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Statement of Deficiencies
Citation Summary Sheet

For: HEALTHPLUS SURGERY CENTER, LLC (23116 / NJ23116)

Survey Event: LGDO11, Exit Date 09/07/2018

Citations Cited This Visit

Regulation Type	Regulation ID	Regulation Version	Building Number	Tag Number	Tag Title	Scope/ Severity
State	3B6I	9.00	00	0000	INITIAL COMMENTS	
State	3B6I	9.00	00	1157	GEN REQUIREMENTS: PERSONNEL	
State	3B6I	9.00	00	2278	PHARMACEUTICAL SVCS: POLICIES & PROCEDURES	
State	3B6I	9.00	00	2299	PHARMACEUTICAL SVCS: POLICIES & PROCEDURES	
State	3B6I	9.00	00	2306	PHARMACEUTICAL SVCS: POLICIES & PROCEDURES	
State	3B6I	9.00	00	2320	PHARMACEUTICAL SVCS: POLICIES & PROCEDURES	
State	3B6I	9.00	00	2432	PHARMACEUTICAL SVCS: STORAGE OF DRUGS	
State	3B6I	9.00	00	3070	SURG & ANES SVCS: SURG POL & PROCEDURES	
State	3B6I	9.00	00	4050	INFEC PREV & CONTROL: ADMINISTRATOR'S RESP	
State	3B6I	9.00	00	4057	INFEC PREV & CONTROL: ADMINISTRATOR'S RESP	
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State	3B6I	9.00	00	4098	INFEC PREV & CONTROL: POL & PROCEDURES	
State	3B6I	9.00	00	4183	INFEC PREV & CONTROL: INFEC PREV MEASURES	
State	3B6I	9.00	00	4190	INFEC PREV & CONTROL:STRILIZATN PT CARE ITEMS	
State	3B6I	9.00	00	4215	INFEC PREV & CONTROL:STRILIZATN PT CARE ITEMS	
State	3B6I	9.00	00	4216	INFEC PREV & CONTROL:STRILIZATN PT CARE ITEMS	
State	3B6I	9.00	00	4218	INFEC PREV & CONTROL:STRILIZATN PT CARE ITEMS	
State	3B6I	9.00	00	4260	INFEC PREV & CONTROL: CARE/USE OF STERILIZERS	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	23116	A. BUILDING: _____ B. WING _____	C 09/07/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HEALTHPLUS SURGERY CENTER, LLC	190 MIDLAND AVENUE SADDLE BROOK, NJ 07663

(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 000	INITIAL COMMENTS The facility is not in compliance with N.J.A.C. Title 8 Chapter 43A- Standards for Licensing of Ambulatory Care Facilities for this complaint investigation (C# NJ00114661). Findings during the investigation resulted in the Office of Program Compliance of the Department of Health ordering an immediate curtailment of services on September 7, 2018.	A 000		
A1157	8:43A-3.5(a) GEN REQUIREMENTS: PERSONNEL The facility shall develop written job descriptions and ensure that personnel are assigned duties based upon their education, training, and competencies, and in accordance with their job descriptions. This REQUIREMENT is not met as evidenced by: Based on review of employee personnel files and staff interviews, it was determined that the facility failed to ensure that job competencies are performed. Findings include: 1. Upon interview, Staff #8 stated that he/she completed the competencies for the sterile processing (SPD) technicians. Staff #8 stated that he/she also completed his/her own SPD competencies. 2. Upon review of SPD employee personnel files,	A1157		

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

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A1157	Continued From page 1 Staff #8, Staff #9 and Staff #10 lacked evidence of competencies in sterile processing. 3. The above findings were confirmed with Staff #1 and Staff #2.	A1157		
A2278	8:43A-9.3(b)(4) PHARMACEUTICAL SVCS: POLICIES & PROCEDURES The facility's policies and procedures for the administration, control, and storage of medications shall include, but not be limited to, policies and procedures for the use of parenterals, if used, including the labeling of intravenous infusion solutions, such that a supplementary label is affixed to the container of any intravenous infusion solution to which drugs are added. This REQUIREMENT is not met as evidenced by: Based on observation and staff interview conducted on 9/7/18, it was determined that the facility failed to ensure the development and implementation of policies and procedures addressing the preparation and use of parenteral medications. Findings include: Reference #1: The Center for Disease Control website http://www.cdc.gov/injectionsafety/providers/provider_faqs_med-prep.html states, "Medication Preparation Questions, 1. How should I draw up medications? Parenteral medications should be	A2278		

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A2278	Continued From page 2	A2278		

accessed in an aseptic manner. ... Proper hand hygiene should be performed before handling medications and the rubber septum should be disinfected with alcohol prior to piercing it."

1. At 10:40 AM, Staff #19 was observed preparing two (2) parenteral medications in OR #3.

a. Staff #19 failed to perform hand hygiene prior to handling the medication.

b. Staff #19 failed to disinfect the rubber septum of the vials with alcohol prior to piercing them.

2. Policies addressing medication preparation were requested from Staff #1 and #2. The policies provided did not address the deficient findings listed above.

Reference #2: Facility policy titled "Storage of Medications" states, "Purpose ... 6. ...If not administered immediately, all medications (injectable, oral, etc.) removed from the original container or packaging are labeled in a standard format in accordance with law, regulations and standards of practice. The labeling of such medication. At a minimum, the policy requires that labels include: ... Expiration date and time ..."

1. Two (2) single dose bags of 3000 ml of 0.9% Sodium Chloride for Irrigation, with an auxiliary label indicating that 3 ml of epinephrine had been added on 9/7/18 at approximately 8:45 AM, were found attached to an irrigating system in OR #1 and #2 at 10:30 AM.

a. Staff #3 stated that the bags were attached to tubing on the irrigation system and used until finished, or until the end of the day, for multiple

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A2278	Continued From page 3 patients. i. Single dose bags can only be used for one patient. b. The label affixed to the bag stated the date and time of preparation. It did not include the expiration date and time. 3. All policies related to pharmacy and medication preparation were requested from Staff #1 and #2. A policy addressing the use of a single dose bag of Sodium Chloride for Irrigation to which a drug is added, for irrigation of surgical sites, was not included in the policies provided.	A2278		
A2299	8:43A-9.3(b)(7) PHARMACEUTICAL SVCS: POLICIES & PROCEDURES The facility's policies and procedures for the administration, control, and storage of medications shall include, but not be limited to, policies and procedures for the control of drugs subject to the Controlled Dangerous Substances Acts and amendments thereto, in compliance with the New Jersey State Board of Pharmacy Rules, N.J.A.C. 13:39, and all other Federal and State laws and regulations concerning procurement, storage, dispensing, administration, and disposition. This REQUIREMENT is not met as evidenced by: A. Based on document review and staff interview conducted on 9/7/18, it was determined that the	A2299		

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A2299	Continued From page 4	A2299		

facility failed to ensure the development and implementation of policies and procedures addressing Drug Enforcement Agency (DEA) requirements for controlled drug accountability.

Findings include:

Reference #1: Drug Enforcement Agency (DEA) Regulations Title 21 CFR, Part 1305, Section 1305.13(e) states, "The purchaser must record on Copy 3 of the DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser."

1. The number of commercial containers received by the facility and the date received was not recorded on Copy 3 of the DEA Form 222 in the following instances:

a. DEA 222 form, dated 3/15/18, for the purchase of 375 vials of Fentanyl

b. DEA 222 form, dated 4/4/18, for the purchase of 375 vials of Fentanyl

c. DEA 222 form, dated 4/11/18, for the purchase of 375 vials of Fentanyl

d. DEA 222 form, dated 5/29/18, for the purchase of 200 vials of Fentanyl

e. DEA 222 form, dated 6/7/18, for the purchase of 100 vials of Fentanyl and 100 Oxycodone/APAP 10/325 tablets.

f. DEA 222 form, dated 6/13/18, for the purchase of 200 vials of Fentanyl

g. DEA 222 form, dated 1/18/18, for the

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A2299	Continued From page 5 purchase of 100 vials of Fentanyl Reference #2: Drug Enforcement Agency (DEA) Regulations Title 21 CFR, Part 1304, Section 1304..04(a) states, "(1) Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant; ..." Reference #3: Facility policy titled "Control and Accountability of Controlled Dangerous Substances (CDS)" states, "Procedure II. ...9. Keep records of Schedule II drugs separate from all other controlled substances." 1. Upon request, Staff #1 and #2 failed to provide corresponding records of purchase invoices for the purchase of Schedule II CDS recorded on DEA 222 forms dated 3/15/18, 4/4/18, 4/11/18, 5/29/18, 6/6/18, 6/7/18, and 6/13/18. B. Based on document review and staff interview conducted on 9/7/18, it was determined that the facility failed to ensure the development and implementation of policies and procedures addressing the intentional wasting of the entire contents of CDS medication vials. Findings include: 1. Upon interview, Staff #2 stated that the facility does not have a policy and procedure addressing the intentional wasting of the entire contents of a CDS medication vial by an anesthesiologist. Review of Controlled Substance Records identified instances where entire vials of a CDS were wasted, without any indication for the reason it was wasted. Examples include but are not limited to:	A2299		

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A2299	Continued From page 6 a. The wasting of 300 mcg of Fentanyl (100mcg/2ml vial), a Schedule II CDS, by Staff #18 on 6/20/18 b. The wasting of 100 mcg of Fentanyl (100mcg/2ml), a Schedule II CDS, by Staff #18 on 7/3/18 c. The wasting of 100 mcg of Fentanyl (100mcg/2ml vial), a Schedule II CDS, by Staff #18 on 8/1/18 d. The wasting of 4 mg of Versed (2mg/2ml vial), a Schedule IV CDS, by Staff #18 on 6/8/18 e. The wasting of 150 mcg of Fentanyl (100mcg/2ml vial), a Schedule II CDS, by Staff #18 on 5/28/18 (two vials were taken for one patient and 50 mcg were given) 2. These findings were confirmed by Staff #2.	A2299		
A2306	8:43A-9.3(b)(7)(i) PHARMACEUTICAL SVCS: POLICIES & PROCEDURES The facility's policies and procedures for the control of drugs subject to the Controlled Dangerous Substances Acts and amendments thereto shall include, but not be limited to, a provision for a verifiable record system for controlled drugs. This REQUIREMENT is not met as evidenced by: Based on document review and staff interview	A2306		

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A2306	Continued From page 7 conducted on 9/7/18, it was determined that the facility failed to ensure the implementation of policies and procedures for the provision of a verifiable record system for controlled drugs. Findings include: Reference: Facility policy titled Control and Accountability of Controlled Dangerous Substances (CDS) states, "Procedure ... 1. It is the responsibility of all staff that handle CDS drugs to accurately administer, count and document their use." 1. Review of CDS accountability in six (6) medical records (Medical Records #2 through #7) revealed the following discrepancies: a. The administration of Midazolam 2mg is recorded on the anesthesia record, dated 8/28/18, in Medical Record #2. The corresponding Controlled Substance Record lacks evidence of administration of Midazolam to this patient. b. The administration of Fentanyl 100 mcg is recorded on the anesthesia record, dated 8/28/18, in Medical Record #2. The administration of 50 mcg and destruction of 150 mcg of Fentanyl is recorded on the corresponding Controlled Substance Record. c. The administration of Versed 4 mg is recorded on the Peripheral Nerve Blockade record, dated 6/8/18, in Medical Record #3. The administration of 4 mg and wastage of 4 mg of Versed is recorded on the corresponding Controlled Substance Record. d. The administration of Fentanyl 150 mcg is	A2306		

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A2306	Continued From page 8 recorded on the Peripheral Nerve Blockade record, dated 6/8/18, in Medical Record #3. The administration of 100 mcg of Fentanyl is recorded on the Anesthesia Record, for a total of 250 mcg. The administration of a total of 350 mcg of Fentanyl and wastage of 50 mcg, for a total of 400 mcg is recorded on the corresponding Controlled Substance Record. e. The administration of Fentanyl 200 mcg is recorded on the Peripheral Nerve Blockade record, dated 6/20/18, in Medical Record #7. The administration of 200 mcg of Fentanyl is recorded on the Anesthesia Record, for a total administration of 400 mcg. The administration of a total of 500 mcg of Fentanyl is recorded on the corresponding Controlled Substance Record. 2. These findings were confirmed by Staff #2.	A2306		
A2320	8:43A-9.3(b)(7)(iii) PHARMACEUTICAL SVCS: POLICIES & PROCEDURES The facility's policies and procedures for the control of drugs subject to the Controlled Dangerous Substances Acts and amendments thereto shall include, but not be limited to, in all areas of the facility where drugs are dispensed, administered or stored, procedures for the intentional wasting of controlled drugs, including the disposition of partial doses, and for documentation, including the signature of a second person who shall witness the disposition. This REQUIREMENT is not met as evidenced by:	A2320		

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A2320	Continued From page 9 Based on document review conducted on 9/7/18, it was determined that the facility failed to ensure the implementation of policies and procedures addressing the intentional wasting of partial doses of vials/ampules of controlled drugs. Finding include: Reference #1: Facility policy titled Control and Accountability of Controlled Dangerous Substances (CDS) states, "Procedure ...II.1. All CDS drugs are maintained and a record of their use is recorded as follows...5. The amount of medication wasted indicated by two (2) signatures ..." Reference #2: Facility policy titled Control and Accountability of Controlled Dangerous Substances (CDS) states, "III.2.4 When the CDS medications are issued they are issued with a CDS inventory sheet to record: ...7. A witness to the wasting of the CDS drug ... 1. Review of Narcotics Controlled Drugs Audit Sheets revealed that almost every entry had two signatures in the "RN/MD Signatures." Two required for BOS, EOS, Waste and received" column, even when there was no documented wastage. By doing this, it is not clear if a person signed because he/she witnessed a waste. a. The signature for the witnessing of intentional wasting of a CDS needs to be specifically for wastage. A witness should not sign if wastage did not occur or was not witnessed. 2. The administration of 0.5 mg and wastage of 1.5 mg of hydromorphone for Patient #1, on 8/24/18 at 10:00 AM, is recorded on the Narcotics Controlled Drugs Audit Sheet. The sheet lacks a	A2320		

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A2320	Continued From page 10 witness' signature for wastage. 3. The wastage of 75 mcg of Fentanyl on the Controlled Substance Record, dated 6/15/18, lacks the signature of a witness to the wastage. 4. The wastage of 1 mg of Versed on the Controlled Substance Record, dated 8/4/18, lacks the signature of a witness to the wastage. 5. The wastage of 50 mcg of Fentanyl on the Controlled Substance Record, dated 8/4/18, lacks the signature of a witness to the wastage. 6. The wastage of 50 mcg of Fentanyl on the Controlled Substance Record, dated 8/25/18, lacks the signature of a witness to the wastage. 7. The wastage of 50 mcg of Fentanyl on the Controlled Substance Record, dated 6/8/18, lacks the signature of a witness to the wastage. 8. The wastage of 100 mcg of Fentanyl on the Controlled Substance Record, dated 8/1/18, lacks the signature of a witness to the wastage. 9. The documentation for witnessing wastage on all Controlled Substance Records reviewed included the initials of the person witnessing the waste, not the signature. .	A2320		
A2432	8:43A-9.5(b) PHARMACEUTICAL SVCS: STORAGE OF DRUGS	A2432		

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A2432	Continued From page 11 All drugs shall be stored under proper conditions, as indicated by the United States Pharmacopoeia, product labeling, and/or package inserts. This REQUIREMENT is not met as evidenced by: Based on observation conducted on 9/7/18, it was determined that the facility failed to ensure that medications are stored in accordance with manufacturers' recommendation. Findings include: Reference #1: The manufacturer's package insert for Succinylcholine states, "Store in refrigerator 36 degrees to 46 degrees Fahrenheit. The multi-dose vials are stable for up to 14 days at room temperature without significant loss of potency." Reference #2: The manufacturer's package insert for Rocuronium Bromide states, "Rocuronium bromide should be stored in a refrigerator 2 degrees to 8 degrees C ... Upon removal from refrigeration to room temperature storage conditions, use Rocuronium bromide within 60 days..." Reference #3: Facility policy titled "Storage of Medication" states, "3. ... Medications removed from the refrigerator and left in anesthesia carts, must have an out of refrigerator expiration date per manufacturer's instruction. ..."	A2432		

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A2432	Continued From page 12 1. At 10:05 AM, one vial of succinylcholine and one vial of Rocuronium bromide, not dated when removed from the refrigerator, were found on the anesthesia cart in OR #1, stored at room temperature. 2. At 10:30 AM, one vial of succinylcholine, not dated when removed from the refrigerator, was found on the anesthesia cart in OR #3, stored at room temperature.	A2432		
A3070	8:43A-12.6(a)(16)(ii) SURG & ANES SVCS: SURG POL & PROCEDURES Policies and procedures regarding infection prevention and control shall include, but not be limited to, use of aseptic technique and scrub procedures. This REQUIREMENT is not met as evidenced by: Based on observation, staff interview and review of nationally recognized guidelines, it was determined that the facility failed to ensure implementation of aseptic technique in accordance with nationally recognized guidelines and acceptable standards of practice. Findings include: Reference #1: Association of periOperative Registered Nurses (AORN) 2017 Edition Guidelines for Perioperative Practice Guideline for Surgical Attire Recommendation III states, "Personnel entering the semi-restricted and restricted areas should cover the head, hair, ears and facial hair."	A3070		

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A3070	Continued From page 13 1. Upon interview, Staff #1 stated that the center follows AORN guidelines. 2. The facility policy titled, "Operating Room Attire For Personnel" failed to address covering of facial hair. 3. On 9/7/18 during a tour of the surgical suite, the following was observed: a. At 9:35 AM, in Operating Room (OR) #2, (a restricted area,) Staff #13 was observed scrubbed in for a surgical procedure, wearing a surgical mask that failed to cover his beard and facial hair. b. At 10:25 AM, Staff #13, Staff #15, and Staff #16 were observed cleaning and disinfecting OR #2 between patient procedures. Staff #13, Staff #15, and Staff #16, had facial hair that was not covered. 4. The above findings were confirmed with Staff #2.	A3070		
A4050	8:43A-14.1(a) INFEC PREV & CONTROL: ADMINISTRATOR'S RESP The administrator,or designee, shall ensure the development and implementation of an infection prevention and control program. This REQUIREMENT is not met as evidenced by:	A4050		

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A4050	Continued From page 14 Based on staff interview and document review, it was determined that the facility failed to ensure the development and implementation of an infection prevention and control program. Findings include: 1. A request was made to Staff #1 for the facility's Infection Control Plan. 2. Upon review, the Infection Control Plan was dated 2010 and contained the name of a different facility. 3. Staff #1 confirmed that this was the most current Infection Control Plan and that the name was the previous name of the facility.	A4050		
A4057	8:43A-14.1(b) INFEC PREV & CONTROL: ADMINISTRATOR'S RESP The administrator shall designate an infection control professional who shall be responsible for the direction, provision, and quality of infection prevention and control services. The designated person shall be responsible for, but not limited to, developing and maintaining written objectives, policies and procedures, an organizational plan, and a quality improvement program for the infection prevention and control service. The infection control professional may be a consultant; however, there must be a health care professional on site that is responsible for the day-to-day activities related to infection control. This REQUIREMENT is not met as evidenced	A4057		

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A4057	Continued From page 15 by: Based on staff interviews and document review, it was determined that the facility failed to ensure that its Infection Control program is under the direction of a designated and qualified professional who has training in infection control. Findings include: 1. Upon interview, Staff #1 stated that Staff #3 was the designated day to day infection control nurse. 2. Staff #3's personnel file lacked evidence of additional infection control education and training. 3. The above finding was confirmed by Staff #1 and Staff #2.	A4057		
A4071	8:43A-14.2(b) INFEC PREV & CONTROL: POL & PROCEDURES The infection control committee, with assistance from each service in the facility, shall develop, implement, and review, every three years or more frequently as necessary, written policies and procedures regarding infection prevention and control.	A4071		

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A4071	Continued From page 16 This REQUIREMENT is not met as evidenced by: Based on observation, staff interview, document review, and review of nationally recognized guidelines, it was determined that the facility failed to develop and implement policies for a sanitary surgical environment, in accordance with nationally recognized guidelines. Findings include: Reference: AORN (Association of periOperative Registered Nurses) 2017 Edition, Guidelines for Perioperative Practice, Guideline for Environmental Cleaning Recommendation III states, "A clean environment should be reestablished after the patient is transferred from the area. ...Recommendation III.c.3. states, Items that are used during patient care should be cleaned and disinfected after each patient use, including anesthesia carts..." 1. Upon interview, Staff #1 stated that the center follows AORN guidelines. 2. The facility policy titled, "Cleaning of the Operating Room between cases and the beginning of the day," failed to address cleaning of the anesthesia cart between patient procedures, in accordance with the above AORN reference. 3. On 9/7/18 at 10:25 AM, during observation of a room turnover in OR #2, the following was revealed: a. Staff #13, Staff #15, and Staff #16 were observed cleaning and disinfecting OR #2 between patient procedures.	A4071		

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A4071	Continued From page 17 i. Staff #13, Staff #15, and Staff #16 failed to ensure the anesthesia medication preparation area was cleaned and disinfected. ii. Staff #19 was observed preparing medications on the cart, for the next surgical procedure. iii. Upon interview Staff #19 confirmed the OR staff are responsible for cleaning and disinfecting the anesthesia cart at the end of the procedure.	A4071		
A4098	8:43A-14.2(b)(4) INFEC PREV & CONTROL: POL & PROCEDURES The infection control committee, with assistance from each service in the facility, shall develop, implement, and review, every three years or more frequently as necessary, written policies and procedures regarding infection prevention and control, including, but not limited to, policies and procedures regarding the following: Infection control practices, including universal precautions, in accordance with the Occupational Safety and Health Administration (OSHA) rule 29 CFR Part 1910.1030, Occupational Exposure to Bloodborne Pathogens, incorporated herein by reference. This REQUIREMENT is not met as evidenced by: A. Based on staff interview and document review, it was determined that the facility failed to ensure that policies and procedures regarding	A4098		

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infection prevention and control are reviewed every three (3) years.

Findings include:

1. Infection control policies and procedures, provided by Staff #1 for review, lacked evidence that they had been reviewed by the infection control committee within the past three (3) years.

2. Staff #1 confirmed that the policies were out dated and had not been reviewed or revised within the past three (3) years. Staff #1 stated that the policies were last reviewed in 2010.

B. Based on observation, staff interview, and review of Occupational Safety and Health Administration (OSHA) regulations, it was determined that the facility failed to transport soiled instruments in accordance with OSHA regulations.

Findings include:

Reference: OSHA (Occupational Safety and Health Administration) 29 CFR part 1910.1030(d)(2)(xiii) states, "Specimens of blood or other potentially infectious materials shall be placed in a container which prevents leakage during collection, handling, processing, storage, transport, or shipping. ... 1910.1030 (d)(2)(xiii)(B) states, "If the outside contamination of the primary container occurs, the primary container shall be placed within a second container which prevents leakage during handling, processing, storage, transport, ..."

1. On 9/7/18 at 10:27 AM, in OR #2, Staff #13 was observed placing a non-leak proof soiled instrument tray on an open cart, covering the cart

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A4098	Continued From page 19 with a red biohazard bag, and transporting the cart to the decontamination area. 2. Upon interview, Staff #3 confirmed that the container the instruments were in was not a leak proof container. 3. The policy and procedure for transporting soiled instruments was requested from Staff #1 and not received by the end of the survey.	A4098		
A4183	8:43A-14.3(a)(5) INFEC PREV & CONTROL: INFEC PREV MEASURES Infection prevention activities shall be based on Centers for Disease Control and Prevention Guidelines, and Hospital Infection Control Practices Advisory Committee (that is, HICPAC) recommendations. An exception to the adoption of the following guideline shall be allowed providing that there is a sound infection control rationale based upon scientific research or epidemiologic data. The following published guideline is incorporated herein by reference, as amended and supplemented: Guideline for Hand Hygiene in Health-Care Settings: Recommendation of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force, published in the Morbidity and Mortality Weekly Report at MMWR 2002; 51 (No. RR-16), published by the Coordinating Center for Health Information and Service, available at http://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf and at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5116a1.htm.	A4183		

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A4183	Continued From page 20 This REQUIREMENT is not met as evidenced by: Based on observation, staff interview, and review of Center for Disease Control and Prevention (CDC) Guidelines and Recommendations, it was determined that the facility failed to ensure that hand hygiene is performed in accordance with CDC Guidelines and recommendations. Findings include: Reference: Guideline for Hand Hygiene in Health Care Settings: Recommendation of the Healthcare Infection Control Practices Advisory Committee[HICPAC] and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force, published in the CDC Morbidity and Mortality Weekly Report at MMWR 2002; 51 (No. RR-16) page 32 states,"Recommendations: 1. Indications for Handwashing and Hand antisepsis. A. When hands are visibly dirty or contaminated with pertinacious material or are visibly soiled with blood or other body fluids, wash hands with either a non-antimicrobial soap and water or an antimicrobial soap and water. B. If hands are not visibly soiled, use an alcohol-based hand rub for routinely decontaminating hands in all other clinical situations described in items 1C-J C. Decontaminate hands before having direct contact with patients ... I. Decontaminate hands after contact with inanimate objects (including medical equipment) in the immediate vicinity of the patient. J. Decontaminate hands after removing gloves. ..."	A4183		

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A4183	Continued From page 21 1. On 9/7/18 at 10:25 AM, Staff #13 and Staff #15 were observed cleaning and disinfecting OR #2 between patient procedures. a. Staff #13 and Staff #15, removed gloves and failed to perform hand hygiene prior to leaving the OR. 2. At 10:39 AM, Staff #17 was observed leaving OR #1, removed his/her shoe covers with his/her ungloved hands, failing to perform hand hygiene prior to exiting the OR suite. Staff #17 then entered the pre-operative area and transported a patient to the OR. 3. The above findings were confirmed by Staff #2.	A4183		
A4190	8:43A-14.4(a)(1) INFEC PREV & CONTROL:STRILIZATN PT CARE ITEMS Methods for processing reusable medical devices shall conform with the following or revised or later editions, if in effect, incorpated herein by reference: The Association for the Advancement of Medical Instrumentation (AAMI) requirements, "Good Hospital Practice: Steam Sterilization and Sterility Assurance," ST 46. This REQUIREMENT is not met as evidenced	A4190		

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A4190	Continued From page 22 by: A. Based on observation, staff interviews and review of facility documents, it was determined that the facility failed to follow acceptable infection control guidelines. Findings include: Reference #1: AAMI guidelines, ST 79, Section 810.3.1, states, "Terminally sterilized items should be allowed to cool to room temperature before handling. Reference #2. Facility policy, Load and Unloading Steam Sterilizer, states, "Unloading Procedures: 5. At the end of the sterilization cycle, allow time for the packs to cool down inside the sterilizer. a. All packs should be inspected for moisture: if wet, the pack should be considered contaminated and completely re-processed." 1. Upon interview, Staff #11 stated that, due to the volume of procedures, trays are not always allowed to dry in the sterilizer before being used for surgical procedures. Reference #3: AAMI guidelines, ST 79, Section 8.4.3, "Inspection," states, "Instruments should be carefully inspected for cleanliness and flaws or damage and dried before packaging." 1. During the unwrapping of two sterilized/processed trays, brown rust like substances were observed on the liner of both trays. a. Upon inspection, five (5) sterilized instruments contained brown rust like stains. 2. The above findings were confirmed with Staff	A4190		

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A4190	Continued From page 23 #8, Staff #9, Staff #1 and Staff #2. 3. Upon interview, Staff #5 confirmed that if a tray is opened in the OR, and rust like stains are visible on the white liner, the circulating nurse is notified and he/she makes the decision whether or not to use the instruments for the procedure. 4. On 9/7/18 at 10:43 AM, a staff member, scrubbed in for a surgical procedure, was observed using a cotton swab to clean the lens of a sterile athroscopy scope and camera. a. At 12:15 PM, Staff #5, confirmed that a cotton swab is used to wipe the lens of the arthroscopy scope and camera, to remove any debris or residue. B. Based on observation and staff interview, it was determined that the facility failed to ensure that instruments were cleaned and/or disinfected immediately after use to prevent the formation of biofilm. Findings include: Reference: ST 79, section 6.3 Care and handling of contaminated reusable items at point of use, states, "...To prevent the formation of biofilm, definitive cleaning should occur as soon as possible." 1. Upon interview, Staff #13 stated that the instruments he/she transported into the decontamination room, had not been disinfected immediately after use. 2. This was confirmed with Staff #1 and Staff #2. C. Based on observation and staff interview, it	A4190		

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A4190	Continued From page 24 was determined that the facility failed to have manufacturer's instructions for use (IFUs) available for all of the facility instrumentation. Findings include: Reference #1: ST 79, section 7.2.2, Manufacturers' instructions states, "The written instructions of the device manufacturer should always be followed. The manufacturers' instructions should be kept on file and periodically reviewed for updates. If there are no specific instructions available, then the manufacturer should be contacted to provide documentation." 1. Upon request, Staff #8 and Staff #9 were unable to provide the IFUs for all of the instrumentation. This included IFUs for the Miltek (bone cutter forceps) and Konig (bone cutter) manufacturing brands, as well as the Welsh Allen brand for laryngoscope blades. 2. This was confirmed by Staff #1 and Staff #2. Reference #2: CaviWipe Manufacturer's IFU states, "...Cleaning instructions: Use one CaviWipe towelette to completely preclean surface of all gross debris. ...For use as a disinfectant: Use a second CaviWipe towelette to thoroughly wet the surface. Repeated use of the product may be required to ensure that the surface remains visibly wet for 3 minutes..." 1. During a tour of the OR suite, at 9:35 AM, a stretcher was observed in the hallway, outside of OR #2. The stretcher contained a sheet with a wet red stain, approximately 2 inches in diameter. a. Upon interview Staff #12 stated the stretcher was for the patient who was presently having	A4190		

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surgery and will be used to transport the patient to the post operating area.

b. At 10:19 AM, 44 minutes after the stretcher was initially observed with the wet red stain, this surveyor asked Staff #12 if the stained sheet will be changed. Staff #12 asked Staff #20 to change the sheet.

c. Staff #20, removed the sheet and wiped the stretcher with one CaviWipe, failing to use a second CaviWipe towelette to thoroughly wet the surface and disinfect the stretcher.

2. The above finding was confirmed by Staff #12 and Staff #1.

D. Based on observation and staff interviews, it was determined that the facility failed to ensure that it adheres to transmission-based precautions.

Findings include:

Reference: ST 79, section 4.6, Standard/transmission-based precautions states, "Standard/transmission -based precautions are intended to supplement infection prevention and control practices such as washing hands and wearing personal protective equipment to avoid contact with contaminated items, blood, or body fluids. Appropriate PPE must be used to prevent exposure to blood and body fluids."

1. Personal protective equipment (PPE) was not easily accessible for staff in order to avoid exposure to blood-borne pathogens.

a. PPE was stored on the opposite wall from the door of the decontamination room, requiring staff

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A4190	Continued From page 26 to cross through the room in their scrubs to obtain PPE. b. Staff #1 was observed entering the decontamination room without any PPE. E. Based on staff interviews, document review, and review of nationally recognized guidelines, it was determined that the facility failed to ensure that its policy for sterilizer qualification testing is in accordance with The Association for the Advancement of Medical Instrumentation (AAMI) requirements. Findings include: Reference #1: AAMI (Advancement of Medical Instrumentation) ST79: 2017 Comprehensive guide to steam sterilization and sterility assurance in health care facilities section 13.8. Qualification testing 13.8.1 General considerations states, "Qualification testing with a BI [Biological Indicator] PCD [Process Challenge Device] should be performed on all sterilizers after sterilizer installation, relocation, malfunctions, major repairs ...for dynamic-air-removal sterilizers, three consecutive cycles should be run, one right after the other, with a PCD...yielding negative results from all test BI's and appropriate readings from all physical monitors and CI's [Chemical Indicators]. In addition, three consecutive Bowie-Dick tests should be run, one after the other with each test result demonstrating sufficient air removal. ...Rationale: Testing in this order presents a greater challenge." Reference #2: Facility policy titled "Monitoring of Sterilization Cycles" states, "Procedure: ...Biological Monitors Wrapped cycles ...3. ...d.	A4190		

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A4190	Continued From page 27 Upon installation of a new sterilizer, three (3) consecutive Bowie-Dick tests should be performed followed be three (3) consecutive BI's for each cycle. ..." 1. The facility policy titled "Sterilization Maintenance and Monitoring," is not in accordance with AAMI guidelines referenced above regarding qualification testing of Pre-Vac sterilizers following installation. 2. At 11:30 AM, in the Sterilization Room, the Getinge 633HC Pre-Vac (Pre-Vacuum) Sterilizer was observed without a maintenance sticker or a biomedical sticker. a. Upon interview, Staff #2 indicated that the sterilizer is new. i. Upon review of the sterilization records, Validation testing was performed on the sterilizer on 2/26/18, by the service representative. ii. The qualification testing performed on 2/26/18 revealed the following: - Loads one (1), two (2), three (3) and four (4) were Pre-Vac cycles run at 273 degrees Fahrenheit and contained a Bowie-Dick Test. - Loads five (5) and six (6) were Pre-Vac cycles run at 275 degrees Fahrenheit and contained a BI test pack. iii. For newly installed Pre-Vac sterilizers, AAMI recommends that Qualification testing be performed by running three (3) consecutive cycles containing a BI test pack, followed by three (3) consecutive cycles containing a Bowie-Dick test pack. Testing in this order presents a greater challenge.	A4190		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	23116	A. BUILDING: _____ B. WING _____	C 09/07/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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A4190	Continued From page 28 3. The above finding was confirmed by Staff #2 and Staff #8. F. Based on observation, staff interviews, and review of nationally recognized guidelines, it was determined that the facility failed to ensure adherence to AAMI guidelines for reprocessing instruments. Findings include: Reference: AAMI ST79: 2017 Comprehensive guide to steam sterilization and sterility assurance in health care facilities section 8.2 Instruments states, "...b) Instruments should be positioned to allow the sterilant to come in contact with all surfaces. 1. On 9/7/18 at 11:30 AM, in the Sterilization Room in the presence of Staff #1, Staff #2, and Staff #8, during inspection of a sterilized Hand Instrument Tray, a small autoclavable bag containing multiple instruments was observed within the wrapped set. 2. Review of the instrument count sheet for the Hand Tray revealed that there were forty-three (43) loose instruments within the bag. a. Forty-three (43) loose instruments contained within a small autoclavable bag, does not allow for the sterilant to come in contact with all surfaces of each instrument. 3. The above finding was confirmed with Staff #1, Staff #2 and Staff #8.	A4190		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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A4215	Continued From page 29	A4215		
A4215	8:43A-14.4(g) INFEC PREV & CONTROL:STRILIZATN PT CARE ITEMS The manufacturer's instructions for cleaning, testing, disassembly, and sterilization of equipment shall be readily available and followed by employees. This REQUIREMENT is not met as evidenced by: Based on staff interview, it was determined that the facility failed to have manufacturer's instructions for use for the sterilizer. Findings include: Reference #1: ST 79, section 7.2.2, Manufacturers' instructions state: "The written instructions of the device manufacturer should always be followed. The manufacturers' instructions should be kept on file and periodically reviewed for updates. If there are no specific instructions available, then the manufacturer should be contacted to provide documentation." 1. Upon request, Staff #8 and Staff #9 were unable to provide the manual/IFU for the Getinge Sterilizer. 2. This was confirmed by Staff #1 and Staff #2.	A4215		
A4216	8:43A-14.4(g)(1) INFEC PREV & CONTROL:STRILIZATN PT CARE ITEMS	A4216		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	23116	A. BUILDING: _____ B. WING _____	C 09/07/2018

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A4216	Continued From page 30 All hinged instruments shall be processed in an open position. This REQUIREMENT is not met as evidenced by: Based on observation, staff interviews, and a review of a facility policy and procedure, it was determined that the facility failed to ensure that hinged instruments are processed in an open position. Findings include: Reference: Facility policy titled, "Use and Sterilization of Patient Care Items Packaging, Count Sheets" states, "...Surgical Instruments ...5. All hinged instruments should be in the open position." 1. On 9/7/18 at 10:05 AM, during a tour of the Instrument Room, in the presence of Staff #1, Staff #2, and Staff #8, eight (8) hinged instruments were found in the closed position, wrapped in sterile peel packages after having been reprocessed.	A4216		
A4218	8:43A-14.4(h) INFEC PREV & CONTROL:STRILIZATN PT CARE ITEMS Sterilized materials shall be stored, handled and transported to maintain sterility. Package integrity shall be maintained until used.	A4218		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	23116	A. BUILDING: _____ B. WING _____	C 09/07/2018

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A4218	Continued From page 31 This REQUIREMENT is not met as evidenced by: Based on observation, staff interviews, and review of nationally recognized guidelines, it was determined that the facility failed to ensure that sterilized items are stored to maintain package integrity. Findings include: Reference: AAMI (Association for the Advancement of Medical Instrumentation) ST79: 2107 Comprehensive guide to steam sterilization and sterility assurance in health care facilities, section 11.1.1 states, "Sterile items should be stored under environmentally controlled conditions in a manner that reduces the potential for contamination. ...Sterile items should be ...4. positioned so that packaging is not crushed, bent, compressed, or punctured and so that their sterility is not otherwise compromised. ...Rationale: ...Compression of packages can force air and microorganisms into the package contents, cause seals to burst, or puncture the packaging, all of which lead to contamination. ...Stacking can result in damage to the wrap caused by undue pressure from the weight." 1. On 9/7/18 at 10:05 AM, in the Instrument Room, the following was observed: a. Multiple peel-packaged instruments were lying flat, stacked on top of each other, compromising the integrity of the package and its contents. b. There was a plastic bin that contained thirty (30) sterile packages of Kidney basins, Iodine cups, and various surgical instruments.	A4218		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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A4218	Continued From page 32 i. The sterile packages were crushed, bent, and compressed within the plastic bin. 2. The above findings were confirmed by Staff #1 and Staff #2.	A4218		
A4260	8:43A-14.5(b) INFEC PREV & CONTROL: CARE/USE OF STERILIZERS The biological indicator shall be applicable for the process used and shall be stored and used in accordance with the manufacturer's recommendations. This REQUIREMENT is not met as evidenced by: Based on observation, staff interview, document review, and review of manufacturer's instructions for use (IFU), it was determined that the facility failed to ensure biological indicators are used in accordance with the manufacturer's instructions. Findings include: Reference: 3M Attest 41382 BI [biological indicator] Manufacturer's IFU states, "Indications for Use ... Use the 3M Attest 41382 Rapid 5 Steam-Plus Test Pack to monitor: 1. 121 degrees C (Celsius) (250 degrees F [Fahrenheit]) gravity steam sterilization cycles; 2. 132 degrees C (270 degrees F) vacuum assisted steam sterilization cycles. ... Precautions ... Do not use the 3M Attest 41382 Rapid 5 Steam-Plus Test Pack to monitor	A4260		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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A4260	Continued From page 33 sterilization cycles which it is not designed to challenge: ... " 1. During a tour of the Sterilization Room, a Getinge Model 633HC steam sterilizer was observed. Staff #8 confirmed the sterilizer is used as a Pre-Vac sterilizer. a. On 9/7/18, review of sterilization records dated 8/22/18 and 9/4/18, revealed the following: i. On 8/22/18, load one (1) was processed, using the 3M Attest 41382 BI, in the Pre-Vac cycle at 275 degrees F, with 4 minute exposure time. ii. On 9/4/18, loads one (1) and two (2) were processed, using the 3M Attest 41382 BI, in the Pre-Vac cycle at 275 degrees F, with 4 minute exposure time. 2. Upon review of the IFU for the 3M Attest BI, the 3M Attest 41382 BI is not indicated for Pre-Vac cycles at 275 degrees F.	A4260		

STATE FORM: REVISIT REPORT

PROVIDER / SUPPLIER / CLIA / IDENTIFICATION NUMBER	MULTIPLE CONSTRUCTION	DATE OF REVISIT
23116 Y1	A. Building B. Wing Y2	9/27/2018 Y3

NAME OF FACILITY	STREET ADDRESS, CITY, STATE, ZIP CODE
HEALTHPLUS SURGERY CENTER, LLC	190 MIDLAND AVENUE SADDLE BROOK, NJ 07663

This report is completed by a State surveyor to show those deficiencies previously reported that have been corrected and the date such corrective action was accomplished. Each deficiency should be fully identified using either the regulation or LSC provision number and the identification prefix code previously shown on the State Survey Report (prefix codes shown to the left of each requirement on the survey report form).

ITEM Y4	DATE Y5	ITEM Y4	DATE Y5	ITEM Y4	DATE Y5
ID Prefix A1157 Reg. # 8:43A-3.5(a) LSC	Correction Completed 09/27/2018	ID Prefix A2278 Reg. # 8:43A-9.3(b)(4) LSC	Correction Completed 09/27/2018	ID Prefix A2299 Reg. # 8:43A-9.3(b)(7) LSC	Correction Completed 09/27/2018
ID Prefix A2306 Reg. # 8:43A-9.3(b)(7)(i) LSC	Correction Completed 09/27/2018	ID Prefix A2320 Reg. # 8:43A-9.3(b)(7)(iii) LSC	Correction Completed 09/27/2018	ID Prefix A2432 Reg. # 8:43A-9.5(b) LSC	Correction Completed 09/27/2018
ID Prefix A3070 Reg. # 8:43A-12.6(a)(16)(ii) LSC	Correction Completed 09/27/2018	ID Prefix A4050 Reg. # 8:43A-14.1(a) LSC	Correction Completed 09/27/2018	ID Prefix A4057 Reg. # 8:43A-14.1(b) LSC	Correction Completed 09/27/2018
ID Prefix A4071 Reg. # 8:43A-14.2(b) LSC	Correction Completed 09/27/2018	ID Prefix A4098 Reg. # 8:43A-14.2(b)(4) LSC	Correction Completed 09/27/2018	ID Prefix A4183 Reg. # 8:43A-14.3(a)(5) LSC	Correction Completed 09/27/2018
ID Prefix A4190 Reg. # 8:43A-14.4(a)(1) LSC	Correction Completed 09/27/2018	ID Prefix A4215 Reg. # 8:43A-14.4(g) LSC	Correction Completed 09/27/2018	ID Prefix A4216 Reg. # 8:43A-14.4(g)(1) LSC	Correction Completed 09/27/2018

REVIEWED BY STATE AGENCY ☐	REVIEWED BY (INITIALS)	DATE	SIGNATURE OF SURVEYOR	DATE
REVIEWED BY CMS RO ☐	REVIEWED BY (INITIALS)	DATE	TITLE	DATE

STATE FORM: REVISIT REPORT

PROVIDER / SUPPLIER / CLIA / IDENTIFICATION NUMBER	MULTIPLE CONSTRUCTION	DATE OF REVISIT
23116 Y1	A. Building B. Wing Y2	9/27/2018 Y3

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ITEM Y4	DATE Y5	ITEM Y4	DATE Y5	ITEM Y4	DATE Y5
ID Prefix A4218	Correction	ID Prefix A4260	Correction		
Reg. # 8:43A-14.4(h)	Completed	Reg. # 8:43A-14.5(b)	Completed		
LSC	09/27/2018	LSC	09/27/2018		

REVIEWED BY STATE AGENCY ☐	REVIEWED BY (INITIALS)	DATE	SIGNATURE OF SURVEYOR	DATE
REVIEWED BY CMS RO ☐	REVIEWED BY (INITIALS)	DATE	TITLE	DATE

FOLLOWUP TO SURVEY COMPLETED ON	☐ CHECK FOR ANY UNCORRECTED DEFICIENCIES. WAS A SUMMARY OF UNCORRECTED DEFICIENCIES (CMS-2567) SENT TO THE FACILITY?
9/7/2018	☐ YES ☐ NO

POC approved 9/24/18

HealthPlus Surgery Center | Plan of Correction V2 | Survey Date 9/7/18

TAG	SYSTEMIC CHANGE	MONITORING PLAN	RESPONSIBLE PARTY	REPORTS TO	COMPLETION DATE
A1157 GEN REQ: PERSONNEL	All current staff had sterile processing competencies completed by an outside consultant certified in sterile processing. An outside consultant certified in sterile processing will complete sterile processing competencies for all new hires within 90 days of hire. An outside consultant certified in sterile processing will complete annual competencies for all sterile processing staff.	A quarterly audit of competencies will be completed for 100% of the sterile processing staff. Audits will be completed for a period of one year. A Clinical Operations Committee will be created and meet on a quarterly basis. The QA committee will report in to the Clinical Operations Committee. The Clinical Operations Committee will report to the Governing Body. DON will collate data and report to the Administrator, QA committee, Clinical Operations Committee and Governing Body quarterly.	Director of Nursing	Administrator IC Committee QA Committee Clinical Operations Committee Governing Body	Competencies completed by 9/14/18 Quarterly audits 9/26/18
A2278 PHARMACEUTICAL SVCS: P&P a. P&P on use of parenteral medications	A new policy on the preparation & use of parenteral medications will be developed in conjunction with a quality consultant & pharmacy consultant. Policy will use national references. Policy will be approved by the Clinical Operations Committee & Governing Body. All staff, physicians & anesthesia providers will be educated on the policy.	A medication safety audit tool will be developed. A total of 60 random monthly audits will be completed for 6 months. A Clinical Operations Committee will be created and meet on a quarterly basis. The QA committee will report in to the Clinical Operations Committee. The Clinical Operations Committee will report to the Governing Body. All policies & procedures will be reviewed annually and approved by the Infection Control Committee, Patient Care Committee, Clinical Operations Committee and Governing Body. DON will collate data on a monthly basis and report data to the Administrator monthly and to the QA committee, Clinical Operations Committee and Governing Body quarterly.	Director of Nursing	Administrator IC Committee QA Committee Clinical Operations Committee Governing Body	Policy will be effective 9/26/18. All staff & providers will be educated on the new policies by 9/26/18. Medication audits 10/18-4/19
A2299 PHARMACEUTICAL SVCS: P&P a. P&P on procurement, storage, dispensing, administration & disposition of CDS b. P&P on intentional	A new policy on the procurement, storage, dispensing, administration, intentional wasting & disposition of Controlled Drug Substances (CDS) will be developed in conjunction with a quality consultant & pharmacy consultant. Policy will use federal standards as references. Policy will be approved by the Clinical Operations Committee & Governing Body. All staff, physicians & anesthesia providers will be educated on the policy.	A Controlled Drug Substance (CDS) audit tool will be developed. A total of 60 random monthly audits will be completed for 6 months. A Clinical Operations Committee will be created and meet on a quarterly basis. The QA committee will report in to the Clinical Operations Committee. The Clinical Operations Committee will report to the Governing Body.	Director of Nursing	Administrator IC Committee QA Committee Clinical Operations Committee Governing Body	Policy will be effective 9/26/18. All staff & providers will be educated on the new policies by 9/26/18.

wasting of entire contents of CDS		All policies & procedures will be reviewed annually and approved by the Infection Control Committee, Patient Care Committee, Clinical Operations Committee and Governing Body. DON will collate data on a monthly basis and report data to the Administrator monthly and to the QA committee, Clinical Operations Committee and Governing Body quarterly.			Controlled Drug audits 10/18-4/19
A2306 PHARMACEUTICAL SVCS: P&P a. Provision of a verifiable record system for CDS	A new medication management policy & procedure will be developed including a verifiable record system for Controlled Drug Substances (CDS). The policy will be developed in conjunction with a quality consultant & pharmacy consultant. Policy will use federal standards as references. Policy will be approved by the Clinical Operations Committee & Governing Body. All staff, physicians & anesthesia providers will be educated on the policy.	A Controlled Drug Substance (CDS) audit tool will be developed. A total of 60 random monthly audits will be completed for 6 months. A Clinical Operations Committee will be created and meet on a quarterly basis. The QA committee will report in to the Clinical Operations Committee. The Clinical Operations Committee will report to the Governing Body. All policies & procedures will be reviewed annually and approved by the Infection Control Committee, Patient Care Committee, Clinical Operations Committee and Governing Body. DON will collate data on a monthly basis and report data to the Administrator monthly and to the QA committee, Clinical Operations Committee and Governing Body quarterly.	Director of Nursing	Administrator IC Committee QA Committee Clinical Operations Committee Governing Body	Policy will be effective 9/26/18. All staff & providers will be educated on the new policies by 9/26/18. Controlled Drug audits 10/18-4/19
A2320 PHARMACEUTICAL SVCS: P&P a. P&P for wasting CDS with signature of witness	A new medication management policy & procedure will be developed including a procedure for wasting of Controlled Drug Substances(CDS) with a witness. The policy will be developed in conjunction with a quality consultant & pharmacy consultant. Policy will use federal standards as references. Policy will be approved by the Clinical Operations Committee & Governing Body. All staff, physicians & anesthesia providers will be educated on the policy. A new anesthesia narcotic & controlled drug record will be added in addition to the patient anesthesia record. A procedure will be developed in conjunction with the new record to have an end of shift count with the anesthesia	A Controlled Drug Substance (CDS) audit tool will be developed. A total of 60 random monthly audits will be completed for 6 months. A Clinical Operations Committee will be created and meet on a quarterly basis. The QA committee will report in to the Clinical Operations Committee. The Clinical Operations Committee will report to the Governing Body. All policies & procedures will be reviewed annually and approved by the Infection Control Committee, Patient Care Committee, Clinical Operations Committee and Governing Body.	Director of Nursing	Administrator IC Committee QA Committee Clinical Operations Committee Governing Body	Policy will be effective 9/26/18. All staff & providers will be educated on the new policies by 9/26/18. Controlled Drug audits 10/18-4/19 New anesthesia narcotic &

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	provider to verify the number of returned CDS vials.	DON will collate data on a monthly basis and report data to the Administrator monthly and to the QA committee, Clinical Operations Committee and Governing Body quarterly. An anesthesia dose documentation audit tool will be developed. The tool will provide for a 3 way match between the medical record, narcotic count record and the anesthesia narcotic & controlled drug record. A total of 60 random monthly audits will be completed for 6 months. DON will collate data on a monthly basis and report data to the Administrator monthly and to the QA committee, Clinical Operations Committee and Governing Body quarterly.			controlled drug record will be effective 9/26/18. Anesthesia dose documentation audits 10/18-4/19
A2432 PHARMACEUTICAL SVCS: STORAGE OF DRUGS a. All drugs stored under proper conditions	A new medication management policy & procedure will be developed including a section on storage of medications under proper conditions. The policy will be developed in conjunction with a quality consultant & pharmacy consultant. Policy will use federal standards as references. Policy will be approved by the Clinical Operations Committee & Governing Body. All staff, physicians & anesthesia providers will be educated on the policy.	A medication safety audit tool will be developed. A total of 60 random monthly audits will be completed for 6 months. An infection control committee will be created and meet on a quarterly basis. A Clinical Operations Committee will be created and meet on a quarterly basis. The infection control committee will report in to the Clinical Operations Committee. The Clinical Operations Committee will report to the Governing Body quarterly. All policies & procedures will be reviewed annually and approved by the Infection Control Committee, Patient Care Committee, Clinical Operations Committee and Governing Body. DON will collate data on a monthly basis and report data to the Administrator monthly and to the Infection Control Committee, QA committee, Clinical Operations Committee and Governing Body quarterly.	Director of Nursing	Administrator IC Committee QA Committee Clinical Operations Committee Governing Body	Policy will be effective 9/26/18. All staff & providers will be educated on the new policies by 9/26/18. Medication audits 10/18-4/19
A3070 SURG & ANES SVCS: P&P a. Failure to use aseptic technique for surgical attire	A dress code policy will be developed in conjunction with a quality consultant. Policy will reflect AORN Perioperative Guidelines for practice regarding surgical attire and facial hair. Policy will be approved by the Clinical Operations Committee & Governing Body. All staff, physicians & anesthesia providers will be educated	A surgical attire audit tool will be developed and monitor compliance with the policies and AORN standards. A total of 60 random monthly audits will be completed for 6 months. An infection control committee will be created and meet on a quarterly basis. A Clinical Operations Committee will be	Director of Nursing	Administrator IC Committee QA Committee Clinical Operations Committee Governing Body	Policy will be effective 9/26/18. All staff & providers will be educated on the

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	on the policy.	created and meet on a quarterly basis. The infection control committee will report in to the Clinical Operations Committee. The Clinical Operations Committee will report to the Governing Body quarterly. All policies & procedures will be reviewed annually and approved by the Infection Control Committee, Patient Care Committee, Clinical Operations Committee and Governing Body. DON will collate data on a monthly basis and report data to the Administrator monthly and to the Infection Control Committee, QA committee, Clinical Operations Committee and Governing Body quarterly.			new policies by 9/26/18. Surgical attire audits 10/18-4/19
A4050 INFEC PREV & CNTRL: ADMIN RESP a. Failure to develop & implement an IC program	An infection control risk assessment will be completed by a Certified Infection Control Nurse. Based on the results of the Infection Control Risk Assessment an annual infection control plan will be developed in conjunction with a quality consultant and Certified Infection Control Nurse. Current infection Control policies will be reviewed and updated as necessary. Policies will be referenced with national practice standards. Any new policies or policy changes will be approved by the Clinical Operations Committee & Governing Body. All staff, physicians & anesthesia providers will be educated on the policy.	An infection control audit tool will be developed. The tool will include components of the infection control plan based on the risk assessment. At a minimum the tool will address: environmental cleaning, medication safety, sharps safety and injection practices, surgical attire, surgical site infections, sterilization, Prophylactic antibiotics, compliance with infection control policies, compliance with AORN standards and hand hygiene. A monthly infection control audit will be completed for 6 months. Data will be collated on a monthly basis and reported to the Infection Control Committee. An infection control committee will be created and meet on a quarterly basis. A Clinical Operations Committee will be created and meet on a quarterly basis. The infection control committee will report in to the Clinical Operations Committee. The Clinical Operations Committee will report to the Governing Body quarterly. The infection control risk assessment, infection control plan, policies & procedures will be reviewed annually and approved by the Infection Control Committee, Patient Care Committee, Clinical Operations Committee and Governing Body. DON will collate data and report to the Administrator,	Director of Nursing	Administrator IC Committee QA Committee Clinical Operations Committee Governing Body	Infection Control Risk Assessment & Infection Control Plan effective 9/26/18 Infection Control Audits 10/18-4/19

		Infection Control Committee, QA committee, Clinical Operations Committee and Governing Body quarterly.			
A4183 INFEC PREV & CNTRL: INFEC PREV MEASURES a. Failure to ensure hand hygiene is performed in accordance with CDC guidelines	Current infection Control policies will be reviewed and updated as necessary in conjunction with a quality consultant and Certified Infection Control Nurse. Policies to be reviewed & updated will include at a minimum: hand hygiene. Policies will be referenced with national practice standards. Any new policies or policy changes will be approved by the Clinical Operations Committee & Governing Body. All staff, physicians & anesthesia providers will be educated on the policy.	An infection control audit tool will be developed. The tool will include components of the infection control plan based on the risk assessment. At a minimum the tool will address: environmental cleaning, medication safety, sharps safety and injection practices, surgical attire, surgical site infections, sterilization, Prophylactic antibiotics, compliance with infection control policies, compliance with AORN standards and hand hygiene. A monthly infection control audit will be completed for 6 months. Data will be collated on a monthly basis and reported to the Infection Control Committee. An infection control committee will be created and meet on a quarterly basis. A Clinical Operations Committee will be created and meet on a quarterly basis. The infection control committee will report in to the Clinical Operations Committee. The Clinical Operations Committee will report to the Governing Body quarterly. All policies & procedures will be reviewed annually and approved by the Infection Control Committee, Patient Care Committee, Clinical Operations Committee and Governing Body. DON will collate data and report to the Administrator, Infection Control Committee, QA committee, Clinical Operations Committee and Governing Body quarterly.	Director of Nursing	Administrator IC Committee QA Committee Clinical Operations Committee Governing Body	Infection Control Policies effective 9/26/18 All staff & providers will be educated on the new policies by 9/26/18 Infection Control Audits 10/18-4/19
A4190 INFEC PREV &CNTRL: STRILIZATN PT CARE ITEMS a. Failure to reprocess sterile items in accordance with AAMI ST79 b. Failure to let sterile items cool to room temperature before handling c. Failure to inspect for wet packs and	Current infection Control policies will be reviewed and updated as necessary in conjunction with a quality consultant, Certified Infection Control Nurse and Certified Sterile Processing Consultant. Policies to be reviewed & updated will include at a minimum: transmission based precautions, reprocessing soiled instruments in accordance with AAMI ST79, immediate treatment of soiled instruments, following manufacturer IFU for processing instruments, sterilizer qualification testing, & biomedical inspection. Policies will be referenced with national practice standards-AAMI ST79 ,APIC,SHEA & AORN Guidelines. Any new policies or policy changes will be approved by the Clinical	A sterilization audit tool will be developed. At a minimum the tool will address: compliance with facility policies, compliance with AAMI standards, staff knowledge of facility policies & AAMI standards, staff knowledge and compliance with reprocessing items according to manufacturer IFU, staff releasing items at room temperature, staff inspection for wet packs, rust on instruments, gross debris on clean instruments, treatment at point of use, use of PPE, availability of PPE, sterilizer qualification testing per AAMI standards, and biomedical inspection. The sterilization audit will be completed for 6 months. Data will be collated on a monthly basis and reported to the Infection Control Committee.	Director of Nursing	Administrator IC Committee QA Committee Clinical Operations Committee Governing Body	Infection Control Policies effective 9/26/18 All staff & providers will be educated on the new policies by 9/26/18 Infection Control Audits 10/18-4/19

		approved by the Infection Control Committee, Patient Care Committee, Clinical Operations Committee and Governing Body. DON will collate data and report to the Administrator, Infection Control Committee, QA committee, Clinical Operations Committee, and Governing Body quarterly.			
A4098 INFEC PREV & CNTRL: P&P a. Failure to develop & review IC policies every 3 years b. Failure to transport soiled instruments in OSHA compliance	Current infection Control policies will be reviewed and updated as necessary in conjunction with a quality consultant and Certified Infection Control Nurse. Policies to be reviewed & updated will include at a minimum: care of contaminated instruments. Policies will be referenced with national practice standards. Any new policies or policy changes will be approved by the Clinical Operations Committee & Governing Body. All staff, physicians & anesthesia providers will be educated on the policy.	An infection control audit tool will be developed. The tool will include components of the infection control plan based on the risk assessment. At a minimum the tool will address: environmental cleaning, medication safety, sharps safety and injection practices, surgical attire, surgical site infections, sterilization, Prophylactic antibiotics, compliance with infection control policies, compliance with AORN standards and hand hygiene. A monthly infection control audit will be completed for 6 months. Data will be collated on a monthly basis and reported to the Infection Control Committee. A random monthly audit of 40 cases will be performed on the care, handling & transportation of soiled instruments. The audit will look for immediate use of a facility approved surgical instrument foam, and transportation of soiled instruments in compliance with OSHA standards and facility policies. DON will collate results on a monthly basis. Results will be reported to the Infection Control Committee, Quality Improvement Committee, Clinical Operations Committee and Governing Body. An infection control committee will be created and meet on a quarterly basis. A Clinical Operations Committee will be created and meet on a quarterly basis. The infection control committee will report in to the Clinical Operations Committee. The Clinical Operations Committee will report to the Governing Body quarterly. All policies & procedures will be reviewed annually and approved by the Infection Control Committee, Patient Care Committee, Clinical Operations Committee and Governing Body. DON will collate data and report to the Administrator,	Director of Nursing	Administrator IC Committee QA Committee Clinical Operations Committee Governing Body	Infection Control Policies effective 9/26/18 All staff & providers will be educated on the new policies by 9/26/18 Infection Control Audits 10/18-4/19

		Infection Control Committee, QA committee, Clinical Operations Committee and Governing Body quarterly.			
A4057 INFEC PREV & CNTRL: ADMIN RESP a. Failure to designate & train an onsite ICP	A staff member will be designated as the onsite infection control professional to work in conjunction with the Certified Infection Control Consultant. The onsite infection control nurse will complete AORN's ASC Infection Prevention Course. An authority statement will be signed for the onsite infection control nurse by the medical director.	A monthly log will be created to document the education & training activities of the onsite infection control nurse. Monthly activities & findings will be reported to the Infection Control Committee. Infection Control nurse will be mentored by Certified Infection Control Nurse & Quality Consultant with APIC training in infection control. An infection control committee will be created and meet on a quarterly basis. A Clinical Operations Committee will be created and meet on a quarterly basis. The infection control committee will report in to the Clinical Operations Committee. The Clinical Operations Committee will report to the Governing Body quarterly. DON will collate data and report to the Administrator, Infection Control Committee, QA committee, Clinical Operations Committee and Governing Body quarterly.	Director of Nursing	Administrator IC Committee QA Committee Clinical Operations Committee Governing Body	Designate IC nurse by 9/21/18 Medical Director sign authority statement by 9/21/18 IC nurse complete AORN course by 9/24/18 IC Nurse start monthly log by 11/1/18
A4071 INFEC PREV & CNTRL: P&P a. Failure to develop IC policies b. Failure to implement AORN Guidelines for IC c. Failure to follow P&P for room turnover d. Failure to clean & disinfect surfaces	Current infection Control policies will be reviewed and updated as necessary in conjunction with a quality consultant and Certified Infection Control Nurse. Policies to be reviewed & updated will include at a minimum: cleaning & sanitation of horizontal surfaces and room turnover. Policies will be referenced with national practice standards. Any new policies or policy changes will be approved by the Clinical Operations Committee & Governing Body. All staff, physicians & anesthesia providers will be educated on the policy.	An infection control audit tool will be developed. The tool will include components of the infection control plan based on the risk assessment. At a minimum the tool will address: environmental cleaning, medication safety, sharps safety and injection practices, surgical attire, surgical site infections, sterilization, Prophylactic antibiotics, compliance with infection control policies, compliance with AORN standards and hand hygiene. A monthly infection control audit will be completed for 6 months. Data will be collated on a monthly basis and reported to the Infection Control Committee. An infection control committee will be created and meet on a quarterly basis. A Clinical Operations Committee will be created and meet on a quarterly basis. The infection control committee will report in to the Clinical Operations Committee. The Clinical Operations Committee will report to the Governing Body quarterly. All policies & procedures will be reviewed annually and	Director of Nursing	Administrator IC Committee QA Committee Clinical Operations Committee Governing Body	Infection Control Policies effective 9/26/18 All staff & providers will be educated on the new policies by 9/26/18 Infection Control Audits 10/18-4/19

reprocess items before use d. Failure to maintain instruments rust free e. Failure to ensure items properly cleaned before sterilization f. Failure to ensure instruments are immediately treated at point of use g. Failure to follow manufacturer's IFU h. Failure to follow transmission based precautions i. Failure to make PPE easily accessible j. Failure to ensure sterilizer qualification testing following installation per AAMI guidelines k. Failure to ensure sterilizer was biomed inspected l. Failure to ensure adherence to AAMI standards	Operations Committee & Governing Body. All staff, physicians & anesthesia providers will be educated on the policy.	An infection control committee will be created and meet on a quarterly basis. A Clinical Operations Committee will be created and meet on a quarterly basis. The infection control committee will report in to the Clinical Operations Committee. The Clinical Operations Committee will report to the Governing Body quarterly. All policies & procedures will be reviewed annually and approved by the Infection Control Committee, Patient Care Committee, Clinical Operations Committee and Governing Body. An audit of equipment being inspected by Biomedical Engineering will be completed monthly for a period of 6 months. A Certified Sterile Processing Consultant will be onsite for weekly audits for a period of one month, then biweekly audits for a period of two months, then monthly audits for a period of three months. DON will collate data and report to the Administrator, Infection Control Committee, QA committee, Clinical Operations Committee and Governing Body quarterly.			Biomedical Audits 10/18-4/19 Sterile Processing Consultant Audits 10/18-4/19
A4215 INFEC PREV & CNTRL: STRILIZATN PT CARE ITEMS a. Failure to have IFU available for staff b. Failure to follow IFU	HealthPlus has contracted with a Sterile Processing consulting company. Four certified sterile processing managers with extensive experience were onsite for the entire week of 9/10/18 and will continue onsite until all manufacturer IFU's are immediately available for staff. All current staff had sterile processing competencies completed by an outside consultant certified in sterile processing. Part of the competency process was using correct manufacturer IFU for reprocessing instruments. The	A random monthly audit of manufacturer IFU's for 10 instruments will be completed for a period of 6 months. A sterilization audit tool will be developed. At a minimum the tool will address: compliance with facility policies, compliance with AAMI standards, staff knowledge of facility policies & AAMI standards, staff knowledge and compliance with reprocessing items according to manufacturer IFU, staff releasing items at room temperature, staff inspection for wet packs, rust on instruments, gross debris on clean instruments, treatment at point of use, use of PPE,	Director of Nursing	Administrator IC Committee QA Committee Clinical Operations Committee Governing Body	Manufacturer IFU for high use items received by 9/14/18 Contract with One Source for IFU effective by 9/21/18

	facility will also contract with OneSource to have immediate online access to manufacturer IFU.	availability of PPE, sterilizer qualification testing per AAMI standards, and biomedical inspection. The sterilization audit will be completed for 6 months. Data will be collated on a monthly basis and reported to the Infection Control Committee. A Certified Sterile Processing Consultant will be onsite for weekly audits for a period of one month, then biweekly audits for a period of two months, then monthly audits for a period of three months. An infection control committee will be created and meet on a quarterly basis. A Clinical Operations Committee will be created and meet on a quarterly basis. The infection control committee will report in to the Clinical Operations Committee. The Clinical Operations Committee will report to the Governing Body quarterly. DON will collate data and report to the Administrator, Infection Control Committee, QA committee, Clinical Operations Committee and Governing Body quarterly.			Audits of Manufacturer IFU 10/18-4/19 Sterile Processing Consultant Audits 10/18-4/19
A4216 INFEC PREV & CNTRL: STRILIZATN PT CARE ITEMS a. Failure to process hinged instruments in open position	HealthPlus has contracted with a Sterile Processing consulting company. Four certified sterile processing managers with extensive experience were onsite for the entire week of 9/10/18 and will continue onsite until all sterile instrument trays have been opened, refurbished, cleaned and reprocessed. All items will be reprocessed using manufacturer IFU and AAMI ST79. All hinged items will be in the open position. The facility is focusing on high volume instruments since those are reprocessed most frequently. All current staff had sterile processing competencies completed by an outside consultant certified in sterile processing. Part of the competency process was correct reprocessing of hinged instruments.	A random monthly audit of 80 hinged instruments will be completed for a period of 6 months. A Certified Sterile Processing Consultant will be onsite for weekly audits for a period of one month, then biweekly audits for a period of two months, then monthly audits for a period of three months. An infection control committee will be created and meet on a quarterly basis. A Clinical Operations Committee will be created and meet on a quarterly basis. The infection control committee will report in to the Clinical Operations Committee. The Clinical Operations Committee will report to the Governing Body quarterly. DON will collate data and report to the Administrator, Infection Control Committee, QA committee, Clinical	Director of Nursing	Administrator IC Committee QA Committee Clinical Operations Committee Governing Body	Audits of Hinged Instruments 10/18-4/19 Sterile Processing Consultant Audits 10/18-4/19

ok

		Operations Committee and Governing Body quarterly.			
A4218 INFEC PREV & CNTRL: STRILIZATN PT CARE ITEMS a. Failure to ensure that sterilized items are stored to maintain package integrity	HealthPlus has contracted with a Sterile Processing consulting company. Four certified sterile processing managers with extensive experience were onsite for the entire week of 9/10/18 and will continue onsite until all sterile instrument trays have been opened, refurbished, cleaned and reprocessed. All items will be reprocessed using manufacturer IFU and AAMI ST79. All sterile items will be stored to maintain package integrity. All current staff had sterile processing competencies completed by an outside consultant certified in sterile processing. Part of the competency process was correct storage to maintain package integrity.	A random monthly audit of 80 peel packs & instrument trays will be completed for a period of 6 months to check package integrity. A random monthly audit of 40 peel packs & instrument trays will be completed for an additional 6 months to check package integrity. At the end of the one year of audits the facility will determine if the audits need to continue or if a different audit should be conducted on sterile processing. An infection control committee will be created and meet on a quarterly basis. A Clinical Operations Committee will be created and meet on a quarterly basis. The infection control committee will report in to the Clinical Operations Committee. The Clinical Operations Committee will report to the Governing Body quarterly. A Certified Sterile Processing Consultant will be onsite for weekly audits for a period of one month, then biweekly audits for a period of two months, then monthly audits for a period of three months. An infection control committee will be created and meet on a quarterly basis. A Clinical Operations Committee will be created and meet on a quarterly basis. The infection control committee will report in to the Clinical Operations Committee. The Clinical Operations Committee will report to the Governing Body quarterly. DON will collate data and report to the Administrator, Infection Control Committee, QA committee, Clinical Operations Committee and Governing Body quarterly.	Director of Nursing	Administrator IC Committee QA Committee Clinical Operations Committee Governing Body	Audits of Package Integrity 10/18-10/19 Sterile Processing Consultant Audits 10/18-4/19
A4260 INFEC PREV & CNTRL: ARE & USE OF STERILIZERS a. Failure to use a biological indicator that is applicable for the process in accordance with IFU	HealthPlus has contracted with a Sterile Processing consulting company. Four certified sterile processing managers with extensive experience were onsite for the entire week of 9/10/18. The consultants worked to reset sterile processing time and temperature of cycles and purchase the appropriate biological indicators for the cycles being used. The sterile processing consultants and will continue onsite until all sterile instrument trays have	A random monthly audit of biological indicators in accordance with manufacturer instructions will be completed by the certified sterile processing consultant for a period of 6 months. An infection control committee will be created and meet on a quarterly basis. A Clinical Operations Committee will be created and meet on a quarterly basis. The infection control	Director of Nursing	Administrator IC Committee QA Committee Clinical Operations Committee Governing Body	Sterile Processing Consultant Audits 10/18-4/19

	been opened, refurbished, cleaned and reprocessed. All items will be reprocessed using manufacturer IFU and AAMI ST79. All sterile items will be stored to maintain package integrity. All current staff had sterile processing competencies completed by an outside consultant certified in sterile processing. Part of the competency process was using correct biological indicators in accordance with manufacturer instructions.	committee will report in to the Clinical Operations Committee. The Clinical Operations Committee will report to the Governing Body quarterly. A Certified Sterile Processing Consultant will be onsite for weekly audits for a period of one month, then biweekly audits for a period of two months, then monthly audits for a period of three months. An infection control committee will be created and meet on a quarterly basis. A Clinical Operations Committee will be created and meet on a quarterly basis. The infection control committee will report in to the Clinical Operations Committee. The Clinical Operations Committee will report to the Governing Body quarterly. DON will collate data and report to the Administrator, Infection Control Committee, QA committee, Clinical Operations Committee and Governing Body quarterly.			

Respectfully Submitted,

[redacted]

Administrator

HealthPlus Surgery Center

State of New Jersey
DEPARTMENT OF HEALTH
PO BOX 358
TRENTON, N.J. 08625-0358
www.nj.gov/health

PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

SHEREEF M. ELNAHAL, MD, MBA
Commissioner

September 7, 2018

[redacted]
Healthplus Surgery Center, LLC
190 Midland Avenue
Saddle Brook, NJ 07663

Via Facsimile: 646-448-9150

RE: Curtailment of Services Order
Facility ID# NJ23116

Dear [redacted]:

This letter confirms the telephone call of September 7, 2018 at 3:00 p.m. between you and staff of Health Facility Survey and Field Operations (Survey"), and the Office of Licensing Certificate and Need (DOH), wherein you were **ordered to curtail all services at Healthplus Surgery Center, LLC, effective immediately.** This order shall remain in place until formally lifted by the Department.

This action is being taken based on a recommendation from Survey staff and taken in accordance with N.J.A.C. 8:43E-3.6, during an on-site complaint survey conducted on September 7, 2018, during which deficient practices were identified related to serious breaches of infection control with the sterile processing process and inability to ensure the sterility of the instruments.

Please be advised that N.J.A.C. 8:43E-3.4(a)(2) provides for a penalty of $250 per day for each patient admitted in violation of this curtailment order. Please also be advised that you may be subject to other enforcement remedies in addition to the curtailment order.

The deficiencies found include, but are not limited to:

- Instructions For Use (IFU's) were not available for all instruments.
- Biologicals are being used incorrectly and validation testing is not being done correctly.

- No competencies completed for 3 staff regarding infection control.
- Sterile instruments observed with debris in hinges, rusty and discolored.

FORMAL HEARING

Healthplus Surgery Center, LLC is entitled to a prompt formal hearing at the Office of Administrative law (OAL) to challenge the curtailment.

Healthplus Surgery Center, LLC must advise the Department within 30 days of this letter to request an OAL hearing regarding this matter. Please forward your OAL hearing request to:

Attention: OAL Hearing Requests
Office of Legal and Regulatory Compliance, Room 805
New Jersey State Department of Health
P.O. Box 360
Trenton, New Jersey 08625-0360

Corporations are not permitted to represent themselves in OAL proceedings. Therefore, if Healthplus Surgery Center, LLC is owned by a corporation, representation by counsel is required.

If Healthplus Surgery Center, LLC requests an OAL hearing regarding this matter, the facility is further required to submit a written response to each charge specified in this order, which shall accompany your request for a hearing.

Please call 609-984-8128 if you have any questions regarding this curtailment.

Sincerely,

[redacted] Director
Program Compliance
Division of Certificate of Need and Licensing
New Jersey Department of Health

GR/jn
Control #AX18013

State of New Jersey
DEPARTMENT OF HEALTH
PO BOX 358
TRENTON, N.J. 08625-0358
www.nj.gov/health

PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

SHEREEF M. ELNAHAL, MD, MBA
Commissioner

[redacted]
Healthplus Surgery Center, LLC
190 Midland Avenue
Saddle Brook, NJ 07663

VIA FACSIMILE (646) 448-9150 & FIRST CLASS MAIL

RE: LIFTING of Curtailment of Services
Facility ID# NJ23116

Dear [redacted],

This will confirm this afternoon's phone call between you and staff of the Office of Program Compliance, wherein you were advised that the curtailment of services for Healthplus Surgery Center, LLC, that was imposed on September 7, 2018 was lifted, effective immediately.

This action is being taken based on a recommendation from Health Facility Survey and Field Operations, indicating, as of today's revisit, the facility is back in compliance.

If you have any questions, you may call [redacted], Office of Program Compliance and Health Care Financing at (609) 984-8161.

Sincerely,

[redacted]
Director
Program Compliance
Division of Certificate of Need and Licensing

GR:lk
September 27, 2018
Control #AX18013

State of New Jersey
DEPARTMENT OF HEALTH
PO BOX 367
TRENTON, N.J. 08625-0367

www.nj.gov/health

PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

SHEREEF M. ELNAHAL, MD, MBA
Commissioner

September 13, 2018

[redacted]
Administrator
Healthplus Surgery Center, LLC
190 Midland Avenue
Saddle Brook, NJ 07663

Re: Complaint #NJ00114661

Dear [redacted]:

Thank you for your courtesy and cooperation extended during the complaint investigation conducted on September 7, 2018 by surveyors from the New Jersey Department of Health.

Enclosed is the statement of deficiencies; please reply to each deficiency on an item-by-item basis with your Plan of Correction (PoC).

The PoC must include:

1. How you will correct the specific findings cited for each deficiency.

2. What systemic changes will be implemented to ensure that each deficient practice does not recur.

3. How the facility will monitor its corrective actions to ensure that the deficient practice is being corrected and will not recur, i.e. what program will be put into place to monitor the continued effectiveness of the systemic changes. The plan must identify the individual responsible for monitoring, how and when the monitoring will be conducted, how long and how often monitoring will take place, what the goal is for compliance, and to whom the results will be reported.

4. The date on which each item addressed on the PoC will be corrected.

5. Do not reference and/or include attachments with your PoC.

6. Do not include names of individuals in the PoC. Use of titles is acceptable, such as, Administrator, Director of Nursing, Infection Control Practitioner, etc.

Please be advised that the PoC will not be accepted for review by this office and will be returned to you if it contains reference to and/or attachments and/or names of individuals.

All responses should be numbered to correspond with the number of your deficiency statements. Please sign and date the first page of the deficiency statement with your plan of correction. Return these forms to this office within ten (10) business days of receipt of this letter, to my attention. Any delay or lack of response may jeopardize the licensure of your facility.

Please be advised that some or all of the deficiencies cited in the enclosed survey report may be referred to the Office of Program Compliance ("OPC") for imposition of enforcement remedies, including civil penalties. OPC will advise you, at a later date and under separate cover, of any enforcement actions and your appeal rights.

Please do not hesitate to contact me, if you have any questions regarding the deficiencies at (609) 292-9900.

Sincerely,

[redacted]
SHCSE
Survey and Certification

Encl.

State of New Jersey
DEPARTMENT OF HEALTH
PO BOX 367
TRENTON, N.J. 08625-0367
www.nj.gov/health

PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

SHEREEF M. ELNAHAL, MD, MBA
Commissioner

October 17, 2018

[redacted]
Administrator
Healthplus Surgery Center, LLC
190 Midland Avenue
Saddle Brook, NJ 07663

Dear [redacted]:

Thank you for the courtesy and cooperation extended during the State revisit survey of your facility on September 27, 2018 by surveyors from the New Jersey Department of Health.

Enclosed is the revisit report which indicates that the deficiencies identified during the survey of September 7, 2018 were corrected.

Should you have questions, please do not hesitate to contact me at (609) 292-9900.

Sincerely,

[redacted]
SHCSE
Survey and Certification

Encl.