA), in accordance with the orders of the operating surgeon, anesthesiologist, or CRNA, may administer topical anesthesia, local anesthesia, minimal sedation and moderate sedation, in accordance with all applicable rules, policies, directives and guidelines issued by the Texas Board of Nursing. When an RN who is not a CRNA administers sedation, as permitted in this paragraph, the facility shall: (A) verify that the registered nurse has the requisite training, education, and experience; (B) maintain documentation to support that the registered nurse has demonstrated competency in the administration of sedation;	T 241		

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T 241	Continued From page 7	T 241		

(C) with input from the facility's qualified anesthesia providers, develop, implement and enforce detailed, written policies and procedures to guide the registered nurse; and
(D) ensure that, when administering sedation during a procedure, the registered nurse has no other duties except to monitor the patient.

This Requirement is not met as evidenced by:
Based on observation, interview, and record review the facility failed to ensure documented competencies for 4 of 4 registered nurses (RN) who administer sedation (RN # 3, 10, 12, 22)

Findings include:

Observation of suction abortion procedure (Patient # 1) on 12-09-15 at 10:45 a.m. revealed RN # 3 administered versed 2 mg/ml and fentanyl 100 mcg prior to the procedure.

Interview on 12-09-15 at 12:30 p.m. with RN # 3 he was asked about his training to administer sedation. RN # 3 said he did not have formal training / documented competency but had been paired with a mentor.

Record review on 12-10-15 of the personnel /training records for for RN # 3,10, 12, & 22 failed to reveal documented competency/training to administer sedation.

Interview on 12-10-15 at 11:50 a.m. with Director of Nurses (DON) # 5 she said staff received training beginning in the recovery unit. The DON went on to say "it is important for new staff to learn monitoring for potential complications and learn a sense of what is normal." She went on to

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T 241	Continued From page 8 say the staff then began a mentorship program in the procedure room. They were paired with an experienced staff member for as much time as needed to ensure they were comfortable administering sedation. DON # 5 stated the staff was trained in administering sedation but there was no formal documented competency of this training. Record review on 12-10-15 of facility job description for RN read: " Essential Functions:...Procedure Room: ..Administer medications, including medication used for anesthesia purposes, as ordered by the operating physician. Note: only Registered Nurses who have granted privileges to administer anesthesia (based in training and demonstrated competency) are allowed to administer anesthesia.."	T 241		