45th Day 10/11/19

Division of Health Care Facilities

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
POC #2	TNPL53526	A. BUILDING _____ 9/23/19 B. WING _____ SR	08/27/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
KNOXVILLE CENTER FOR REPRODUCTIVE HE	1547 WEST CLINCH AVENUE KNOXVILLE, TN 37916

Acceptable

(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
A 001	1200-8-10 Initial This Rule is not met as evidenced by: A Licensure survey was conducted on 8/26/19 - 8/27/19 at Knoxville Center for Reproductive Health. The facility was found to not be in substantial compliance with Chapter 1200-8-10, Standards for Ambulatory Surgery Treatment Centers.	A 001	The nursing supervisor/Infection control officer will be responsible for monitoring compliance of all deficiencies cited.	9/30/19
A 425	1200-8-10-.04(20)(b) Administration (20) Infection Control. (b) The physical environment of the ambulatory surgical treatment center shall be maintained in a safe, clean and sanitary manner. This Rule is not met as evidenced by: Based on review of facility policy, review of the Centers for Disease Control and Prevention (CDC) Guidelines, review of the Association of Peri-Operative Registered Nurses (AORN) Guidelines, observation, and interview, the facility failed to maintain sterile technique during 1 of 1 observations made and failed to ensure an opened multi-dose vial of medication was dated, timed, and initialed in 1 (pre-operative prep area) of 9 patient care areas observed. The findings include: Review of the facility policy "Medication Administration Policy" dated 8/2/13 revealed "...All multi-dose vial medications must be labeled with date opened and RN [Registered Nurse] initials. These medications expire 28 days after initially	A 425	Per facility policy: All multi-dose vial medications shall be opened, dated, timed and initialled by nursing personnel. The nursing supervisor/infection control officer will be responsible for ensuring this facility policy is followed by completing this procedure herself or monitoring and/or observing the practice is being properly performed by others. Education/In-service for handling of MDV's occurred 9/19/19. The signature sheet is attached of all participating staff. The proper handling is now included in the daily RN checklist. To verify	9/30/19

Division of Health Care Facilities
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Kim Denson — TITLE: Administrator — (X6) DATE: 9/12/19

STATE FORM 6899 9CTK11 If continuation sheet 1 of 5

Kim Denson Administrator 9/20/19

SEP 20 2019

Division of Health Care Facilities

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	TNPL53526	A. BUILDING: _____ B. WING _____	08/27/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
KNOXVILLE CENTER FOR REPRODUCTIVE HE	1547 WEST CLINCH AVENUE KNOXVILLE, TN 37916

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A 425	Continued From page 1 opened regardless of manufacturer listed expiration date..." Review of CDC guidelines for "Injection Safety" dated 6/20/19 revealed "...If a multi-dose has been opened or accessed (e.g., [for example] needle-punctured) the vial should be dated and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial..." Review of AORN "Guidelines for Perioperative Practice" dated 2016, revealed "...Items introduced to the sterile field should be opened, dispensed, and transferred by methods that maintain the sterility and integrity of the item and the sterile field. Sterile items that are not opened, dispensed, and transferred by methods that maintain sterility and integrity may contaminate the sterile field..." Observation and interview with Surgical Assistant (SA) #1 on 8/26/19 at 1:00 PM, in treatment room #1, revealed SA #1 was setting up the procedure room for a patient procedure. Continued observation revealed a covered sterile stainless steel tray was sitting on a table. Further observation revealed SA #2 removed the cover from the stainless steel tray, which contained sterile surgical instruments and then retrieved a packaged sterile instrument from the countertop, opened the sterile package, and dropped the sterile instrument into the stainless steel tray with the other surgical instruments. Continued observation revealed the SA then touched the sterile surgical instruments that were located inside the stainless steel tray with the outside of the instrument packaging. Interview with SA #1 confirmed the SA was not aware the instrument packaging had touched the sterile surgical	A 425	completion, the checklist log will be reviewed weekly by the nursing Supervisor/ Infection Control officer. A copy of the RN checklist is attached. The log is also reviewed by the QA/PI committee annually. The weekly infection control monitoring sheet is also attached. 9/30/19 Continuing education will be provided by the nursing supervisor/infection control officer to all surgery assistants regarding concepts and practices for establishing and maintaining a sterile field. She will observe their practices and procedures to ensure sterile technique is being maintained and shall monitor these practices by routine evaluation.	

Division of Health Care Facilities

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	TNPL53526	A. BUILDING: _____ B. WING _____	08/27/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
KNOXVILLE CENTER FOR REPRODUCTIVE HE	1547 WEST CLINCH AVENUE KNOXVILLE, TN 37916

(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
A 425	Continued From page 2 instruments. Interview with the Co-Administrator/Nurse Practitioner #1 on 8/26/19 at 1:15 PM, in the recovery room, confirmed staff were expected to maintain sterile technique when setting up for a surgical procedure. Observation and interview with the Co-Administrator/Nurse Practitioner #1 on 8/26/19 at 1:20 PM, of a pre-operative prep area outside the procedure rooms, revealed 1 opened undated 50 milliliter multi-dose vial of 1% Lidocaine (numbing medicine). Interview with the Co-Administrator/Nurse Practitioner #1 confirmed the Lidocaine was opened and undated. Continued interview confirmed the facility failed to follow facility policy.	A 425	Education regarding sterile technique and sterilization procedures will be provided 9/23/19. The nursing supervisor/ Infection control officer will be responsible for the training. Sterile technique will be observed by the nursing supervisor/ infection control officer for a period of 30 days. A minimum of two cases shall be observed in each procedure room each procedure day. Continued education will be provided on a quarterly basis to promote improved practices and competency. The facility's goal for sustaining compliance is to strive for a culture of safety by providing continued education and training, monitoring existing procedures and practices and evaluating and revising infection control policies as needed. Infection Control and clinical policy guidelines are reviewed by the QA/PI committee annually.	9/30/19 9/23/19
A 436	1200-8-10-.04 (20)(c)6. Administration (20) Infection Control. (c) The chief executive officer or administrator shall assure that an infection control committee including members of the medical staff, nursing staff and administrative staff develops guidelines and techniques for the prevention, surveillance, control and reporting of facility infections. Duties of the committee shall include the establishment of: 6. A method of control used in relation to the sterilization of supplies and water, and a written policy addressing reprocessing of sterile supplies;	A 436		9/30/19

Division of Health Care Facilities

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	TNPL53526	A. BUILDING: _____ B. WING _____	08/27/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
KNOXVILLE CENTER FOR REPRODUCTIVE HE	1547 WEST CLINCH AVENUE. KNOXVILLE, TN 37916

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A 436	Continued From page 3 This Rule is not met as evidenced by: Based on review of a manufacturer's manual, review of a facility sterilization log book, review of the facility's procedure log book, observation, and interview, the facility failed to maintain a complete sterilization log book and failed to document the reading of a biological indicator (used to demonstrate whether conditions during a steam cycle were adequate to achieve a defined level of microorganism inactivation) for 1 of 1 autoclaves (used for steam sterilization). The findings include: Review of the Manufacturer's Instruction Manual for "...Biological Indicators for Steam Sterilization...," undated, revealed "...for optimal quality assurance of hospital-sterilized goods, we recommend that an [named] biological indicator be used to monitor every load of steam sterilized supplies...record results...log book for steam sterilization..." Review of the facility's sterilization log book dated 8-19-19 revealed no documentation of the load number, date and time in the incubator, dated and time out of the incubator, and whether the results of the controls (indicates if sterilization was done correctly) had positive or negative results. Review of the facility's procedure log revealed surgical procedures were performed on 8/19/19 and 8/22/19. Observation and interview with Sterilization Technician #1 on 8/26/19 at 1:30 PM, of the sterilization log book in the Sterilization Room,	A 436	9/30/19 The biological testing results that were not recorded the week of 8/19/19 occurred while the sterilization technician was on vacation. The individual responsible for overseeing this procedure during her absence will receive additional training to ensure proper documentation is noted. Our facility policy follows the following CDC guidelines- "A spore test should be used on each sterilizer at least weekly." Follow-up discussion with the sterilization technician revealed the surveyor reviewed only one of two sterilization log books.	

Division of Health Care Facilities

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	TNPL53526	A. BUILDING: _____ B. WING _____	08/27/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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A 436	Continued From page 4 confirmed surgical procedures were done on 8/19/19 and 8/22/19. Further interview confirmed the log book was incomplete and there was no documentation in the sterilization log book to indicate biological testing was performed.	A 436	The technician states she provided the biological indicator log but failed to provide the surveyor with the "Sterilization Maintenance Log". This log provides documentation of mechanical and chemical indicators and is completed each procedure day. A copy of the log is attached. The nursing supervisor/infection control officer will review the logs weekly to confirm procedures are being performed and results are documented as indicated. A copy of the weekly infection control monitoring sheet is attached.	9/30/19

PRINTED: 09/05/2019
FORM APPROVED

Division of Health Care Facilities

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	TNPL53526	A. BUILDING 01 - MAIN B. WING	08/27/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
KNOXVILLE CENTER FOR REPRODUCTIVE HE	1547 WEST CLINCH AVENUE KNOXVILLE, TN 37916

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A 001	1200-8-10 Initial This Rule is not met as evidenced by: Construction Type: II (111) Stories: 1 Constructed: 1950's (no drawings available) Sprinkled: NO Census: 0 Certified beds: 2 procedure rooms A Life Safety Code Survey was conducted by the State of Tennessee Department of Health Division of Health Licensure and Regulation Office of Health Care Facilities on 8/27/2019. During this life safety survey, this facility was found in substantial compliance with the requirements for participation in Medicare/Medicaid with chapter 1200-08-10, Standards for Ambulatory Surgical Treatment Centers., Life Safety from Fire, and the related National Fire Protection Association (NFPA) standard 101-2012.	A 001		
A 002	1200-8-10 No Deficiencies During the Life Safety portion of the annual Licensure survey conducted on 8/27/2018, no deficiencies were cited under 1200-08-10, Standards for Ambulatory Surgical Treatment Centers.	A 002		

Division of Health Care Facilities
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Kim Denison, Administrator
TITLE
(X6) DATE: 9/5/19

September 20, 2019

Provider #TNPL53526

Clarifications added to POC #2

The nursing supervisor/infection control officer will be responsible for monitoring compliance of all deficiencies cited.

Education/in-service for handling of MDV's occurred 09/19/19. The signature sheet is attached of all participating staff. The proper handling is now included in the daily RN checklist. To verify completion, the checklist log will be reviewed weekly by the nursing supervisor/infection control officer. A copy of the daily RN checklist log is attached. This log is also reviewed by the QA/PI committee annually. The weekly infection control monitoring sheet is also attached.

Education regarding sterile technique and sterilization procedures will be provided on Monday, September 23rd, 2019. The nursing supervisor/infection control officer will be responsible for the training.

Sterile technique will be observed by the nursing supervisor/infection control officer each procedure day during a 30 day period. A minimum of two cases shall be observed in each procedure room each procedure day. Continued education will be provided on a quarterly basis to promote improved practices and ensure competency.

The facility's goal for sustaining compliance is to strive for a culture of safety by providing continued education and training, monitoring existing procedures and practices and evaluating and revising infection control policies as needed. Infection control and clinical policy guidelines are reviewed by the QA/PI committee annually.