

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 09/16/2021
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 31C0001023	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 08/04/2021
NAME OF PROVIDER OR SUPPLIER BERGEN-PASSAIC EYE SURGERY			STREET ADDRESS, CITY, STATE, ZIP CODE 18-01 POLLITT DRIVE, SUITE 4 FAIR LAWN, NJ 07410		
(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) COMPLETION DATE
Q 000	INITIAL COMMENTS Survey date: August 4, 2021 This was a condition level Federal Recertification, Federal Focused Infection Control Survey, and State Re-licensure Survey. The facility is not in compliance with Federal requirements under 42 CFR Part 416, Conditions of Coverage for Ambulatory Surgical Centers and State requirements under Title 8, Chapter 43A, Manual of Standards for Licensing of Ambulatory Care Facilities. The following Condition was determined to be out of compliance: 416.51 Infection Control	Q 000			
Q 083	PERFORMANCE IMPROVEMENT PROJECTS CFR(s): 416.43(d) (1) The number and scope of distinct improvement projects conducted annually must reflect the scope and complexity of the ASC's services and operations. (2) The ASC must document the projects that are being conducted. The documentation, at a minimum, must include the reason(s) for implementing the project, and a description of the project's results This STANDARD is not met as evidenced by: Based on staff interview and review of facility documents, it was determined the facility failed to ensure quality assessment and performance improvement (QAPI) projects are selected based on the needs of the facility and the belief that patient health outcomes and safety will improve.	Q 083			

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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Q 083	Continued From page 1 Findings include: 1. Upon interview on 8/3/21 at 1:40 PM, Staff #2 identified him/herself as the person responsible for the facility's QAPI program. Staff #2 was asked to describe the performance improvement project(s) the facility was currently conducting. He/she stated, "We just completed a project on falls." A request was made to Staff #2 regarding the facility's data collection related to the performance improvement project and the rationale for why the project was suggested. 2. Staff #2 was asked if the facility has had a recent issue with patient falls. Staff #2 confirmed that the facility has not had any patient falls. Staff #2 was asked why the facility selected a performance improvement project on falls if that was not a concern of the facility. He/she stated, "The falls project was chosen for us. We have a corporate partner and there were a lot of falls in the corporate group, but not necessarily us. Falls was one of the projects that everyone in the group did."	Q 083			
Q 181	N.J.A.C. 8:43A - 18.2(f) ADMINISTRATION OF DRUGS CFR(s): 416.48(a) Drugs must be prepared and administered according to established policies and acceptable standards of practice. This STANDARD is not met as evidenced by:	Q 181			

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Q 181	<p>Continued From page 2</p> <p>A. Based on observation, review of the manufacturer's package insert, and staff interview, it was determined the facility failed to ensure medications are stored in accordance with manufacturer's instructions.</p> <p>Findings include:</p> <p>Reference: Manufacturer's package insert for Proparacaine Hydrochloride Ophthalmic Solution 0.5% states, "... Store between 2 degrees to 8 degrees Celsius (36 to 46 degrees Fahrenheit)."</p> <p>1. On 8/4/21 at 10:00 AM, in Exam Room # one (1) - fifteen (15) milliliter (ml) bottle of Proparacaine Hydrochloride Ophthalmic Solution 0.5% was found stored in a cabinet at room temperature, not refrigerated as required by the manufacturer.</p> <p>2. Staff #2 confirmed the above finding on 8/4/21 at 10:00 AM.</p> <p>N.J.A.C. 8:43A-9.5 (b)</p> <p>B. Based on observation, staff interviews, and review of facility documents, it was determined the facility failed to ensure expired medications are removed from inventory.</p> <p>Findings include:</p> <p>Reference: Facility policy, "Storage and Control of Drugs and Syringes" states, "... Expiration dates of medications will be checked monthly... Discontinued, outdated, and short-dated medications... are discarded... "</p> <p>1. On 8/4/21 between 10:40 AM and 11:30 AM,</p>	Q 181			

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Q 181	<p>Continued From page 3</p> <p>the following expired medications were found in the code cart located in the NJ Exec Order 26.4b1 area:</p> <p>a. Four (4) - one (1) milliliter (ml) vials of Phenylephrine 10 milligram (mg)/ ml with an expiration date of 7/21</p> <p>b. Three (3) - five (5) ml containers of Lidocaine Jelly 2% with an expiration date of 7/21</p> <p>c. One (1) - thirty (30) ml container of Lidocaine Jelly 2% with an expiration date of 7/21</p> <p>2. On 8/4/21 between 10:40 AM and 11:30 AM, the following expired medications were found in the code cart located in the NJ Exec Order 26.4b1 Unit:</p> <p>a. Two (2) - five (5) ml containers of Lidocaine Jelly 2% with an expiration date of 7/21</p> <p>3. Staff #19 confirmed the above findings on 8/4/21 at 11:30 AM.</p> <p>N.J.A.C. 8:43A-9.5 (f)</p> <p>C. Based on observation, staff interviews, and review of facility policy and procedure, it was determined that the facility failed to ensure that single use medications are used solely for one patient and that multidose ophthalmic drops that are opened are labeled and dated with the date opened, and discarded after twenty-eight days or by the expiration date.</p> <p>Findings include:</p> <p>Reference: Facility policy, "Medication Policies" states, "... All medications, including eye drops,</p>	Q 181			

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Q 181	<p>Continued From page 4</p> <p>must be prepared and administered according to established guidelines... Any multi-dose vials of medications intended and designed by the manufacturer for multiple uses will be opened, labeled, and dated with the date opened, and discarded after 28 days, or by the expiration date, or manufacturer's recommendation if sooner... All medication vials labeled by the manufacturer for single patient or single dose use will be used only for one single patient or one single dose... "</p> <p>1. On 8/4/21 at 10:00 AM, in Exam Room # NU E two (2) - 118 milliliter (ml) bottles of Purified Water 98.3% Ophthalmic Solution Eyewash were found opened and partially filled, available for patient use. The manufacturer's label stated that the eyewash was "Single Use."</p> <p>a. Staff #2 confirmed the above finding on 8/4/21 at 10:05 AM.</p> <p>b. Upon interview on 8/4/21 at 12:40 PM, Staff #9 stated the single use eyewash should have been discarded after a single use.</p> <p>2. On 8/4/21 at 10:10 AM, in Exam Room # NU E the following multi-use ophthalmic drops were found opened and undated, stored in a drawer, and available for patient use:</p> <p>a. One (1) - 15 ml container of Tropicamide Ophthalmic Solution 1%</p> <p>b. One (1) - 2.5 ml container of Flurbiprofen Sodium Ophthalmic Solution 0.03%</p> <p>c. Upon interview on 8/4/21 at 10:15 AM, Staff #2 stated Exam Room # NU was not in use on the survey day. The date and time the ophthalmic</p>	Q 181			

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Q 181	<p>Continued From page 5</p> <p>drops were opened and the expiration dates could not be determined.</p> <p>d. Staff #2 confirmed this finding on 8/4/21 at 10:15 AM.</p> <p>3. On 8/4/21 at 10:30 AM, in Operating Room # multi-use ophthalmic drops were found stored in a cart. The following multi-use ophthalmic drops were opened, undated, and available for patient use:</p> <p>a. One (1) - 2.5 ml container of Flurbiprofen Sodium Ophthalmic Solution 0.03%</p> <p>b. Two (2) - 5 ml containers of Levobunolol Hydrochloride Ophthalmic Solution 0.5%</p> <p>c. One (1) - 5 ml container of Tobramycin Ophthalmic Solution 0.3%</p> <p>d. One (1) - 5 ml container of Timolol Maleate Ophthalmic Solution 0.5%</p> <p>e. Two (2) - 5 ml containers of Prednisolone Acetate Ophthalmic Suspension 1%</p> <p>f. One (1) - 15 ml container of Pilocarpine Hydrochloride Ophthalmic Solution 1%</p> <p>g. One (1) - 5 ml container of Brimonidine Tartrate Ophthalmic Solution 0.2%</p> <p>h. One (1) - 5 ml container of Ofloxacin Ophthalmic Solution 0.3%</p> <p>i. One (1) - 3.5 gram tube of Erythromycin Ophthalmic Ointment 0.5%</p>	Q 181			

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Q 181	<p>Continued From page 6</p> <p>j. Upon interview on 8/4/21 at 10:35 AM, Staff #19 was unable to determine the expiration dates of the opened ophthalmic medications.</p> <p>k. Staff #19 confirmed the above findings on 8/4/21 at 10:30 AM.</p> <p>4. On 8/4/21, staff were interviewed regarding the facility's procedure for use, beyond use dating, and storage of multi-use ophthalmic drops. Facility staff provided information that did not reconcile with the facility's policy referenced above. Upon interview, the following was indicated:</p> <p>a. At 10:15 AM, Staff #2 stated he/she was not sure of the process the facility followed for the use and dating of multi-use ophthalmic drops.</p> <p>b. At 10:20 AM, Staff #9 stated multi-use ophthalmic drops were labeled with patient specific labels, used only for one (1) patient, and were given to the patient at the end of the operative day.</p> <p>c. At 10:35 AM, Staff #19 stated that multi-use ophthalmic drops were opened, labeled with a fourteen (14) day expiration date, and used for multiple patients.</p> <p>N.J.A.C. 8:43A-9.5 (f)</p> <p>D. Based on observation, staff interview, review of New Jersey State Board of Pharmacy guidelines, and review of policy and procedure, it was determined the facility failed to ensure all medications and syringes are kept locked when not in use.</p>	Q 181			

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Q 181	<p>Continued From page 7</p> <p>Findings include:</p> <p>Reference #1: Facility policy, "Pharmaceutical Services - Storage and Control of Drugs and Syringes" states, "All syringes and medications, including eye drops, must be properly stored and controlled in compliance with... NJ State Board of Pharmacy Rules NJAC 13:39... Procedure: 1. All drugs shall be stored in locked storage areas. Drug storage areas will be kept locked when not in use. ... 9. Syringes will be maintained under lock and key. ... "</p> <p>Reference #2: New Jersey State Board of Pharmacy N.J.A.C. 13:39-9.23 states, " ... Storage and Security... a) Provisions shall be made for adequate safe storage of drugs wherever they are stored in the health care facility. 1) All drugs shall be secured for safe use and protected against illicit diversion... "</p> <p>1. On 8/3/21 at 11:54 AM, in the [REDACTED] NJ Exec Order 26.4b1 NJ Exec O [REDACTED], the following was observed:</p> <p>a. The anesthesia cabinet was found unlocked and unattended with medications inside.</p> <p>b. The cabinet directly adjacent to the anesthesia cabinet was found unlocked and unattended with syringes inside.</p> <p>2. Staff #9 confirmed the above findings on 8/3/21 at 11:54 AM.</p> <p>3. On 8/4/21 at 10:10 AM, in Exam Room # [REDACTED] needles were found stored in a drawer that was unlocked and unattended.</p> <p>a. Staff #2 confirmed the above finding on 8/4/21</p>	Q 181			

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Q 181	Continued From page 8 at 10:10 AM.	Q 181			
Q 225	<p>4. On 8/4/21 at 10:40 AM, in Operating Room # two (2) open metal baskets containing needles and syringes were found on top of the anesthesia cart, unattended.</p> <p>a. Staff #19 confirmed the above finding on 8/4/21 at 10:40 AM.</p> <p>N.J.A.C. 8:43A-9.3(a) N.J.A.C. 8:43A-9.3(b)6</p> <p>SUBMISSION AND INVESTIGATION OF GRIEVANCES CFR(s): 416.50(d)(4),(5), & (6)</p> <p>The ASC must establish a grievance procedure for documenting the existence, submission, investigation, and disposition of a patient's written or verbal grievance to the ASC. The following criteria must be met:</p> <p>(1) The grievance process must specify timeframes for review of the grievance and the provisions of a response.</p> <p>(2) The ASC, in responding to the grievance, must investigate all grievances made by a patient, the patient's representative, or the patient's surrogate regarding treatment or care that is (or fails to be) furnished.</p> <p>(3) The ASC must document how the grievance was addressed, as well as provide the patient, the patient's representative, or the patient's surrogate with written notice of its decision. The decision must contain the name of an ASC contact person, the steps taken to investigate the grievance, the</p>	Q 225			

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Q 225	<p>Continued From page 9</p> <p>result of the grievance process and the date the grievance process was completed.</p> <p>This STANDARD is not met as evidenced by: Based on review of three (3) of three (3) medical records (#21, #22, #23), staff interviews, and review of facility documents, it was determined the facility failed to ensure all grievances lodged by patients receive a follow-up written response.</p> <p>Findings include:</p> <p>Reference: Facility policy, "Patient Complaints and Grievances" states, "... Procedure: 1. In all instances of patient complaints, the Administrator, in consultation with other appropriate staff members, will attempt to resolve the complaint satisfactorily on an informal basis. ... 2. If this cannot be accomplished promptly, the complaint will be considered a grievance, and facility will provide the patient or his/her designee with a written response within thirty days of receiving the grievance."</p> <p>1. Review of the facility's complaint and grievance log on 8/3/21 revealed the following:</p> <p>a. Patient #21 had a procedure performed at the facility on [redacted]. On the [redacted] NJ Exec Order 26.4b1 NJ Exec Order 26.4b1 Questionnaire/Call" form dated [redacted] NJ Exec Order 26, the section labeled "Comments/Others" states; "Patient states, 'This was [redacted] NJ Exec Order 26.4b1, and was told to arrive at 6:30 AM. I was not called in until 10:30 AM to the OR. Waiting in the [redacted] NJ Exec Order 26.4b1 is [redacted] NJ Exec Order 26.4b1.' [Name of physician] office suggested patient to call [redacted] NJ Exec Order 26.4b1 with [redacted] NJ Exec Order 26.4b1 s."</p> <p>(i) There was no evidence in the complaint log or in the medical record that the patient's complaint</p>	Q 225			

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Q 225	<p>Continued From page 10 was resolved informally.</p> <p>(ii) There was no evidence in the complaint log or in the medical record that the facility provided the patient with a written response to his/her complaint within thirty (30) days.</p> <p>b. Patient #22 had a procedure performed at the facility on [REDACTED] NJ Exec Order 26. On the [REDACTED] NJ Exec Order 26.4b1 [REDACTED] NJ Exec Order 26.4b1 Questionnaire/Call" form dated [REDACTED] NJ Exec Order 26.4b1, the section labeled "Comments/Others" states, [REDACTED] NJ Exec Order 26.4b1 had [REDACTED] NJ Exec Order 26.4b1 [REDACTED] NJ Exec Order 26.4b1, stated [REDACTED] NJ Exec Order 26.4b1 and would not [REDACTED] NJ Exec Order 26.4b1 [REDACTED] NJ Exec Order 26.4b1.</p> <p>(i) There was no evidence in the complaint log or in the medical record that the patient's complaint was resolved informally.</p> <p>(ii) There was no evidence in the complaint log or in the medical record that the facility provided the patient with a written response to his/her complaint within thirty (30) days.</p> <p>c. Patient #23 had a procedure performed at the facility on [REDACTED] NJ Exec Order 26. On the [REDACTED] NJ Exec Order 26.4b1, the section labeled "Comments/Others" states, "Pt. (patient) spoke to [REDACTED] NJ Exec Order 26.4b1 requesting [REDACTED] NJ Exec Order 26.4b1. Pt. told to come in but then had to [REDACTED] NJ Exec Order 26.4b1 and [REDACTED] NJ Exec Order 26.4b1 to be called back 10 min (minutes) [REDACTED] NJ Exec Order 26.4b1.</p> <p>(i) There was no evidence in the complaint log or in the medical record that the patient's complaint was resolved informally.</p>	Q 225			

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Q 225	Continued From page 11 (ii) There was no evidence in the complaint log or in the medical record that the facility provided the patient with a written response to his/her complaint within thirty (30) days. 2. Staff #1, Staff #2, and Staff #3 confirmed the above findings on 8/4/21 at 2:45 PM.	Q 225			
Q 240	N.J.A.C. 8:43A - 16.1(a) INFECTION CONTROL CFR(s): 416.51 The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases. This CONDITION is not met as evidenced by: Based on observation, document review, and staff interviews, it was determined the facility failed to ensure the maintenance of an infection control program that minimizes infections and communicable diseases. Findings include: 1. The facility failed to ensure implementation of policies and procedures for cleaning in between surgical procedures. (Cross Refer to Tag Q-0241) 2. The facility failed to ensure sterilized items are stored to maintain sterility, in accordance with the Association for the Advancement of Medical Instrumentation (AAMI) guidelines.(Cross Refer to Tag Q-0242) 3. The facility failed to ensure the enzymatic detergents are used in accordance with the manufacturer's instructions for use. (Cross Refer	Q 240			

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NAME OF PROVIDER OR SUPPLIER BERGEN-PASSAIC EYE SURGERY			STREET ADDRESS, CITY, STATE, ZIP CODE 18-01 POLLITT DRIVE, SUITE 4 FAIR LAWN, NJ 07410		
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Q 240	Continued From page 12 to Tag Q-0242)	Q 240			
Q 241	<p>4. The facility failed to ensure its infection control program is under the direction of a designated and qualified professional with training in infection control. (Cross Refer to Tag Q-0243)</p> <p>5. The facility failed to ensure follow disinfectant wipes manufacturer's instructions for use. (Cross Refer to Tag Q-0242)</p> <p>SANITARY ENVIRONMENT CFR(s): 416.51(a)</p> <p>The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice.</p> <p>This STANDARD is not met as evidenced by: A. Based on observation of post procedure room turnover cleaning, staff interview, and review of nationally recognized guidelines, it was determined the facility failed to ensure the medication preparation area is cleaned and disinfected after each surgical procedure.</p> <p>Findings include:</p> <p>Reference: AORN (Association of PeriOperative Registered Nurses) Perioperative Standards and Recommended Practices, 2019 edition, pg. 180 states, "Recommendation III... A clean environment should be reestablished after the patient is transferred from the area... III.c. Operating and procedure rooms must be cleaned after each patient. ... III.c.3. Items that are used during patient care should be cleaned and</p>	Q 241			

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Q 241	<p>Continued From page 13</p> <p>disinfected after each patient use, including anesthesia carts and equipment... "</p> <p>1. During an observation of [REDACTED] NJ Exec Order 26.4b1 [REDACTED] cleaning on 8/4/2021 at 11:06 AM, Staff #15 was observed cleaning Operating Room (OR) # [REDACTED]</p> <p>a. The anesthesia cart, a medication preparation area, was not cleaned and disinfected after the patient was transferred out of the room.</p> <p>2. Upon interview, Staff #2 stated the anesthesia cart is supposed to be cleaned by the anesthesiologists.</p> <p>N.J.A.C. 8:43 A-14.3(a)</p> <p>B. Based on random observation and staff interview, it was determined the facility failed to ensure all equipment is clean.</p> <p>Findings include:</p> <p>1. During a tour of OR # [REDACTED] on 8/4/2021 at 11:06 AM, tape was observed on the anesthesia cart, rendering the surface uncleanable.</p> <p>2. Staff #2 confirmed the above finding on 8/4/21 at 11:06 AM.</p> <p>3. On 8/4/21 at 11:30 AM, in the Preoperative area, three (3) [REDACTED] NJ Exec Order 26.4b1 [REDACTED] glucometers were found stored in a cabinet. The glucometers each had a paper sign secured with multiple pieces of clear, sticky, narrow tape on the back of the device, rendering the surface uncleanable.</p> <p>4. Staff #19 confirmed the above finding on</p>	Q 241			

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Q 241	<p>Continued From page 14 8/4/21 at 11:30 AM.</p> <p>N.J.A.C. 8:43 A - 14.2(b) C. Based on random observation, staff interviews, and review of nationally recognized guidelines, it was determined the facility failed to ensure ventilation standards are maintained at all times.</p> <p>Findings include:</p> <p>Reference #1: ANSI/AAMI ST79 3.3.5.5 Heating, ventilation and air conditioning (HVAC) operating parameters states, "The health care organization should identify which version of ANSI/ASHRAE/ASHE 170 will be used based on when the HVAC system was initially installed or last upgraded. The health care facility should establish and implement systemic processes for monitoring HVAC performance parameters and a mechanism for identifying and resolving variances within rooms throughout the facility where sterile processing occurs."</p> <p>Reference #2: 2014 ANSI/ASHRAE/ASHE 170 Table 7.1 Design Parameters-prohibits Air Recirculation by Means of Room Units.</p> <p>1. On 8/4/2021 at 9:45 AM, during the entrance conference, Staff #1 confirmed the facility's Infection Control program adheres to AAMI guidelines.</p> <p>2. During a tour conducted on 8/4/21 at 10:30 AM, in the presence of Staff #2, an individual split room air handling unit was observed installed and being used within the clean workroom.</p> <p>a. The split unit air-handler is a ^{NJ Exec Order 25.4b1} i</p>	Q 241			

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Q 241	<p>Continued From page 15</p> <p>NJ Exec Order 26.4b1 NJ Exec Order 26.4b1</p> <p>(i) Staff #2 stated the handling unit was installed to use as supplemental air cooling for the clean workroom.</p> <p>3. Staff #2 and Staff #3 confirmed the above finding on 8/4/21 at 2:45 PM.</p> <p>N.J.A.C. 8:43A-19.1(a)</p> <p>D. Based on random observation, staff interviews, and review of Centers for Disease Control and Prevention (CDC) guidelines, it was determined the facility failed to ensure staff adheres to CDC guidelines regarding hand hygiene and glove use.</p> <p>Findings include:</p> <p>Reference #1: CDC 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings (http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf) pages 50-51 states, "... Gloves that are removed properly will prevent hand contamination. Hand hygiene following glove removal further ensures that the hands will not carry potentially infectious material that might have penetrated through unrecognized tears or that could contaminate the hands during glove removal."</p> <p>Reference #2: CDC, Morbidity and Mortality Weekly Report (MMWR), Recommendations and Reports, Guideline for Hand Hygiene in Health-Care Settings, October 25, 2002, Vol. 51, No. RR-16, pg. 33 states, "... Recommendations... D. Remove gloves after caring for a patient. Do not wear the same pair of</p>	Q 241			

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Q 241	<p>Continued From page 16</p> <p>gloves for the care of more than one patient, and do not wash gloves between uses with different patients."</p> <p>1. Upon entry into the facility on 8/3/21 at 10:05 AM, the following was observed:</p> <p>a. Staff #5 greeted the survey team at the facility entrance wearing gloves. While wearing gloves, Staff #5 screened survey staff for NJ Exec Order 26.4b1 performing a temperature check and filling out a NJ Exec Order 26.4b1 questionnaire for each surveyor. He/she then left the area to notify the US FOIA (b)(6) of the survey team's arrival.</p> <p>b. Staff #5 returned to the entrance area wearing gloves. Staff #5 applied hand sanitizer to his/her gloves and walked over to the NJ Exec Order 26.4b NJ Exec Order 26.4b1 screening area wearing the same gloves.</p> <p>2. Staff #1, Staff #2, and Staff #3 confirmed the above findings on 8/4/21 at 2:45 PM.</p> <p>N.J.A.C. 8:43A - 14.3(a)5 N.J.A.C. 8:43A - 14.3(a)7</p> <p>E. Based on observation, staff interviews, review of manufacturer's instructions for use, and review of CDC guidelines, it was determined the facility failed to ensure all containers of NJ Exec Order 26.4b1s cleaners are closed when not in use.</p> <p>Findings include:</p> <p>Reference #1: Product Label for CaviWipes 1 states, "... Description... Disinfecting Towelettes are multi-purpose disinfectant/decontaminant cleaning wipes for use on hard, non-porous</p>	Q 241			

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Q 241	Continued From page 17 inanimate surfaces. ... To Dispense Towelettes... When not in use, keep center cap closed to prevent solution loss. ... "	Q 241			
	Reference #2: Centers for Disease Control and Prevention, "Guideline for Disinfection and Sterilization in Healthcare Facilities (2008) https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html " states, "... 5. Cleaning and Disinfecting Environmental Surfaces in Healthcare Facilities... 5.c. Follow manufacturer's instructions for proper use of disinfecting (or detergent) products... "				
	1. On 8/3/21 at 11:04 AM, during a tour of the NJ Exec Order 26.4b1 , the following was observed:				
	a. On a supply cart located outside of the glass doors to the NJ Exec Order 26.4b1 , a container of NJ Exec Order 26.4b1 was observed with the lid open.				
	b. In the NJ Exec Order 26.4b1 , in both the NJ Exec and NJ Exec Order 26.4b1 , patient care bays, containers of NJ Exec Order 26.4b1 were observed with the lids open.				
	2. Staff #1 and Staff #2 confirmed the above findings on 8/3/21 at 2:15 PM.				
Q 242	N.J.A.C 8:43A-14.3(a) INFECTION CONTROL PROGRAM CFR(s): 416.51(b) The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevent program must include documentation that the ASC has considered, selected, and implemented	Q 242			

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Q 242	<p>Continued From page 18</p> <p>nationally recognized infection control guidelines.</p> <p>This STANDARD is not met as evidenced by:</p> <p>A. Based on observation, staff interviews, and review of manufacturer's instructions for use (IFUs) for NJ Exec Order 26.4b1 Germicidal Wipes, it was determined the facility failed to ensure all staff use germicidal wipes in accordance with manufacturer's instructions for use.</p> <p>Findings include:</p> <p>Reference: CaviWipes Germicidal Wipes, manufacturer's instruction for use states, "Disinfects in one (1) minute."</p> <p>1. During an observation of room turnover cleaning in OR # NJ at 10:54 AM, Staff #13 was observed cleaning the OR mattress using NJ Exec Order 26.4b1 Germicidal Wipes. He/she was questioned regarding the contact time of the germicidal wipes and stated it was three (3) minutes to five (5) minutes.</p> <p>2. During a tour of the NJ Exec Order 26.4b1 on Room at 11:08 AM, Staff #12 was questioned regarding the contact time for the NJ Exec Order 26.4b1 Germicidal Wipes. He/she stated the contact time was two (2) minutes.</p> <p>3. The manufacturer's instructions for NJ Exec Order 26.4b1 NJ Ex Germicidal Wipes were reviewed with Staff #2 and confirmed the contact time is one (1) minute.</p> <p>B. Based on observation of the substerile area, staff interview, and review of nationally recognized infection control guidelines, it was</p>	Q 242			

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Q 242	<p>Continued From page 19</p> <p>determined the facility failed to ensure sterile items are stored in a manner that maintains sterility.</p> <p>Findings include:</p> <p>Reference: AORN Guidelines For Perioperative Practice, 2016 edition Recommendation XV pages 838-839 states, "Sterilized materials should be labeled and stored in a manner to ensure sterility... "</p> <p>1. During the entrance conference conducted on 8/3/2021, Staff #2 confirmed the facility follows AORN and CDC (Centers for Disease Control and Prevention) guidelines.</p> <p>2. During a tour of the substerile area on 8/4/2021 at 11:37 AM, the following was observed:</p> <p>a. Nine (9) crushed sterile packages of NJ Exec Order instruments</p> <p>b. Twelve (12) crushed sterile packages of sterile packaged forceps</p> <p>c. Twelve (12) plastic storage drawers containing sterile packaged instruments were stored on top of one another, with the weight of the instruments crushing and compromising the sterility of the packages.</p> <p>3. Staff #2 confirmed the above findings on 8/4/21 at 2:45 PM.</p> <p>N.J.A.C. 8:43 A-17(b)</p> <p>C. Based on random observation, staff interviews, and review of manufacturer's instructions for use,</p>	Q 242			

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Q 242	<p>Continued From page 20</p> <p>it was determined the facility failed to ensure the manufacturer's instructions for the enzymatic cleaner are followed.</p> <p>Findings include:</p> <p>Reference: Manufacturer's Instructions for Use for SuperNova enzymatic states "... concentration .25 oz (one quarter ounce) per gallon of water... "</p> <p>1. On 8/4/2021 at 12:01 PM, a sink filled with water and an enzymatic solution was observed in the NJ Exec Order 26.4b1 area.</p> <p>a. The water level was below the 2 1/2 gallon mark.</p> <p>b. Upon interview, Staff #4 stated they fill the sink with 2.5 gallons of distilled water and add 0.62 oz of NJ Exec Order 26.4b1 enzymatic.</p> <p>c. Staff #4 stated the amount of water in the sink was approximately 2 gallons and confirmed the correct concentration of the enzymatic cleaner was not in accordance with the manufacturer's instructions for use.</p> <p>2. Staff #1 and Staff #2 confirmed the above findings on 8/4/21 at 2:45 PM.</p> <p>N.J.A.C. 8:43 A-14.4(a)</p> <p>D. Based on review of two (2) of seven (7) employee health files (#6, #12), staff interviews, and review of facility policy and procedure, it was determined the facility failed to ensure documentation of NJ Exec Order 26.4b1 is maintained for every employee.</p>	Q 242			

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Q 242	Continued From page 21 Findings include: Reference: Facility policy, "Rubella and Rubeola Testing" states, "... Each employee and/or staff member who cannot document the results of a previous rubella screening test shall be given a rubella screening test, upon employment or application to the staff. ... 2. Employees/Staff members born in 1957 or later will be given a measles (rubeola) screening test including new employees upon employment or staff members upon application to the staff. ... Results will be communicated in writing to the employee/staff member and documented in the employee staff record." 1. Review of the employee health files for Staff #6 and Staff #12 lacked evidence of a [REDACTED] screening test. 2. Staff #1, Staff #2, and Staff #3 confirmed the above findings on 8/4/21 at 2:45 PM. N.J.A.C. 8:43A - 3.7(b) N.J.A.C. 8:43A - 3.7(c) Q 266 DISCHARGE - ORDER CFR(s): 416.52(c)(2) [The ASC must -] Ensure each patient has a discharge order, signed by the physician who performed the surgery or procedure in accordance with applicable State health and safety laws, standards of practice, and ASC policy. This STANDARD is not met as evidenced by: Based on (1) of three (3) medical records	Q 242			
		Q 266			

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Q 266	<p>Continued From page 22</p> <p>reviewed for NJ Exec Order 26.4b1) and NJ Exec Order 26.4b1) orders (#1), staff interviews, and review of facility policy and procedure, it was determined the facility failed to ensure the post-op order form is complete.</p> <p>Findings include:</p> <p>Reference: Facility policy, "Medical Services, Medical Record Entries and Orders" states, "1. Physician entries in the medical record will be complete, legible, and clear. They will be writing as close to contemporaneously to the event as possible, dated, and signed by the person making the entry."</p> <p>1. Review of Medical Record #1 on 8/4/21 at 2:12 PM revealed the following:</p> <p>a. In the section labeled "Post-Op Orders," the following boxes were left blank:</p> <ul style="list-style-type: none"> i. Diet ii. Discontinue saline lock iii. Activity iv. Medications v. Discharge home <p>b. The area indicating when the patient should return to the doctor for follow up care was left blank.</p> <p>2. Staff #3 confirmed the above findings on 8/4/21 at 2:20 PM.</p>	Q 266			

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NAME OF PROVIDER OR SUPPLIER BERGEN-PASSAIC EYE SURGERY		STREET ADDRESS, CITY, STATE, ZIP CODE 18-01 POLLITT DRIVE, SUITE 4 FAIR LAWN, NJ 07410		
(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
A2334	<p>8:43A-9.3(b)(9) PHARMACEUTICAL SVCS: POLICIES & PROCEDURES</p> <p>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 and limitation of use of drugs marked "sample."</p> <p>This REQUIREMENT is not met as evidenced by: Based on observation, staff interview, and review of facility policy and procedure, it was determined the facility failed to ensure sample medications are not available for use in the facility.</p> <p>Findings include:</p> <p>Reference: Facility policy, "Medication Policies" states, "...The facility does not use sample drugs..."</p> <p>1. On 8/4/21 at 10:05 AM, in Exam Room # [REDACTED] seven (7) - 1.5 milliliter (ml) bottles of Systane lubricant eye drops labeled "Sample-Not for Resale" were found stored in the cabinet.</p> <p>a. This finding was confirmed by Staff #2 on 8/4/21 at 10:05 AM.</p> <p>2. On 8/4/21 at 10:48 AM, in Operating Room # [REDACTED] two (2) boxes containing Omidria Ophthalmic Solution labeled "Professional Trial Product-Not for Sale" were found stored in a medication cart.</p> <p>b. Staff #19 confirmed the above findings on 8/4/21 at 10:48 AM.</p>	A2334		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

New Jersey Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 24208	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 08/04/2021
NAME OF PROVIDER OR SUPPLIER BERGEN-PASSAIC EYE SURGERY		STREET ADDRESS, CITY, STATE, ZIP CODE 18-01 POLLITT DRIVE, SUITE 4 FAIR LAWN, NJ 07410		
(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
A3224	<p>8:43A-12.9(a)(3) SURG & ANES SVCS: SURG SVC EMERG EQUIP</p> <p>Emergency equipment available to the operating room in a surgical service shall include, at least, a difficult airway container or cart which shall be immediately available for handling emergencies. The emergency equipment shall include, but not be limited to, resuscitation equipment, and equipment to open and maintain an airway.</p> <p>This REQUIREMENT is not met as evidenced by: Based on observation and staff interview, it was determined the facility failed to ensure a difficult airway kit or cart is immediately available for emergencies.</p> <p>Findings include:</p> <p>1. On 8/4/21 at 2:20 PM, Staff #3 confirmed the facility did not have a difficult airway kit or cart immediately available for emergencies.</p>	A3224		
A4532	<p>8:43A-16.1(b) PT RIGHTS: POL & PROCEDURES</p> <p>The staff of the facility shall receive in-service education concerning the implementation of policies and procedures regarding patient rights annually and as part of new employee orientation.</p> <p>This REQUIREMENT is not met as evidenced by: Based on review of seven (7) of seven (7) staff education files (#2, #4, #6, #7, #8, #12, #18) and</p>	A4532		

New Jersey Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 24208	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 08/04/2021
NAME OF PROVIDER OR SUPPLIER BERGEN-PASSAIC EYE SURGERY		STREET ADDRESS, CITY, STATE, ZIP CODE 18-01 POLLITT DRIVE, SUITE 4 FAIR LAWN, NJ 07410		
(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
A4532	Continued From page 2 staff interview, it was determined the facility failed to ensure all staff receive in-service training on patient rights annually and upon hire. Findings include: 1. Staff education files for Staff #2, Staff #4, Staff #6, Staff #7, Staff #8, Staff #12, and Staff #18, lacked evidence of in-service training on patient rights. 2. Upon interview on 8/4/21 at 2:15 PM, Staff #2 confirmed the facility does not provide staff in-service training on patient rights.	A4532		

Bergen-Passaic Eye Surgery Center
Provider ID Number 31C0001023

18-01 Pollitt Dr., Suite 4, Fair Lawn, NJ 07410

Date Survey Completed: 08/04/2021

Date of Re-Survey: 10/18/2021

PLAN OF CORRECTION

This Plan of Correction (POC) addresses the deficiencies noted during the revisit to the facility on **October 18, 2021**, of the original survey on **August 3-4, 2021**. The deficiencies have been addressed, and the Board and management of **Bergen-Passaic Cataract Laser and Surgery Center LLC, dba Bergen-Passaic Eye Surgery Center** are committed to complying with all Standards and Conditions for Coverage of the Medicare program.

ID Prefix Tag	Deficiency	Details of Correction	Monitoring Mechanism (Responsible Person)	Date of Implementation
Q240	<p>INFECTION CONTROL CFR(s): 416.51</p> <p>The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases.</p> <p>This CONDITION is not met as evidenced by: Based on document review and staff interviews, it was determined the facility failed to ensure that staff education and monitoring regarding infection control practices, is implemented.</p>	<p>Immediate Action Taken: The Core Leadership Management Team (CLT), which includes the Administrator (CEO), Director of Nursing (DON), Infection Control/Regulatory Compliance RN (ICRN) met with the NJDOH CMS Surveyor to review the Plan of Correction (POC) implementation of education and monitoring regarding infection control practices.</p> <p>The CLT submitted the deficiency letter and results of the Conditional Revisit survey conducted on October 18, 2021, to the Board.</p> <p>Systemic Change: The CLT took action to address the Condition-level deficiencies in Q240 416.51 Findings 1 through 8 to ensure that staff education and monitoring regarding</p>	<p>The Core Leadership Management Team (CLT), under supervision of the Board, is responsible for correcting these deficiencies.</p> <p>The Board and the CLT took responsibility for the CONDITION-level deficiency described in Q 240 following and is ensuring correction.</p>	<p>The Board was notified on October 22, 2021</p> <p>The corrective actions in Q 240 will be reported to the Board through the facility's Clinical</p>

Classified as Confidential

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Q240	Continued From page 1	<p>infection control practices are implemented as per the PoC and to ensure an adequate an Infection Control Program consistent with CMS Conditions of Participation.</p> <p>See Tags Q240 - Q242 for details of actions taken to correct deficiencies noted in these Tags. Facility Policies and Procedures, in-services and ongoing checks and rounds will be implemented to ensure systemic changes.</p>	<p>See each individual deficiency Q240 - Q242 following, for a description of monitoring mechanisms for complying with these components of the Q 240 Condition-level deficiency. The COC and Board as described in individual deficiencies will receive reports from the CLT in order to monitor compliance and correction of all deficiencies.</p>	<p>Operations Committee (COC) as noted.</p> <p>The corrective actions in Q240 - Q242 will be reported to the Board through the facility's Clinical Operations Committee as noted.</p>
Q240	Findings 1 & 2:	<p>Findings 1 & 2: Immediate Action Taken: The Core Leadership Team, CEO, DON, and ICRN, took immediate action to address education on proper Operating Room (OR) cleaning and disinfection</p> <p>Systemic Change: A comprehensive education and in-service process, including documentation of same will be developed and instituted for proper Operating Room (OR) cleaning and disinfection between cases.</p> <p>A comprehensive monitoring process, including documentation of same will be developed and instituted for proper Operating Room (OR) cleaning and disinfection between cases.</p>	<p>OK 10/21/21</p> <p>NJ Exec Order 26.4b1</p>	

<p>Q240</p>	<p>Continued From page 2</p> <p>1.The facility failed to conduct staff education on proper Operating Room (OR) cleaning and disinfection between cases, as indicated on the facility's plan of correction (PoC).</p> <p>2. The facility failed to monitor compliance with the proper cleaning and disinfection of the OR between cases, as indicated on the facility's PoC.</p> <p>Findings 3 & 4:</p>	<p>1. The US FOIA (b)(6) and US FOIA (b)(6) designee will ensure all clinical team members are educated and in-serviced on proper Operating Room (OR) cleaning and disinfection between cases; including that the proper dry time is observed.</p> <p>2. The Director of Nursing (DON) and on-site Infection Control/Regulatory Compliance RN (ICRN) or designee will monitor compliance by bi-weekly visual observation of each OR cleaning and disinfection between cases (2 times per week for each OR). Documentation of the observation will be entered in the Room Turn Over Log.</p> <p>Findings 3 & 4: Immediate Action Taken: Tape was removed from all equipment as of the prior survey on August 4, 2021. Newly installed glucometers were permanently identified for cleaning and monitoring after the prior survey on August 4, 2021.</p> <p>Systemic Change: A comprehensive education and in-service process, including documentation of same will be developed and instituted for the use of tape on equipment in the facility and manufacturer's instructions for use (IFUs) for cleaning and disinfecting glucometers.</p> <p>A comprehensive monitoring process,</p>	<p>1. The DON, ICRN or designee will monitor compliance by clinical team member signed education confirmation. 100% of the eligible staff will be educated by October 21, 2021. All other clinical team members will be educated before their first shift. Education compliance will be reported to the COC, which will report to the Board quarterly.</p> <p>2. The DON, ICRN or designee will monitor compliance by random visual observation of each OR and document observations in the room turn over log. Once 100% compliance is achieved routine monitoring will continue for 6 months. Compliance will be reported to the COC, which will report to the Board quarterly.</p>	<p>1. Education of the eligible clinical team members will be completed by October 21, 2021.</p> <p>2. Observation will begin on October 22, 2021. Initial audits will be no less than 6 months.</p>
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<p>Q240</p>	<p>Continued From page 3</p> <p>3. The facility failed to conduct staff education on the use of tape on equipment and manufacturer's instructions for use (IFUs) for cleaning and disinfecting glucometers, as indicated on the facility's PoC</p> <p>4. The facility failed to monitor compliance with the use of tape on equipment, and cleaning and disinfecting glucometers, as indicated on the facility's PoC.</p>	<p>including documentation of same will be developed and instituted for the use of tape on equipment in the facility and manufacturer's instructions for use (IFUs) for cleaning and disinfecting glucometers.</p> <p>3a. The [US FOIA (b)(6)] and on-site [US FOIA (b)(6)] [US FOIA (b)(6)] or their appointed designee will ensure all clinical team members are educated and in-serviced on the use of tape on equipment.</p> <p>3b. The [US FOIA (b)(6)] and on-site [US FOIA (b)(6)] [US FOIA (b)(6)] or their appointed designee will ensure all registered nurses (RNs) are educated and in-serviced on manufacturer's instructions for use (IFUs) the cleaning and disinfecting glucometers.</p> <p>4. Compliance will be monitored by weekly random rounds of clinical areas for use of tape on equipment and cleaning and disinfecting glucometers. Observation findings will be documented.</p>	<p>3a. The [US FOIA (b)(6)] or designee will monitor compliance by clinical team member signed education confirmation. 100% of the eligible staff will be educated by Oct 21, 2021. All other clinical team members will be educated before their first shift. Education compliance will be reported to the COC, which will report to the Board quarterly.</p> <p>3b. The [US FOIA (b)(6)] or designee will monitor compliance by all registered nurses (RNs) signed education confirmation. 100% of the eligible RNs will be educated by October 21, 2021. All other RNs will be educated before their first shift. Education compliance will be reported to the COC, which will report to the Board quarterly.</p> <p>4. The DON, ICRN or designee will monitor compliance by weekly visual observation of use of tape on equipment and cleaning and disinfecting glucometers. Documentation of the observation will be entered in the log. Once 100% compliance is achieved routine monitoring will continue for 6 months. Compliance will be reported to the COC, which will report to the Board quarterly.</p>	<p>3a. Education of the eligible clinical team members will be completed by October 21, 2021.</p> <p>3b. Education of eligible RNs will be completed by October 21, 2021.</p> <p>4. Observation will begin on October 22, 2021. Initial audits will be no less than 6 months.</p>
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<p>Q240</p>	<p>Continued From page 5</p> <p>6. The facility failed to monitor compliance with the discontinued use of the supplemental air-cooling system in the clean workroom, as indicated on the facility's PoC.</p> <p>Findings 7 & 8:</p>	<p>6. Compliance will be monitored by daily random rounds of clean workroom clinical areas for discontinued use of the supplemental air-cooling system. Observation findings will be documented</p> <p>Findings 7 & 8</p> <p>Immediate Action Taken: The Core Leadership Team, US FOIA (b)(6) and US FOIA (b)(6) took immediate action to address education on the guidelines and proper use of disinfection and sterilization of surfaces in the Center, relating to the contact time for NJ Exec Order 28.4b1 germicidal wipes.</p> <p>Systemic Change: A comprehensive education and in-service process, including documentation of same will be developed and instituted for proper use of disinfection and sterilization of surfaces in the Center, relating to the contact time for CaviWipes germicidal wipes.</p> <p>A comprehensive monitoring process, including documentation of same will be developed and instituted for proper use of disinfection and sterilization of surfaces in the Center, relating to the contact time for CaviWipes germicidal wipes.</p>	<p>6. The DON, ICRN or designee will monitor compliance by random weekly visual observation of the clean workroom for discontinued use of the supplemental air-cooling system. Documentation of the observation will be entered in the log. Once 100% compliance is achieved routine monitoring will continue for 6 months. Compliance will be reported to the COC, which will report to the Board quarterly.</p> <p>NJ Exec Order 28.4b1</p> <p>OK 10/29/21</p>	<p>6. Observation will begin on October 22, 2021. Initial audits will be no less than 6 months.</p>
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<p>Q240</p>	<p>Continued From page 6</p> <p>7.The facility failed to conduct staff education on following the IFU for contact time for <small>NJ Exec Order 26.4b1</small> germicidal wipes, as indicated on the facility's PoC.</p> <p>8. The facility failed to monitor compliance with the manufacturer's instructions for use for contact time when using <small>NJ Exec Order 26.4b1</small> germicidal wipes, as indicated on the facility's PoC.</p>	<p>7. The <small>US FOIA (b)(6)</small> and on-site <small>US FOIA (b)(6)</small> <small>US FOIA (b)(6)</small> or their appointed designee will ensure all clinical team members are educated on following the IFU for contact time for CaviWipes germicidal wipes.</p> <p>8. Compliance will be monitored by weekly random rounds of the ORs and clinical areas observing and documenting that all clinical team members are following the IFU for contact time for CaviWipes germicidal wipes.</p>	<p>7. The <small>US FOIA (b)(6)</small> or designee will monitor compliance by clinical team member signed education confirmation. 100% of the eligible staff will be educated by October 21, 2021. All other clinical team members will be educated before their first shift. Education compliance will be reported to the COC, which will report to the Board quarterly.</p> <p>8. The DON, ICRN or designee will monitor compliance by weekly random visual rounds of observing and documenting that all clinical team members are following the IFU for contact time for CaviWipes germicidal wipes. Documentation of the observation will be entered in the log. Once 100% compliance is achieved routine monitoring will continue for 6 months. Compliance will be reported to the COC, which will report to the Board quarterly.</p>	<p>7. Education of the eligible clinical team members will be completed by October 21, 2021.</p> <p>8. Observation will begin on October 22, 2021. Initial audits will be no less than 6 months.</p>
<p>Q241</p>	<p>SANITARY ENVIRONMENT CFR(s): 416.51(a)</p> <p>The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice.</p> <p>This STANDARD is not met as evidenced by:</p>	<p>Immediate Action Taken: The Core Leadership Management Team met with the NJDOH CMS Surveyor to review the Plan of Correction (POC) implementation to provide a functional and sanitary environment for the provision of</p>	<p><small>NJ Exec Order 26.4b1</small></p> <p>OK 10/29/21</p>	

<p>Q241</p>	<p>Continued From page 7</p> <p>A. Based on document review and staff interviews, it was determined the facility failed to conduct staff education regarding proper OR cleaning and disinfection between cases, as indicated in the facility's Plan of Correction (PoC).</p> <p>Findings include:</p> <p>1. The facility's PoC, dated 9/30/21, states, "Systemic Change: 1. The facility will ensure that all surfaces in the OR are properly cleaned and disinfected between cases... The Director of Nursing (DON) will</p>	<p>surgical services by adhering to professionally acceptable standards of practice.</p> <p>The CLT submitted the deficiency letter and results of the Conditional Revisit survey conducted on October 18, 2021, to the Board.</p> <p>Systemic Change: The [redacted] took action to address the Standard-level deficiencies in Q241 416.51(a) A through F to ensure that staff education and monitoring concerning provision of a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice is implemented as per the PoC.</p> <p>A. The [redacted] and on-site [redacted] or their appointed designee will ensure all clinical team members are educated and in-serviced on proper Operating Room (OR) cleaning and disinfection between cases; including that the proper dry time is observed</p>	<p>The CLT under supervision of the Board, is responsible for correcting these deficiencies.</p> <p>The Board and the CLT took responsibility for the Standard-level deficiency described in Q241416.51(a) A through F following and is ensuring correction.</p> <p>The corrective actions in Q241 will be reported to the Board through the facility's Clinical Operations Committee (COC) as noted.</p> <p>A. The [redacted] or designee will monitor compliance by clinical team member signed education confirmation. 100% of the eligible staff will be educated by October 21, 2021. All other clinical team members will be educated before their first shift. Education compliance will be reported to the COC, which will report to the Board quarterly.</p> <p>OK 10/21/21</p>	<p>The Board was notified on October 22, 2021</p> <p>The corrective actions in Q241 will be reported to the Board through the facility's COC as noted.</p> <p>A. Education of the eligible clinical team members will be completed by October 21, 2021.</p>
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<p>Q241</p>	<p>Continued From page 8</p> <p>ensure that in-service education is completed, documented, and reported to the COC, which reports to the Board.... In-service education was completed as of August 31, 2021."</p> <p>2. During the entrance conference at 10:00 AM, a request was made to Staff#1 and Staff#2 for the staff education conducted regarding the cleaning and disinfection of the OR between cases. No staff education was provided.</p> <p>3. Upon interview at 11:30 AM, Staff#3 confirmed that there was no evidence that staff education regarding the cleaning and disinfection of the OR between cases, was conducted.</p> <p>B. Based on document review and staff interviews, it was determined the facility failed to monitor compliance with the proper cleaning and disinfection of the OR between cases, as indicated on the facility's PoC.</p> <p>Findings Include: 1. The facility's PoC, dated 9/30/21, states, "Systemic Change: 1. The facility will ensure that all surfaces in the OR are properly cleaned and</p>	<p>B. The Director of Nursing (DON) and on-site Infection Control/Regulatory Compliance RN (ICRN) or designee will monitor compliance by bi-weekly visual observation of each OR cleaning and disinfection between cases (2 times per week for each OR). Documentation of the observation will be entered in the Room Turn Over Log.</p>	<p>B. The DON, ICRN or designee will monitor compliance by random visual observation of each OR and document observations in the room turn over log. Once 100% compliance is achieved routine monitoring will continue for 6 months. Compliance will be reported to the COC, which will report to the Board quarterly.</p> <p>OK 10/21/21</p> <p>NJ Exec Order 28.4b1</p>	<p>B. Observation will begin on October 22, 2021. Initial audits will be no less than 6 months.</p>
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<p>Q241</p>	<p>Continued From page 9</p> <p>disinfected between cases... The US FOIA (b)(6) will monitor compliance by random visual observation of each OR and document the observation in the OR Log daily. ... Monitoring has been ongoing since the date of the survey August 4, 2021."</p> <p>2. During the entrance conference at 10:00 AM, a request was made to Staff#1 and Staff#2 for the observations documented on the daily OR Logs beginning August 4, 2021. The OR Logs provided did not include observations of the proper cleaning and disinfection of the OR between cases.</p> <p>3. Upon interview at 11:30 AM, Staff#3 confirmed that the OR Logs did not include observations of the proper cleaning and disinfection of the OR between cases.</p> <p>C. Based on document review and staff interviews, it was determined the facility failed to conduct staff education on the use of tape on equipment and manufacturer's instructions for use (IFUs) for cleaning and disinfecting glucometers, as indicated on the facility's PoC.</p>	<p>C. The US FOIA (b)(6) and on- US FOIA (b)(6) appointed designee will ensure all clinical team members are educated and in-serviced on the use of tape on equipment.</p>	<p>C. The US FOIA (b)(6) or designee will monitor compliance by clinical team member signed education confirmation. 100% of the eligible staff will be educated by Oct 21, 2021. All other clinical team members will be educated before their first shift. Education compliance will be reported to the COC, which will report to the Board quarterly.</p>	<p>C. Education of the eligible clinical team members will be completed by October 21, 2021.</p>
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OK 10/21/21
NJ Exec Order 28.4b1

<p>Q241</p>	<p>Continued From page 10</p> <p>Findings include:</p> <p>1. The facility's PoC, dated 9/30/21, states, "Immediate Action Taken: 1. Tape was removed off the anesthesia cart... Systemic Change: 1. All clinical staff have been re-educated about the use of tape in the facility. ...Immediate Action Taken:1. Three (3) new glucometers were purchased, and the older units were discarded. 2. All clinical personnel have received training on the units, a review of the manufacturer's instructions for use as well as cleaning and disinfection. ... The US FOIA (b)(6) will ensure that in-service education is completed... In-service education was completed as of August 15, 2021."</p> <p>2. During the entrance conference at 10:00 AM, a request was made to Staff#1 and Staff#2 for staff education regarding the use of tape in the facility, and the staff education regarding the manufacturer's instructions for use for the cleaning and disinfection of glucometers. No staff education was provided.</p>	<p>The US FOIA (b)(6) and on-site US FOIA (b)(6) ensure all registered nurses (RNs) are educated and in-serviced on manufacturer's instructions for use (IFUs) the cleaning and disinfecting glucometers.</p>	<p>The US FOIA (b)(6) or designee will monitor compliance by all registered nurses (RNs) signed education confirmation. 100% of the eligible RNs will be educated by October 21, 2021. All other RNs will be educated before their first shift. Education compliance will be reported to the COC, which will report to the Board quarterly.</p> <p><i>OK 10/29/21</i></p>	<p>Education of eligible RNs will be completed by October 21, 2021.</p>
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<p>Q241</p>	<p>Continued From page 11</p> <p>3. Upon interview at 11:30 AM, Staff#3 confirmed that there was no evidence of staff education regarding the use of tape in the facility, or evidence of staff education regarding manufacturer's instructions for use for the cleaning and disinfection of glucometers.</p> <p>D. Based on document review and staff interviews, it was determined the facility failed to monitor compliance with the use of tape on equipment, and cleaning and disinfecting glucometers, as indicated on the facility's PoC.</p> <p>Findings include:</p> <p>1. The facility's PoC, dated 9/30/21, states, "Immediate Action Taken: 1. Tape was removed off the anesthesia cart... Systemic Change: 2. The [REDACTED] and on- [REDACTED] atory [REDACTED] designee will monitor compliance by visual observation of the anesthesia carts and document the observation on the audit log. ... The [REDACTED] are responsible to monitor compliance of the systemic changes weekly... Monitoring has been ongoing since the date of the survey, August 4, 2021. ...Immediate Action Taken: 1. Three (3) new glucometers were</p>	<p>D. Compliance will be monitored by weekly random rounds of clinical areas for use of tape on equipment and cleaning and disinfecting glucometers. Observation findings will be documented</p>	<p>D. The DON, ICRN or designee will monitor compliance by weekly visual observation of use of tape on equipment and cleaning and disinfecting glucometers. Documentation of the observation will be entered in the log. Once 100% compliance is achieved routine monitoring will continue for 6 months. Compliance will be reported to the COC, which will report to the Board quarterly.</p> <p>OK [REDACTED] 10/29/21</p>	<p>D. Observation will begin on October 22, 2021. Initial audits will be no less than 6 months.</p>
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<p>Q241</p>	<p>Continued From page 12</p> <p>purchased, and the older units were discarded...2. Facility Policies and Procedures... and ongoing checks and rounds will be implemented to ensure systemic changes... The DON and ICRN are responsible to monitor compliance with the systemic changes at least monthly... Monitoring has been ongoing since the date of the survey, August 4, 2021."</p> <p>2. During the entrance conference at 10:00 AM, a request was made to Staff#1 and Staff#2 for the monthly monitoring rounds regarding the use of tape in the facility and the cleaning and disinfecting of glucometers. No evidence of monthly monitoring was provided.</p> <p>3. Upon interview at 11:30 AM, Staff#3 confirmed that there was no evidence of monthly monitoring regarding the use of tape in the facility and the cleaning and disinfecting of glucometers.</p> <p>E. Based on document review and staff interviews, it was determined the facility failed to conduct staff education on the discontinued use of the supplemental air-cooling system in the clean workroom, as indicated on the facility's PoC.</p>	<p>E. The US FOIA (b)(6) and on- US FOIA (b)(6) appointed designee will ensure all clinical team members are educated on the discontinued use of the supplemental air-cooling system in the clean workroom.</p>	<p>E. The US FOIA (b)(6) or designee will monitor compliance by clinical team member signed education confirmation. 100% of the eligible staff will be educated by October 21, 2021. All other clinical team members will be educated before their first shift. Education compliance will be reported to the COC, which will report to the Board quarterly.</p>	<p>E. Education of the eligible clinical team members will be completed by October 21, 2021.</p>
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OK
10/24/21
NJ Exec Order 28.4b1

Q241	<p>Continued From page 13</p> <p>Findings include:</p> <p>1. The facility's PoC, dated 9/30/21, states, "Immediate Action Taken: 1. The individual split room air handling unit that was observed and being used as a supplemental air cooling for the clean workroom was immediately disconnected and removed from use. ... Systemic Change... 3. All clinical staff have been educated about the discontinued use of the supplemental air cooling for the clean workroom."</p> <p>2. During the entrance conference at 10:00 AM, a request was made to Staff#1 and Staff#2 for staff education conducted regarding the discontinued use of the split room air handling unit. No staff education was provided.</p> <p>3. Upon interview at 11:30 AM, Staff#3 confirmed that there was no evidence of staff education conducted regarding the discontinued use of the split room air handling unit.</p> <p>F. Based on document review and staff interviews, it was determined the facility failed to monitor compliance with the discontinued use of the supplemental air-cooling system in the clean workroom, as indicated on the facility's PoC.</p>	<p>F. Compliance will be monitored by daily random rounds of clean workroom clinical areas for discontinued use of the supplemental air-cooling system. Observation findings will be documented.</p>	<p>F. The DON, ICRN or designee will monitor compliance by random weekly visual observation of the clean workroom for discontinued use of the supplemental air-cooling system. Documentation of the observation will be entered in the log. Once 100% compliance is achieved routine monitoring will continue for 6 months.</p>	<p>F. Observation will begin on October 22, 2021. Initial audits will be no less than 6 months.</p>
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OK 10/21/21

Q241	Continued From page 10			
	<p>Findings include:</p> <p>1. The facility's PoC, dated 9/30/21, states, "Immediate Action Taken: 1. The individual split room air handling unit that was observed and being used as a supplemental air cooling for the clean workroom was immediately disconnected and removed from use. ... The DON and ICRN are responsible to monitor compliance with the systemic change daily and report to the COC which will report to the Board. ... Monitoring began as of September 16, 2021."</p> <p>2. During the entrance conference at 10:00 AM, a request was made to Staff#1 and Staff#2 for evidence of monitoring for compliance regarding the discontinued use of the supplemental air-cooling system in the clean workroom. No evidence of monitoring was provided.</p> <p>3. Upon interview at 11:30 AM, Staff#3 confirmed that there was no evidence of monitoring regarding the discontinued use of the supplemental air-cooling system in the clean workroom.</p>			
Q242	<p>INFECTION CONTROL PROGRAM CFR(s): 416.51(b)</p> <p>The ASC must maintain an ongoing program designed to prevent, control,</p>	<p>Immediate Action Taken: The Core Leadership Management Team</p>		

<p>Q242</p>	<p>Continued From page 15</p> <p>and investigate infections and communicable diseases. In addition, the infection control and prevent program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines.</p> <p>This STANDARD is not met as evidenced by:</p> <p>A. Based on document review and staff interviews, it was determined the facility failed to conduct staff education regarding adherence to manufacturer's instructions for use regarding contact time for [NJ Exec Order 26.4b1] germicidal wipes, as indicated on the facility's PoC.</p> <p>1. The facility's PoC, dated 9/30/21, states, "Systemic Change... 2. All staff will be educated on following manufacturer's instructions for proper</p>	<p>met with the NJDOH CMS Surveyor to review the Plan of Correction (POC) implementation to maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases as per AAMI guidelines.</p> <p>The CLT submitted the deficiency letter and results of the Conditional Revisit survey conducted on October 18, 2021, to the Board.</p> <p>Systemic Change: The [US FOIA (b)(6)] took action to address the deficiencies in Q242 416.51(b) to ensure that staff education and monitoring is implemented as per the PoC, to prevent, control, and investigate infections and communicable diseases and to ensure a sanitary environment is in place as part of a comprehensive Infection Control program.</p> <p>A. The [US FOIA (b)(6)] and on-[US FOIA (b)(6)] appointed designee will ensure all clinical team members are educated on following the IFU for contact time for [NJ Exec Order 26.4b1] germicidal wipes.</p>	<p>The CLT under supervision of the Board, is responsible for correcting these deficiencies.</p> <p>The Board and the CLT took responsibility for the Standard-level deficiency described in Q242 416.51(b) A through B following and is ensuring correction.</p> <p>The corrective actions in Q242 will be reported to the Board through the facility's Clinical Operations Committee (COC) as noted.</p> <p>A. The [US FOIA (b)(6)] or designee will monitor compliance by clinical team member signed education confirmation. 100% of the eligible staff will be educated by October 21, 2021. All other clinical team members will be educated before their first shift. Education compliance will be reported to the COC, which will report to the Board quarterly.</p> <p>OK 10/29/21 [NJ Exec Order 26.4b1]</p>	<p>The Board was notified on October 22, 2021</p> <p>The corrective actions in Q242 will be reported to the Board through the facility's COC as noted.</p> <p>A. Education of the eligible clinical team members will be completed by October 21, 2021.</p>
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<p>Q242</p>	<p>Continued From page 16</p> <p>use of [redacted] NJ Exec Order 26.4b1 leaners, including dry time. ... Re-education was completed as of September 15, 2021."</p> <p>2. During the entrance conference at 10:00 AM, a request was made to Staff#1 and Staff#2 for evidence of staff education regarding following manufacturer's instructions for use for contact time for [redacted] NJ Exec Order 26.4b1 germicidal wipes. No staff education was provided.</p> <p>Continued From page 12</p> <p>3. Upon interview at 11:30 AM, Staff#3 confirmed that there was no evidence of staff education regarding following manufacturer's instructions for use for contact time for [redacted] NJ Exec Order 26.4b1 germicidal wipes.</p> <p>B. Based on document review and staff interviews, it was determined the facility failed to monitor compliance with the manufacturer's instructions for use for contact time when using [redacted] NJ Exec Order 26.4b1 germicidal wipes, as indicated on the facility's PoC.</p> <p>Findings include:</p> <p>1. The facility's PoC, dated 9/30/21, states, "Systemic Change... 2. All staff will be educated on following</p>	<p>B. Compliance will be monitored by weekly random rounds of the ORs and clinical areas observing and documenting that all clinical team members are following the IFU for contact time for CaviWipes germicidal wipes.</p>	<p>B. The DON, ICRN or designee will monitor compliance by weekly random visual rounds of observing and documenting that all clinical team members are following the IFU for contact time for CaviWipes germicidal wipes. Documentation of the observation will be entered in the log. Once 100% compliance is achieved routine monitoring will continue for 6 months. Compliance will be reported to the COC, which will report to the Board quarterly.</p>	<p>B. Observation will begin on October 22, 2021. Initial audits will be no less than 6 months.</p>
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OK 10/29/21

Q242	<p>Continued From page 16</p> <p>manufacturer's instructions for proper use of [REDACTED] cleaners, including dry time. ...The CLT is responsible to monitor compliance with the systemic change by visual observation daily and report to the COC quarterly, which will report to the Board."</p> <p>2. During the entrance conference at 10:00 AM, a request was made to Staff#1 and Staff#2 for evidence of monitoring for compliance with following manufacturer's instructions for use for contact time when using Continued From page 13</p> <p>[REDACTED] germicidal wipes. No evidence of monitoring was provided.</p> <p>3. Upon interview at 11:30 AM, Staff#3 confirmed that there was no evidence of monitoring for compliance with following manufacturer's instructions for use for contact time when using [REDACTED] germicidal wipes.</p>			
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NJ Exec Order 26.4b1

October 28, 2021

Date

Bergen-Passaic Cataract Laser & Surgery Center, LLC
dba Bergen-Passaic Eye Surgery Center

Telephone (201) 414-5649

Classified as Confidential

PLAN OF CORRECTION

This Plan of Correction (POC) addresses the deficiencies noted during the visit to the facility on **August 3-4, 2021**. The deficiencies have been addressed, and the Governing Body and management of **Bergen-Passaic Cataract Laser and Surgery Center LLC** are committed to complying with all Standards and Conditions for Coverage of the Medicare program.

Deficiency	Details of Correction	Monitoring Mechanism (Responsible Person)	Date of Implementation
<p>Q 240 CFR(s): 416.51 INFECTION CONTROL</p> <p>This CONDITION was not met because the facility failed to ensure the maintenance of an infection control program.</p>	<p>Immediate Action Taken:</p> <p>1. The Core Leadership Management Team (CLT), which includes the Administrator (CEO), Director of Nursing (DON), Infection Control/Regulatory Compliance RN (ICRN) met with the NJDOH CMS Survey Team to review and understand all cited deficiencies in the survey and reported all deficiencies to the Board.</p> <p>2. The CLT took immediate action to address the Condition-level deficiencies and ensure an adequate Sanitary Environment Program and an Infection Control Program consistent with CMS Conditions of Participation. See Tags Q 240 - Q 243 for details of actions taken to correct deficiencies noted in these Tags.</p> <p>Systemic Change:</p> <p>1. The facility will implement a comprehensive Sanitary Environment program to prevent the risk of infection and communicable disease, ensure a sanitary environment is in place, as referenced in responses to Q240, Condition 416.51 which follows.</p> <p>2. The facility will implement a comprehensive Infection Control program to prevent transmission of disease, ensure a sanitary environment is in place, including adequate medication management, as referenced in responses to Q240, Condition 416.51 which follows.</p>	<p>See each individual finding in Q 240 - Q 243 following, for a description of monitoring mechanisms for complying with these components of the Q 240 Condition-level deficiency.</p> <p>The Core Leadership Management Team (CLT), under supervision of the Board, is responsible for correcting these deficiencies.</p> <p>The COC and Board as described in individual deficiencies will receive reports from the CLT in order to monitor compliance and correction of all deficiencies.</p>	<p>The corrective actions in Q 240, Q 241, Q 242, and Q 243 will be reported to the Board through the facility's Clinical Operations Committee (COC).</p> <p>The Board, ownership and the CLT took responsibility for the CONDITION-level deficiency described in Q 240 following, as well as all other deficiencies noted on the 2567, and is ensuring correction.</p> <p>The COC was notified of the exit interview remarks at the meeting on August 10, 2021. The information was presented to and discussed by the Board on August 12, 2021.</p>

OK
10/5/21

<p>Q 083 CFR(s): 416.43(d) PERFORMANCE IMPROVEMENT PROJECTS</p> <p>This STANDARD was not met because the facility failed to ensure quality assessment and performance improvement (QAPI) projects were selected based on the needs of the facility.</p> <p>(1) The number and scope of distinct improvement projects conducted annually must reflect the scope and complexity of the ASC's services and operations.</p> <p>(2) The ASC must document the projects that are being conducted. The documentation, at a minimum, must include the reason(s) for implementing the project, and a description of the project's results.</p>	<p>Immediate Action Taken: Requirements for the criteria and selection of Quality Assessment and Performance Improvement (QAPI) projects were reviewed by the Core Leadership Management Team (CLT), which includes the Administrator (CEO), Director of Nursing (DON), Infection Control/Regulatory Compliance RN (ICRN), and the Business Office Manager (BOM), and the Clinical Operations Committee (COC).</p> <p>Systemic Change: 1. The Clinical Operations Committee (COC) will appoint the Performance Improvement Project (PIP) Committee Chair with Board approval to present and discuss the quality data indicators or the identification of medical errors, which may identify quality issues, to be focused upon in the upcoming quarter. The number and scope of Performance Improvement projects will be determined by the ongoing collection and analysis of these quality indicator and performance measure data which identify quality issues within the facility.</p> <p>2. The determination for undertaking each Performance Improvement Project (PIP) will be documented in the COC minutes and include the data to be collected, the manner by which it will be collected, how frequently it will be collected and analyzed, and the measurable impact to improve patient safety, health outcomes, or facility performance. This information and the results of the PIP will be presented to the COC by the PIP Chair.</p> <p>At the COC meeting on August 10, 2021 the DON and the Medical Director discussed the issue of anesthesiology canceling, postponing, or rescheduling surgical cases and its impact on patient care. The COC jointly decided that a study will be conducted to track and review these cases to see what the causes are and if there is an opportunity to reduce the number of occurrences.</p>	<p>The Director of Nursing (DON) is responsible to document the CLT and COC review of the QAPI guidelines and requirements. The DON will present the documentation at the next quarterly COC meeting.</p> <p>The (COC) will present the Performance Improvement Project (PIP) Committee Chair appointment for Board approval.</p> <p>The (PIP) Chair will present the quality data indicators and ongoing projects to the CLT quarterly and documented in the COC minutes and presented to the Board quarterly.</p> <p>The DON is collecting the case data from August 1 through October 31, 2021, for retrospective review by the anesthesia and nursing directors.</p>	<p>Review of the QAPI requirements were completed by September 30, 2021. The results will be reported to the COC, which reports to the Board.</p> <p>The COC will present the PIP Chair to the Board by November 16, 2021.</p> <p>The preliminary data will be presented at the next COC meeting on November 16, 2021.</p> <p style="text-align: right;">OK 10/5/21 NJ Exec Order 26-401</p>
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OK 10/5/21

<p>Q181 Continued from page 3</p> <p>a. Four (4) - one (1) milliliter (ml) vials of Phenylephrine 10 milligram (mg)/ml with an expiration date of 7/21</p> <p>b. Three (3) - five (5) ml containers of Lidocaine Jelly 2% with an expiration date of 7/21</p> <p>c. One (1) - thirty (30) ml container of Lidocaine Jelly 2% with an expiration date of 7/21</p> <p>2. The following expired medications were found in the code cart located in the [REDACTED] Unit NJ Exec Order 26.4b1</p> <p>a. Two (2) - five (5) ml containers of Lidocaine Jelly 2% with an expiration date of 7/21</p> <p>N.J.A.C. 8:43A-9.5(f)</p> <p>C. The facility failed to ensure that single use medications are used solely for one patient and that multidose ophthalmic drops that are opened are labeled and dated with the date opened and discarded after twenty-eight days, by the expiration date or manufacturer's recommendation if sooner.</p> <p>1. The following Single Use medications were found opened and partially filled, available for patient use in Exam Room # [REDACTED]</p>	<p>will ensure that all clinical staff will be retrained on the facility's Medication policies and procedures, and in reading, understanding, and following Manufacturer's Instructions for Use (IFU), Storage and Disposal.</p> <p>2. An RN will be assigned by the DON to monitor expired medication storage on an ongoing monthly basis. Results of audits will be reported to the DON on an audit log. The DON will report the monitoring results to the COC, which reports to the Board</p> <p>3. The Center Contract Pharmacist will also perform a Medication expiration audit quarterly and report the audit results to the DON.</p> <p>Immediate Action Taken:</p> <p>1. Because the open medications were labeled for "single use" the contents were wasted and discarded.</p> <p>Systemic Change:</p> <p>1. The [REDACTED] and on-site [REDACTED] will ensure all clinical staff will be retrained on the facility's Medication policies and procedures for single use medications.</p> <p>2. The Director of Nursing (DON) and on-site Infection Control/Regulatory Compliance RN (ICRN) or their designee will visually monitor and report via audit log the OR and other patient care areas to ensure that safe administration of eye drops protocols are followed,</p>	<p>and handling is presented to the clinical staff. The [REDACTED] will report to the COC, which reports to the Board.</p> <p>An RN will be assigned by the DON to monitor medication expiration monthly. Results of the monitoring be reported to the DON. The DON will report the monitoring results to the COC, which reports to the Board.</p> <p>Results of the Contract Pharmacist's audit will be reported to the DON, who will report the results to the COC, which reports to the Board.</p> <p>The [REDACTED] will ensure that in-service education regarding single use medication policies and handling is presented to the clinical staff. The [REDACTED] will report to the COC, which reports to the Board</p> <p>The DON and ICRN are responsible to monitor the rate of compliance with the systemic change weekly, and report rates of observed compliance to the COC which will report to the Board.</p>	<p>documented and completed by Oct 15, 2021.</p> <p>Monitoring began September 1, 2021. The DON will report the monitoring results and the rate of compliance to the COC quarterly beginning November 2021.</p> <p>Quarterly monitoring by the Contract Pharmacist has been ongoing. The DON reports the monitoring results and the rate of compliance to the COC quarterly.</p> <p>Review and retraining of the clinical staff will be documented and completed by Oct 15, 2021.</p> <p>Weekly monitoring will begin October 4, 2021 and remain ongoing.</p> <p>OK [REDACTED] 10/17/21</p>
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<p>Q181 Continued from page 4</p> <p>a. Two (2) - 118 milliliter (ml) bottles of Purified Water 98.3% Ophthalmic Solution Eyewash</p> <p>2. The following multi-use ophthalmic drops were found in Exam Room [REDACTED] opened and undated, stored in a drawer, and available for patient use:</p> <p>a. One (1) - 15 ml container of Tropicamide Ophthalmic Solution 1%</p> <p>b. One (1) - 2.5 ml container of Flurbiprofen Sodium Ophthalmic Solution 0.03%</p> <p>3. The following multi-use ophthalmic drops were found stored in a cart in Operating Room [REDACTED] opened, undated, and available for patient use:</p> <p>a. One (1) - 2.5 ml container of Flurbiprofen Sodium Ophthalmic Solution 0.03%</p> <p>b. Two (2) - 5 ml containers of Levobunolol Hydrochloride Ophthalmic Solution 0.5%</p> <p>c. One (1) - 5 ml container of Tobramycin Ophthalmic Solution 0.3%</p> <p>d. One (1) - 5 ml container of Timolol Maleate Ophthalmic Solution 0.5%</p> <p>e. Two (2) - 5 ml containers of Prednisolone Acetate Ophthalmic Suspension 1%</p>	<p>limiting all vials and bottles labeled for single patient use to use for one patient only.</p> <p>Immediate Action Taken:</p> <p>1. Because the multi-use medications were open and unlabeled without the date opened and discard date information the contents were wasted and discarded.</p> <p>Systemic Change:</p> <p>1. The [REDACTED] US FOIA (b)(6) and on-site [REDACTED] US FOIA (b)(6) or designee will ensure all clinical staff are re-instructed and re-oriented on the facility's Medication policies and procedures for multi-use medication bottles and vials.</p> <p>2. The Director of Nursing (DON) and on-site Infection Control/Regulatory Compliance RN (ICRN) or their designee will monitor the OR and other patient care areas to ensure that safe administration of eye drops protocols are followed, labeling all multi-use vials with the date opened and proper discard date; after twenty-eight days, by the expiration date or manufacturer's recommendation if sooner.</p>	<p>The [REDACTED] US FOIA (b)(6) will ensure that in-service education regarding multi-use medication policies and handling is presented to the clinical staff. The [REDACTED] US FOIA (b)(6) will report to the COC, which reports to the Board</p> <p>The DON and ICRN are responsible to monitor compliance with the systemic change weekly until 100% compliance is achieved. Rates of observed compliance will be reported to the COC which will report to the Board.</p>	<p>Review and retraining of the clinical staff will be documented and completed by Oct 15, 2021.</p> <p>Weekly monitoring will begin October 4, 2021 and remain ongoing.</p> <p>OK 10/5/21 [REDACTED] NJ Exec Order 25.401</p>
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<p>Q181 Continued from page 5</p> <p>f. One (1) - 15 ml container of Pilocarpine Hydrochloride Ophthalmic Solution 1%</p> <p>g. One (1) - 5 ml container of Brimonidine Tartrate Ophthalmic Solution 0.2%</p> <p>h. One (1) - 5 ml container of Ofloxacin Ophthalmic Solution 0.3%</p> <p>i. One (1) - 3.5 gram tube of Erythromycin Ophthalmic Ointment .5%</p> <p>N.J.A.C. 8:43A-9.5(f)</p> <p>D. Based on observation, staff interview, review of New Jersey State Board of Pharmacy guidelines, and review of policy and procedure, it was determined the facility failed to ensure all medications and syringes are kept locked when not in use.</p> <p>1. In the NJ Exec Order 26.4b1 Area, the following was observed:</p> <p>a. The anesthesia cabinet was found unlocked and unattended with medications inside.</p> <p>b. The cabinet directly adjacent to the anesthesia cabinet was found unlocked and unattended with syringes inside</p>	<p>Immediate Action Taken: All anesthesia carts and cabinets containing medications and/or syringes were immediately locked.</p> <p>Systemic Change: 1. All members of the Anesthesia staff will be instructed on the facility's policies and procedures regarding medication security measures. They will be re-instructed that all medications and syringes must be secured at all times, either in a locked cart or in the</p>	<p>The US FOIA (b)(6) will assist the Anesthesia Director in preparing instruction for all anesthesia staff members regarding medication safety and security. The Anesthesia Director will meet with members of the</p>	<p>Corrective in-service on medication safety and security information will be presented to the anesthesia staff no later than October 15, 2021.</p>
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OK
10/5/21

<p>Q181 Continued from page 6</p> <p>3. In Exam Room #2 needles were found stored in a drawer that was unlocked and unattended</p> <p>4. In Operating Room : [REDACTED] two (2) open metal baskets containing needles and syringes were found on top of the anesthesia cart, unattended.</p> <p>Q225 N.J.A.C. 8:43A-9.3(a) N. J.A.C. 8:43A-9.3(b)6 SUBMISSION AND INVESTIGATION OF GRIEVANCES CFR(s): 416.50(d)(4),(5),&(6)</p> <p>The ASC must establish a grievance procedure for documenting the existence,</p>	<p>personal possession and control of the anesthesia provider.</p> <p>2. The DON and Anesthesia Director or their designee will visually monitor and physically verify to ensure that medications and syringes in the anesthesia carts remain secure at all times. Results will be reported via audit log.</p> <p>US FOIA (b)(6)</p> <p>all clinical staff are re-instructed and re-oriented on the facility's Medication and syringe security policies and procedures.</p> <p>4. The Director of Nursing (DON) and on-site Infection Control/Regulatory Compliance RN (ICRN) or designee will visually monitor and physically verify to ensure that medications and syringes in the OR and other patient care areas remain secure at all times. Results will be reported via audit log.</p> <p>Immediate Action Taken: The Grievance policy criteria were researched and reviewed by the Core Leadership Team (CLT) .</p>	<p>anesthesia staff, individually or as a group, and present corrective information on medication safety and security. The Anesthesia Director will document when the anesthesia staff has completed the in-service and report to the COC, who will inform the Board.</p> <p>The DON and Anesthesia Director are responsible to monitor compliance with the systemic change weekly until 100% compliance is achieved. Rates of observed compliance will be reported to the COC which will report to the Board.</p> <p>The Director of Nursing (DON) will ensure that in-service education regarding medication security policies and procedures is presented to the clinical staff. The DON will report completion to the COC, which reports to the Board</p> <p>The DON and ICRN are responsible to monitor compliance with the systemic change weekly, and report rates of observed compliance to the COC which will report to the Board</p>	<p>Weekly monitoring will begin October 4, 2021 and remain ongoing.</p> <p>Corrective in-service on medication safety and security information will be presented to the clinical staff no later than October 15, 2021.</p> <p>Weekly monitoring will begin October 4, 2021 and remain ongoing</p> <p><i>OK 10/11</i></p>
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<p>Q225 Continued from page 7</p> <p>submission, investigation, and disposition of a patient's written or verbal grievance to the ASC. The following criteria must be met:</p> <p>(1) The grievance process must specify time frames for review of the grievance and the provisions of a response.</p> <p>(2) The ASC, in responding to the grievance, must investigate all grievances made by a patient, the patient's representative, or the patient's surrogate regarding treatment or care that is (or fails to be) furnished.</p> <p>(3) The ASC must document how the grievance was addressed, as well as provide the patient, the patient's representative, or the patient's surrogate with written notice of its decision. The decision must contain the name of an ASC contact person, the steps taken to investigate the grievance, the result of the grievance process and the date the grievance process was completed.</p> <p>This STANDARD is not met as evidenced by: Based on review of three (3) of three (3) medical records (#21,</p>	<p>Systemic Change:</p> <p>1. The grievance policy will be reviewed including the criteria for identifying a grievance. The procures for documenting the existence, submission, investigation, and disposition of a patient's written or verbal grievance against the Center, care, or any other matter as per CFR(s): 416.50(d).</p> <p>2. The time frame for investigating and resolving a grievance is 30 days. Documentation of the how the grievance was addressed and/or resolved will be kept in a central location, the Grievance log, as well as being provided to the patient in writing. The Center Administrator is listed as the ASC contact person.</p> <p>3. All Center personnel will receive a copy of the policy and in-service re-education on the policy.</p> <p>4. The Administrator (CEO) and on-site Infection Control/Regulatory Compliance RN (ICRN) or designee will monitor Grievances and the Grievance log to ensure compliance.</p>	<p>The Administrator (CEO) will submit the grievance policy to the Board for approval if there are any required updates to the policy.</p> <p>In-service education regarding the Grievance policy will be presented to the staff by October 15, 2021.</p> <p>The CEO and ICRN are responsible to monitor compliance weekly for the first quarter and monthly thereafter. Rates of compliance will be reported to the COC which will report to the Board.</p>	<p>The policy was approved on September 27, 2021</p> <p>In-service education on the Grievance Policy will be presented to the staff no later than October 15, 2021.</p> <p>Weekly monitoring will begin in October, 2021.</p> <div data-bbox="1470 1071 1837 1250"> <p>OK 10/5/21</p> <p><small>NJ Exec Order 26.401</small></p> </div>
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<p>Q225 Continued from page 8</p> <p>#22, #23), staff interviews, and review of facility documents, it was determined the facility failed to ensure all grievances lodged by patients receive a follow-up written response.</p> <p>N.J.A.C. 8:43A- 16.1(a) Q 240 1INFECTION CONTROL CFR(s): 416.51</p> <p>The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases.</p> <p>This CONDITION is not met as evidenced by:</p> <p>Based on observation, document review, and staff interviews, it was determined the facility failed to ensure the maintenance of an infection control program that minimizes infections and communicable diseases.</p> <p>Findings include:</p> <ol style="list-style-type: none"> 1. The facility failed to ensure implementation of policies and procedures for cleaning in between surgical procedures. (Cross Refer to Tag Q-0241) 2. The facility failed to ensure sterilized items are stored to maintain sterility, in accordance with the Association for the Advancement of Medical Instrumentation (AAMI) 	<p>Immediate Action Taken:</p> <ol style="list-style-type: none"> 1. The Core Leadership Team, CEO, DON, and ICRN, took immediate action to address the Condition-level deficiencies. See Tags Q 241, Q 242, and Q 243 for details of Immediate Actions taken to correct deficiencies noted in these Tags. <p>Systemic Change:</p> <ol style="list-style-type: none"> 1. Facility Policies and Procedures, in-services and ongoing visually checks and rounds will be implemented to ensure systemic changes. 2. See Tags Q 241, Q 242, and Q 243 for details of changes taken to correct deficiencies noted in these Tags. 	<p>The DON and ICRN are responsible to monitor compliance and report rates of observed compliance to the COC which will report to the Board</p> <p>THE US FOIA (b)(6) will ensure that in-service education is completed, documented, and reported to the COC, which reports to the Board.</p> <p>OK 10/5/21</p>	<p>Monitoring has been ongoing since the date of the survey August 4, 2021.</p> <p>In-service education was completed as of August 31, 2021.</p> <p>NJ Exec Order 25.48</p>
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<p>Q240 Continued From page 9</p> <p>guidelines. (Cross Refer to Tag Q-0242)</p> <p>3. The facility failed to ensure the enzymatic detergents are used in accordance with the manufacturer's instructions for use. (Cross Refer to Tag Q-0242)</p> <p>4. The facility failed to ensure its infection control program is under the direction of a designated and qualified professional with training in infection control. (Cross Refer to Tag Q-0243)</p> <p>5. The facility failed to ensure follow disinfectant wipes manufacturer's instructions for use. (Cross Refer to Tag Q-0242)</p> <p>Q 241 SANITARY ENVIRONMENT CFR(s): 416.51(a)</p> <p>The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice.</p> <p>This STANDARD is not met as evidenced by:</p> <p>A. Based on observation of post procedure room turnover cleaning, staff interview, and review of nationally recognized</p>	<p>Immediate Action Taken:</p> <p>1. The anesthesia cart, a medication preparation area, was cleaned and disinfected.</p> <p>2. OR #3 personnel were reeducated on the post procedure room turnover cleaning.</p>	<p>NJ Exec Order 26.4b1</p>	
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<p>Q241 Continued From page 10</p> <p>guidelines, it was determined the facility failed to ensure the medication preparation area is cleaned and disinfected after each surgical procedure.</p> <p>Findings include: Reference: AORN (Association of Perioperative Registered Nurses) Perioperative</p> <p>Standards and Recommended Practices, 2019 edition, pg. 180 states, "Recommendation III... A clean environment should be established after the patient is transferred from the area... III.c. Operating and procedure rooms must be cleaned after each patient. ... III.c.3. Items that are used during patient care should be cleaned and disinfected after each patient use, including anesthesia carts and equipment."</p> <p>1. During an observation of [REDACTED] NJ Exec Order 26.4b1 cleaning on 8/4/2021 at 11:06 AM, Staff #15 was observed cleaning Operating Room (OR) [REDACTED]</p> <p>a. The anesthesia cart, a medication preparation area, was not cleaned and disinfected after the patient was transferred out of the room.</p>	<p>Systemic Change:</p> <p>1. The facility will ensure that all surfaces in the OR are properly cleaned and disinfected between cases, and that the proper dry time is observed. The Director of Nursing (DON) and on-site Infection Control/Regulatory Compliance RN (ICRN) or designee will monitor compliance by random visual observation of each OR and document the observation in the OR Log daily.</p> <p>2. Facility Policies and Procedures, in-services and ongoing checks and rounds will be implemented to ensure systemic changes. The Director of Nursing (DON) and on-site Infection Control/Regulatory Compliance RN (ICRN) or designee will monitor compliance by random visual observation of each OR and document the observation in the OR Log daily.</p>	<p>The DON and ICRN are responsible to monitor compliance with the systemic changes weekly, and report rates of observed compliance to the COC which will report to the Board</p> <p>The [REDACTED] US FOIA (b)(6) will ensure that in-service education is completed, documented, and reported to the COC, which reports to the Board.</p> <p>The DON and ICRN are responsible to monitor compliance with the systemic changes weekly, and report rates of observed compliance to the COC which will report to the Board</p> <p>OK 10/3/21</p>	<p>Monitoring has been ongoing since the date of the survey August 4, 2021.</p> <p>In-service education was completed as of August 31, 2021.</p> <p>Monitoring has been ongoing since the date of the survey August 4, 2021.</p>
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<p>Q241 Continued From page 11</p> <p>2. Upon interview, Staff #2 stated the anesthesia cart is supposed to be cleaned by the anesthesiologists.</p> <p>N.J.A.C. 8:43A-14.3(a)</p> <p>B. Based on random observation and staff interview, it was determined the facility failed to ensure all equipment is clean.</p> <p>Findings include:</p> <p>1. During a tour of OR #3 on 8/4/2021 at 11:06 AM, tape was observed on the anesthesia cart, rendering the surface uncleanable,</p> <p>3. On 8/4/21 at 11:30 AM, in the Preoperative area, three (3) <small>NJ Exec Order 26.4b1</small> glucometers were found stored in a cabinet. The glucometers each had a paper sign secured with multiple pieces of clear, sticky, narrow tape on the back of the device, rendering the surface uncleanable.</p>	<p>Immediate Action Taken:</p> <p>1. Tape was removed off the anesthesia cart, a medication preparation area, and the cart was cleaned and disinfected.</p> <p>Systemic Change:</p> <p>1. All clinical staff have been re-educated about the use of tape in the facility.</p> <p>2. Facility Policies and Procedures, in-services and ongoing checks and rounds will be implemented to ensure systemic changes. The Director of Nursing (DON) and on-site Infection Control/Regulatory Compliance RN (ICRN) or designee will monitor compliance by visual observation of the anesthesia carts and document the observation on the audit log.</p> <p>Immediate Action Taken:</p> <p>1. Three (3) new glucometers were purchased, and the older units were discarded.</p> <p>2. All clinical personnel have received training on the units, a review of the manufacturer's instructions for use as well as cleaning and disinfection.</p>	<p>The <small>US FOIA (b)(6)</small> will ensure that in-service education is completed, documented, and reported to the COC, which reports to the Board.</p> <p>The DON and ICRN are responsible to monitor compliance of the systemic changes weekly, and report rates of observed compliance to the COC which will report to the Board</p> <p><small>NJ Exec Order 26.4b1</small></p> <p>OK 10/5/21</p>	<p>In-service education was completed as of August 15, 2021</p> <p>Monitoring has been ongoing since the date of the survey, August 4, 2021</p>
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<p>Q241 Continued From page 12</p> <p>N.J.A.C. 8:43A - 14.2(b)</p> <p>C. Based on random observation, Staff interviews, and review of nationally recognized guidelines, it was determined the facility failed to ensure ventilation standards are maintained at all times.</p> <p>Findings include:</p> <p>Reference#1: ANSI/AAMIST79 3.3.5.5 Heating, ventilation and air conditioning (HVAC) operating parameters states, "The healthcare organization should identify which version of ANSI/ASHRAE/ASHE 170 will be used based on when the HVAC system was initially installed or last upgraded. The healthcare facility should establish and implement systemic processes for monitoring HVAC performance</p>	<p>3. Each unit was permanently marked with an indelible identification number, which is able to be cleaned and disinfected.</p> <p>Systemic Change:</p> <p>1.All clinical staff have been re-educated about the use of tape in the facility.</p> <p>2. Facility Policies and Procedures, in-services and ongoing checks and rounds will be implemented to ensure systemic changes</p> <p>Immediate Action Taken:</p> <p>1. The individual split room air handling unit that was observed and being used as a supplemental air cooling for the clean workroom was immediately disconnected and removed from use.</p> <p>2. The facility has placed a work order with the Mechanical Engineering contractor to remove the unit.</p> <p>Systemic Change:</p> <p>1. The facility's mechanical engineering contractor will conduct removal of the unit as part of the Center's planned expansion project approved by NJ DOH and DCA functional review.</p> <p>2. Construction of new Sterile Processing and Decontamination areas occurs during Phase 1A of the project.</p> <p>3.All clinical staff have been educated about the discontinued use of the supplemental air cooling for the clean workroom.</p>	<p>The US FOIA (b)(6) will ensure that in-service education is completed, documented, and reported to the COC, which reports to the Board.</p> <p>The DON and ICRN are responsible to monitor compliance with the systemic changes at least monthly, and report rates of observed compliance to the COC which will report to the Board</p> <p>The DON and ICRN are responsible to monitor compliance with ANSI/AAMIST79 daily, and report compliance to the COC which will report to the Board</p> <p>The CEO is responsible to monitor the expansion project and report to the Board.</p> <p>The CEO is responsible to monitor the expansion project and report to the Board.</p> <p>The DON and ICRN are responsible to monitor compliance with the systemic change daily and report to the COC which will report to the Board</p>	<p>In-service education was completed as of August 15, 2021.</p> <p>Monitoring has been ongoing since the date of the survey, August 4, 2021</p> <p>Monitoring began as of September 16, 2021.</p> <p>Monitoring began as of September 13, 2021 Estimated date of removal is November 26, 2021</p> <p>Monitoring began as of September 13, 2021</p> <p>Monitoring began as of September 16, 2021</p>
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<p>Q241 Continued From page 13</p> <p>parameters and mechanism for identifying and resolving variances within rooms throughout the facility where sterile processing occurs."</p> <p>Reference #2: 2014 ANSI/ASHRAE/ASHE 170 Table 7.1 Design Parameters-prohibits Air Recirculation by Means of Room Units.</p> <p>1. On 8/4/2021at 9:45 AM, during the entrance conference, Staff #1 confirmed Q241 Continued From page 13</p> <p>the facility's Infection Control program adheres to AAMI guidelines.</p> <p>2. During a tour conducted on 8/4/21at 10:30 AM, in the presence of Staff #2, an individual split room air handling unit was observed installed and being used within the clean workroom.</p> <p>a. The split unit air handler is a [REDACTED] NJ Exec Order 26.4b1 [REDACTED] air.</p> <p>(i) Staff #2 stated the handling unit was installed to use as supplemental air cooling for the clean workroom.</p>			
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<p>Q241 Continued From page 14</p> <p>N.J.A.C. 8:43A-19.1(a)</p> <p>D. Based on random observation, staff interviews, and review of Centers for Disease Control and Prevention (CDC) guidelines, it was determined the facility failed to ensure staff adheres to CDC guidelines regarding hand hygiene and glove use.</p> <p>Findings include: Reference #1: CDC 2007 Guidelines for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings (http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf pages 50-51 states, "... Gloves that are removed properly will prevent hand contamination. Hand hygiene following glove removal further ensures that the hands will not carry potentially infectious material that might have penetrated through unrecognized tears or that could contaminate the hands during glove removal."</p> <p>Reference #2: CDC, Morbidity and Mortality Weekly Report (MMWR), Recommendations and Reports, Guideline for Hand Hygiene in Health-Care Settings, October 25, 2002, Vol. 51, No. RR-16, pg. 33 states, "... Recommendations...D. Remove gloves after caring for a patient.</p>	<p>Immediate Action Taken: 1. CDC guidelines regarding hand hygiene and glove use were reviewed with Staff #5.</p> <p>Systemic Change: 1. All staff members have been re-educated on CDC guidelines regarding hand hygiene and glove use.</p> <p>2. Participation in external and internal hand hygiene studies will continue to document and ensure compliance.</p>	<p>The US FOIA (b)(6) will ensure that in-service education is completed, documented, and reported to the COC, which reports to the Board.</p> <p>The ICRN is responsible to monitor hand hygiene weekly for both internal and external studies until 100% compliance is achieved. Afterward random observation no less than monthly will ensue. Reporting to the COC by the ICRN and up to the Board</p> <p>OK 10/15/21</p>	<p>Re-education was complete as of September 1, 2021</p> <p>Weekly monitoring has been in place and will continue as of August 31, 2021.</p>
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<p>Q241 Continued From page 15</p> <p>Do not wear the same pair of gloves for the care of more than one patient, and do not wash gloves between uses with different patients."</p> <p>1. Upon entry into the facility on 8/3/21 at 10:05 AM, the following was observed:</p> <p>a. Staff #5 greeted the survey team at the facility entrance wearing gloves. While wearing gloves, Staff #5 screened survey staff for [REDACTED] NJ Exec Order 26.4b1 performing a temperature check and filling out [REDACTED] NJ Exec Order 26.4b1 screening questionnaire for each surveyor. He/she then left the area to notify the [REDACTED] US FOIA (b)(6) of the survey team's arrival.</p> <p>b. Staff #5 returned to the entrance area wearing gloves. Staff #5 applied hand sanitizer to his/her gloves and walked over to the [REDACTED] NJ Exec Order 26.4b1 screening area wearing the same gloves.</p> <p>N.J.A.C. 8:43A- 14.3(a)5 N.J.A.C. 8:43A- 14.3(a)7</p> <p>E. Based on observation, staff interviews, review of manufacturer's instructions for use, and review of CDC guidelines, it was determined the facility failed to ensure all containers of CaviWipes cleaners are closed when not in</p>			
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<p>Q241 Continued From page 16</p> <p>use.</p> <p>Findings include:</p> <p>Reference#1: Product Label for CaviWipes1 states, "... Description... Disinfecting Towelettes are multi-purpose disinfectant/decontaminant cleaning wipes for use on hard, non-porous inanimate surfaces. ... To Dispense Towelettes... When not in use, keep center cap closed to prevent solution loss.... "</p> <p>Reference #2: Centers for Disease Control and Prevention, "Guideline for Disinfection and Sterilization in Healthcare Facilities (2008) https://www.cdc.gov/infection control/guidelines/disinfection/index.html" states,"... 5. Cleaning and Disinfecting Environmental Surfaces in Healthcare Facilities ... 5.c. Follow manufacturer's instructions for proper use of disinfecting (or detergent) products...."</p> <p>1. On 8/3/21at 11:04 AM, during a tour of the [REDACTED] the following was observed:</p> <p>a. On a supply cart located outside of the glass doors to the [REDACTED] container of [REDACTED] 1" was observed with the lid open.</p>	<p>Immediate Action Taken:</p> <p>1. All CaviWipes containers were immediately closed.</p> <p>Systemic Change:</p> <p>1. All staff will be educated on CDC guidelines and proper use of disinfection and sterilization of surfaces in the Center.</p> <p>2. All staff will be educated on following manufacturer's instructions for proper use of CaviWipes cleaners, including dry time.</p>	<p>The CLT is responsible to monitor compliance with the systemic change daily by visual observation and report to the COC quarterly, which will report to the Board</p> <p>OK 10/5/21</p>	<p>Re-education was complete as of September 15, 2021</p>
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b. In the NJ Exec Order 26.4b1 both the first and second patient care bays 'containers of NJ Exec Order 26.4b1 were observed with the lids open.

N.J.A.C 8:43A-14.3(a)
Q 242 INFECTION CONTROL
PROGRAM CFR(s): 416.51(b)

The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevent program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines.

This STANDARD is not met as evidenced by:

A. Based on observation, staff interviews, and review of manufacturer's instructions for use (IFUs) for NJ Exec Order 26.4b1 Germicidal Wipes, it was determined the facility failed to ensure all staff use germicidal wipes in accordance with manufacturer's instructions for use

Findings include Reference:
NJ Exec Order 26.4b1 Germicidal Wipes, manufacturer's instruction for use states, "Disinfects in one (1) minute."

Immediate Action Taken:

1. Staff members #12 and #13 were immediately re-educated on the manufacturer's instructions for use regarding NJ Exec Order 26.4b1 Germicidal Wipes, including dry time.

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<p>Q 242 Continued From page 18</p> <p>1. During an observation of NJ Exec Order 26.4b1 OR at 10:54AM, Staff #13 was observed cleaning the OR mattress using Germicidal Wipes. He/she was questioned regarding the contact time of the germicidal wipes and stated it was three (3) minutes to five (5) minutes.</p> <p>2. During a tour of the NJ Exec Order 26.4b1 at 11:08 AM, Staff #12 was questioned regarding the contact time for the Germicidal Wipes. He/she stated the contact time was two (2) minutes.</p> <p>3. The manufacturer's instructions for Germicidal Wipes were reviewed with Staff#2 and confirmed the contact time is one (1) minute.</p> <p>B. Based on observation of the substerile area, staff interview, and review of nationally recognized infection control guidelines, it was determined the facility failed to ensure sterile items are stored in a manner that maintains sterility.</p> <p>Findings include:</p>	<p>Systemic Change:</p> <p>1. All staff will be educated on CDC guidelines and proper use of disinfection and sterilization of surfaces in the Center.</p> <p>2. All staff will be educated on following manufacturer's instructions for proper use of disinfectants, including dry time.</p> <p>OK 10/5/21</p>	<p>The CLT is responsible to monitor compliance with the systemic change by visual observation daily and report to the COC quarterly, which will report to the Board</p>	<p>Re-education was complete as of September 15, 2021</p>
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<p>Q 242 Continued From page 19</p> <p>Reference: AORN Guidelines For Perioperative Practice, 2016 edition Recommendation XV pages 838-839 states, "Sterilized materials should be labeled and stored in a manner to ensure stability... "</p> <p>1. During the entrance conference conducted on 8/3/2021, Staff #2 confirmed the facility follows AORN and CDC (Centers for Disease Control and Prevention) guidelines.</p> <p>2. During a tour of the NJ Exec Order 26.4b1 area on 8/4/2021 at 11:37AM, the following was observed:</p> <p>a. Nine (9) crushed sterile packages of Sharp Westcott instruments</p> <p>b. Twelve (12) crushed sterile packages of sterile packaged forceps</p> <p>c. Twelve (12) plastic storage drawers containing sterile packaged instruments were stored on top of one another, with the weight of the instruments crushing and compromising the sterility of the packages.</p> <p>N.J.A.C. 8:43A-17(b)</p> <p>C. Based on random observation, staff interviews and review of manufacturer's instructions for use it was determined the facility failed to ensure the</p>	<p>Immediate Action Taken:</p> <p>1. All crushed sterile packages were immediately removed from the substerile area and returned to Sterile Processing and Decontamination areas to be reprocessed.</p> <p>Systemic Change:</p> <p>1. All clinical staff have been re-educated about the proper storage processes to ensure the integrity of the sterile packaging.</p> <p>2. Varying and smaller sizes of sterile packaging are being sought for the smaller instruments.</p> <p>3. Ongoing checks and rounds will be implemented to ensure changes. The Director of Nursing (DON) and on-site Infection Control/Regulatory Compliance RN (ICRN) or designee will monitor compliance by random visual observation and document the observation in the audit log.</p>	<p>The ICRN met with all SPD staff and in-serviced them immediately on the integrity and proper storage of sterile packages. In-service education is completed, documented, and reported to the COC, which reports to the Board</p> <p>The US FOIA (b)(6) met with the remaining clinical staff and in-serviced them on the integrity and proper storage of sterile packages. In-service education is completed, documented, and reported to the COC, which reports to the Board</p> <p>The DON and ICRN are responsible to monitor compliance weekly and report rates of observed compliance to the COC which will report to the Board</p> <p>NJ Exec Order 26.4b1</p> <p>OK 10/5/21</p>	<p>Re-education was complete as of August 10, 2021</p> <p>Re-education was complete as of September 1, 2021</p> <p>Monitoring has been ongoing since the date of the survey, August 4, 2021</p>
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<p>Q 242 Continued From page 20</p> <p>manufacturer's instructions for the enzymatic cleaner are followed.</p> <p>Findings include:</p> <p>Reference: Manufacturer's Instructions for Use for SuperNova enzymatic states "... concentration .25 oz (one quarter ounce) per gallon of water...."</p> <p>1. On 8/4/2021 at 12:01 PM, a sink filled with water and an enzymatic solution was observed in the decontamination area.</p> <p>a. The water level was below the 2 1/2-gallon mark.</p> <p>b. Upon interview, Staff #4 stated they fill the sink with 2.5 gallons of distilled water and add 0.62 oz of enzymatic. <small>NJ Exec Order 26.4b1</small></p> <p>c. Staff #4 stated the amount of water in the sink was approximately 2 gallons and confirmed the correct concentration of the enzymatic cleaner was not in accordance with the manufacturer's instructions for use.</p> <p>N.J.A.C. 8:43A-14.4(a)</p> <p>D. Based on review of two (2) of seven (7) employee health files</p>	<p>Immediate Action Taken: The enzymatic cleaner was emptied and refilled according to manufacturer's instructions for use</p> <p>Systemic Change: 1. All SPD clinical personnel received an in-service on the enzymatic manufacturer's instructions for use as well as the proper amounts of enzymatic solution and water. Any concentration or level issues will be relayed to the ICRN.</p> <p>2. <small>US FOIA (b)(6)</small> were re-instructed to verify proper fluid amounts were reached by using the "fill-line". Random observational monitoring by CLT personnel will occur weekly and be documented in the audit log.</p>	<p>US FOIA (b)(6)</p> <p>education is completed, documented, and reported to the COC, which reports to the Board.</p> <p>The ICRN is responsible to monitor compliance weekly and report rates of observed compliance to the COC which will report to the Board</p> <p><small>NJ Exec Order 26.4b1</small></p> <p>OK 10/5/21</p>	<p>Re-education was complete as of August 10, 2021</p> <p>Monitoring has been ongoing since the date of the survey, September 1, 2021.</p>
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<p>Q 242 Continued From page 21</p> <p>(#6, #12), staff interviews, and review of facility policy and procedure, it was determined the facility failed to ensure documentation of [REDACTED] and [REDACTED] screening is maintained for every employee.</p> <p>Findings include:</p> <p>Reference: Facility policy, Rubella and Rubeola Testing" states, "... Each employee and/or staff member who cannot document the results of a previous rubella screening test shall be given a rubella screening test, upon employment or application to the staff. ... 2. Employees/Staff members born in 1957 or later will be given a measles (rubeola) screening test including new employees upon employment or staff members upon application to the staff. ... Results will be communicated in writing to the employee/staff member and documented in the employee staff record.... "</p> <p>1. Review of the employee health files for Staff #6 and Staff #12 lacked evidence of a [REDACTED] or [REDACTED] screening test.</p> <p>N.J.A.C. 8:43A- 3.7(b) N.J.A.C. 8:43A- 3.7(c) Q 266 DISCHARGE - ORDER CFR(s): 416.52(c)(2)</p>	<p>Immediate Action Taken: [REDACTED] screening test results were requested of staff # 6 and #12. Results will be communicated in writing to the employees and documented in the staff record.</p> <p>Systemic Change: 1. All employee / staff files will be reviewed for compliance with the facility staff health policy. Staff who are not in compliance will be informed in writing and results obtained and documented.</p>	<p>The Administrator (CEO) will obtain and document the [REDACTED] screening test results.</p> <p>The Administrator (CEO) is responsible for staff compliance with the facility staff health policy. Any delinquent files will be brought into compliance by October 15, 2021. Compliance will be reported to the COC and the Board.</p> <p>OK [REDACTED]</p>	<p>Requests were made by September 1, 2021, and will be complete by October 15, 2021</p> <p>Staff compliance will be complete by October 15, 2021.</p>
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<p>Q 266 Continued From page 22</p> <p>The ASC must ensure each patient has a discharge order, signed by the physician who performed the surgery or procedure in accordance with applicable State health and safety laws, standards of practice, and ASC policy.</p> <p>This STANDARD is not met as evidenced by:</p> <p>Based on (1) of three (3) medical records reviewed for NJ Exec Order 26.4b1, [REDACTED] orders (#1), staff interviews, and review of facility policy and procedure, it was determined the facility failed to ensure the [REDACTED] ensure the [REDACTED] order form is complete.</p> <p>Findings include:</p> <p>Reference: Facility policy, "Medical Services, Medical Record Entries and Orders" states, "1 Physician entries in the medical record will be complete, legible, and clear. They will be writing as close to contemporaneously to the event as possible, dated, and signed by the person making the entry."</p> <p>1. Review of Medical Record #1 on 8/4/21 at 2:12 PM revealed the following:</p> <p>a. In the section labeled [REDACTED]</p>	<p>Immediate Action Taken:</p> <ol style="list-style-type: none"> 1. Staff was alerted to screen all Post-op Orders on the medical record for completeness. 2. For any non-complete post-op orders it will be brought to the surgeon's attention prior to discharging the patient. <p>Systemic Change:</p> <ol style="list-style-type: none"> 1. All staff have been re-educated about the proper completion the post-op order form. The [REDACTED] US FOIA (b)(6) responsible to oversee monitoring of the form use, which will include reporting by the Medical records, nursing, and business departments. <p>In addition the [REDACTED] US FOIA (b)(6) will add monitoring for completeness of the post-op orders to the Monthly nursing chart audit.</p>	<p>The [REDACTED] US FOIA (b)(6) will ensure that in-service education is completed, documented, and reported to the COC, which reports to the Board</p> <p>The DON and ICRN are responsible to monitor compliance weekly and report rates of observed compliance to the COC which will report to the Board [REDACTED] NJ Exec Order 26.4b1</p> <p><i>OK 10/5/21</i></p>	<p>Review and retraining of the staff will be documented and completed by Oct 15, 2021.</p> <p>Weekly monitoring will begin October 4, 2021</p>
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<p>Q 266 Continued From page 23</p> <p><small>NJ Exec</small> Orders," the following boxes were left blank:</p> <ul style="list-style-type: none"> i. Diet ii. Discontinue saline lock iii. Activity iv. Medications v. Discharge home <p>b. The area indicating when the patient should return to the doctor for follow-up care was left blank.</p>	<p>2. The facility's post-op order form will be changed as part of the annual review to include an area for the surgeon's signature, date, and time. The revised form will be presented to the COC and the Board for review and approval. Our surgeons' offices will be contacted to ensure that they are using only the newly revised post-op order form. They will be asked to discard any older forms.</p>	<p>The Business Office Manager (BOM) is responsible to ensure that the post-op order form is amended to include the surgeon's signature, date, and time.</p> <p>The BOM is responsible to re-educate staff and the surgeons' offices about the new form.</p> <p><small>NJ Exec Order 26.48</small></p> <p>OK 10/5/11</p>	<p>Development of the new form is ongoing</p>
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<p>A2334 8:43A-9.3(b)(9) PHARMACEUTICAL SVCS: POLICIES & PROCEDURES A2334</p> <p>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 and limitation of use of drugs marked "sample."</p> <p>This REQUIREMENT is not met as evidenced by</p> <p>Based on observation, staff interview, and review of facility policy and procedure, it was determined the facility failed to ensure sample medications are not available for use in the facility.</p> <p>Findings include: Reference: Facility policy, "Medication Policies" states, "...The facility does not use sample drugs... ."</p> <p>1. On 8/4/21at 10:05AM, in Exam Room #1, seven (7) - 1.5 milliliter(ml) bottles of Systane lubricant eye drops labeled "Sample-Not for Resale" were found stored in the cabinet.</p> <p>2. On 8/4/21at 10:48 AM, in Operating Room #1, two (2) boxes containing Omidria Ophthalmic Solution labeled "Professional Trial Product-Not for Sale" were</p>	<p>Immediate Action Taken:</p> <p>1. The seven (7) - 1.5 milliliter (mI) bottles of Systane lubricant eye drops in Exam Room #1 were immediately wasted and discarded.</p> <p>2. The two (2) boxes containing Omidria Ophthalmic Solution were removed from OR #1 and the pharmaceutical rep contacted to pick up the product.</p> <p>Systemic Change:</p> <p>1. The COC and Board were immediately notified by the CEO and DON re the samples on site. The facility will adhere to its policy of not using sample drugs.</p> <p>2. The Medical Director will contact the Medical Staff to remind the surgeons of the Center's policy to not use sample drugs.</p> <p>The Director of Nursing (DON), and on-site Infection Control/Regulatory Compliance RN (ICRN) will work together to ensure that all clinical staff will be retrained on the facility's Medication sample policy and procedures. Weekly monitoring by visual checks and rounds and documentation in the audit log will be implemented to ensure systemic changes.</p>	<p>The CEO will be responsible for informing any pharmaceutical rep that samples are not allowed in the Center.</p> <p>The Medical Director will contact the Medical staff in writing by October 1, 2021, to remind them of our policy to not use sample drugs at the Center.</p> <p>The DON is responsible to monitor compliance weekly and report rates of observed compliance to the COC which will report to the Board</p> <p></p>	<p>The center has been in compliance with no sample drugs being used in the Center as of August 15, 2021</p> <p>Monitoring has been ongoing since the date of the survey August 16, 2021.</p>
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<p>found stored in a medication cart.</p> <p>A3224 8:43A-12.9(a)(3) SURG & ANES SVCS: SURG SVC EMERGEQUIP A3224</p> <p>Emergency equipment available to the operating room in a surgical service shall include, at least, a difficult airway container or cart which shall be immediately available for handling emergencies. The emergency equipment shall include, but not be limited to, resuscitation equipment, and equipment to open and maintain an airway.</p> <p>This REQUIREMENT is not met as evidenced by</p> <p>Based on observation and staff interview, it was determined the facility failed to ensure a difficult airway kit or cart is immediately available for emergencies.</p> <p>Findings include: 1. On 8/4/21 at 2:20 PM, Staff #3 confirmed the facility did not have a difficult airway kit or cart immediately available for emergencies.</p>	<p>Immediate Action Taken: 1. The Center is pursuing the purchase a difficult airway kit as chosen by the Anesthesia Director.</p> <p>Systemic Change: 1. The Anesthesia Director will be responsible for training appropriate personnel in use of the difficult airway kit as well as documenting training and maintenance.</p>	<p>The Director of Anesthesia will ensure that in-service education is completed, documented, and reported to the COC, which reports to the Board</p> <p>OK 10/5/21</p> <p><small>NJ Exec Order 26.40</small></p>	<p>Anticipated delivery by October 25, 2021.</p> <p>Implementation is November 1, 2021</p>
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<p>A4532 8:43A-16.1(b) PT RIGHTS: POL & PROCEDURES A4532</p> <p>The staff of the facility shall receive in-service education concerning the implementation of policies and procedures regarding patient rights annually and as part of new employee orientation.</p> <p>This REQUIREMENT is not met as evidenced by</p> <p>Based on review of seven (7) of seven (7) staff education files (#2, #4, #6, #7, #8, #12, #18) and staff interview, it was determined the facility failed to ensure all staff receive in-service training on patient rights annually and upon hire.</p> <p>Findings include:</p> <ol style="list-style-type: none"> 1. Staff education files for Staff #2, Staff #1, Staff #6, Staff #7, Staff #8, Staff #12, and Staff #18, lacked evidence of in-service training on patient rights 2. Upon interview on 8/4/21 at 2:15 PM, Staff #2 confirmed the facility does not provide staff in-service training on patient rights. 	<p>Immediate Action Taken:</p> <ol style="list-style-type: none"> 1. Employee training is provided by an online portal. All employees missing training modules including Patient Rights were given time to complete the modules. <p>Systemic Change:</p> <ol style="list-style-type: none"> 1. The ICRN will maintain a report documenting that the patient rights training modules have been completed for each employee. 2. Employees who have delinquent courses are notified by the online portal directly as well as by their immediate supervisor. 	<p>The Infection Control Regulatory Nurse (ICRN) will ensure that the patient rights education and training modules are completed, documented, and reported to the COC, which reports to the Board.</p> <p><i>Handwritten:</i> 6/10/5/21</p> <p><i>Stamp:</i> NJ Exec Order 26.4b1</p>	<p>The patient rights education courses will be complete as of October, 15, 2021</p>
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NJ Exec Order 26.4b1

September 30, 2021

Date

Bergen-Passaic Cataract Laser & Surgery Center, LLC
Telephone (201) 414-5649

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 08/20/2024
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 31C0001023		(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED R 10/18/2021	
NAME OF PROVIDER OR SUPPLIER BERGEN-PASSAIC EYE SURGERY				STREET ADDRESS, CITY, STATE, ZIP CODE 18-01 POLLITT DRIVE, SUITE 4 FAIR LAWN, NJ 07410			
(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) COMPLETION DATE
{Q 000}	INITIAL COMMENTS			{Q 000}			
{Q 240}	<p>A Conditional Revisit survey was conducted on October 18, 2021. The facility is not in compliance with 42 CFR Part 416, Conditions for Coverage for the following:</p> <p>416.51 Infection Control</p> <p>INFECTION CONTROL</p> <p>CFR(s): 416.51</p> <p>The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases.</p> <p>This CONDITION is not met as evidenced by: Based on document review and staff interviews, it was determined the facility failed to ensure that staff education and monitoring regarding infection control practices, is implemented.</p> <p>Findings include:</p> <ol style="list-style-type: none"> 1. The facility failed to conduct staff education on proper Operating Room (OR) cleaning and disinfection between cases, as indicated on the facility's plan of correction (PoC). 2. The facility failed to monitor compliance with the proper cleaning and disinfection of the OR between cases, as indicated on the facility's PoC. 3. The facility failed to conduct staff education on the use of tape on equipment and manufacturer's instructions for use (IFUs) for cleaning and disinfecting glucometers, as indicated on the facility's PoC. 4. The facility failed to monitor compliance with 			{Q 240}			

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

10/28/2021

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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NAME OF PROVIDER OR SUPPLIER BERGEN-PASSAIC EYE SURGERY			STREET ADDRESS, CITY, STATE, ZIP CODE 18-01 POLLITT DRIVE, SUITE 4 FAIR LAWN, NJ 07410		
(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) COMPLETION DATE	
{Q 240}	Continued From page 1 the use of tape on equipment, and cleaning and disinfecting glucometers, as indicated on the facility's PoC. 5. The facility failed to conduct staff education on the discontinued use of the supplemental air cooling system in the clean workroom, as indicated on the facility's PoC. 6. The facility failed to monitor compliance with the discontinued use of the supplemental air cooling system in the clean workroom, as indicated on the facility's PoC. 7. The facility failed to conduct staff education on following the IFU for contact time for NJ Exec Order 26.481 germicidal wipes, as indicated on the facility's PoC. 8. The facility failed to monitor compliance with the manufacturer's instructions for use for contact time when using NJ Exec Order 26.481 germicidal wipes, as indicated on the facility's PoC.	{Q 240}			
{Q 241}	SANITARY ENVIRONMENT CFR(s): 416.51(a) The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice. This STANDARD is not met as evidenced by: A. Based on document review and staff interviews, it was determined the facility failed to conduct staff education regarding proper OR cleaning and disinfection between cases, as indicated in the facility's Plan of Correction (PoC).	{Q 241}			

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NAME OF PROVIDER OR SUPPLIER BERGEN-PASSAIC EYE SURGERY			STREET ADDRESS, CITY, STATE, ZIP CODE 18-01 POLLITT DRIVE, SUITE 4 FAIR LAWN, NJ 07410		
(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) COMPLETION DATE	
{Q 241}	<p>Continued From page 2</p> <p>Findings include:</p> <p>1. The facility's PoC, dated 9/30/21, states, "Systemic Change: 1. The facility will ensure that all surfaces in the OR are properly cleaned and disinfected between cases... The [US FOIA (b)(6)] will ensure that in-service education is completed, documented, and reported to the COC, which reports to the Board. ... In-service education was completed as of August 31, 2021."</p> <p>2. During the entrance conference at 10:00 AM, a request was made to Staff #1 and Staff #2 for the staff education conducted regarding the cleaning and disinfection of the OR between cases. No staff education was provided.</p> <p>3. Upon interview at 11:30 AM, Staff #3 confirmed that there was no evidence that staff education regarding the cleaning and disinfection of the OR between cases, was conducted.</p> <p>B. Based on document review and staff interviews, it was determined the facility failed to monitor compliance with the proper cleaning and disinfection of the OR between cases, as indicated on the facility's PoC.</p> <p>Findings Include:</p> <p>1. The facility's PoC, dated 9/30/21, states, "Systemic Change: 1. The facility will ensure that all surfaces in the OR are properly cleaned and disinfected between cases... The [US FOIA (b)(6)] or designee will monitor compliance by random</p>	{Q 241}			

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NAME OF PROVIDER OR SUPPLIER BERGEN-PASSAIC EYE SURGERY			STREET ADDRESS, CITY, STATE, ZIP CODE 18-01 POLLITT DRIVE, SUITE 4 FAIR LAWN, NJ 07410		
(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) COMPLETION DATE	
{Q 241}	<p>Continued From page 3</p> <p>visual observation of each OR and document the observation in the OR Log daily. ... Monitoring has been ongoing since the date of the survey August 4, 2021."</p> <p>2. During the entrance conference at 10:00 AM, a request was made to Staff #1 and Staff #2 for the observations documented on the daily OR Logs beginning August 4, 2021. The OR Logs provided did not include observations of the proper cleaning and disinfection of the OR between cases.</p> <p>3. Upon interview at 11:30 AM, Staff #3 confirmed that the OR Logs did not include observations of the proper cleaning and disinfection of the OR between cases.</p> <p>C. Based on document review and staff interviews, it was determined the facility failed to conduct staff education on the use of tape on equipment and manufacturer's instructions for use (IFUs) for cleaning and disinfecting glucometers, as indicated on the facility's PoC.</p> <p>Findings include:</p> <p>1. The facility's PoC, dated 9/30/21, states, "Immediate Action Taken: 1. Tape was removed off the anesthesia cart... Systemic Change: 1. All clinical staff have been re-educated about the use of tape in the facility. ... Immediate Action Taken: 1. Three (3) new glucometers were purchased, and the older units were discarded. 2. All clinical personnel have received training on the units, a review of the manufacturer's instructions for use as well as cleaning and disinfection. ... The US FOIA (b)(6) will ensure that in-service education is completed... In-service</p>	{Q 241}			

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NAME OF PROVIDER OR SUPPLIER BERGEN-PASSAIC EYE SURGERY			STREET ADDRESS, CITY, STATE, ZIP CODE 18-01 POLLITT DRIVE, SUITE 4 FAIR LAWN, NJ 07410		
(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) COMPLETION DATE	
{Q 241}	<p>Continued From page 4 education was completed as of August 15, 2021."</p> <p>2. During the entrance conference at 10:00 AM, a request was made to Staff #1 and Staff #2 for staff education regarding the use of tape in the facility, and the staff education regarding the manufacturer's instructions for use for the cleaning and disinfection of glucometers. No staff education was provided.</p> <p>3. Upon interview at 11:30 AM, Staff #3 confirmed that there was no evidence of staff education regarding the use of tape in the facility, or evidence of staff education regarding manufacturer's instructions for use for the cleaning and disinfection of glucometers.</p> <p>D. Based on document review and staff interviews, it was determined the facility failed to monitor compliance with the use of tape on equipment, and cleaning and disinfecting glucometers, as indicated on the facility's PoC.</p> <p>Findings include:</p> <p>1. The facility's PoC, dated 9/30/21, states, "Immediate Action Taken: 1. Tape was removed off the anesthesia cart... Systemic Change: 2. The US FOIA (b)(6) or designee will monitor compliance by visual observation of the anesthesia carts and document the observation on the audit log. ... The US FOIA (b)(6) are responsible to monitor compliance of the systemic changes weekly... Monitoring has been ongoing since the date of the survey, August 4, 2021. ... Immediate Action Taken: 1. Three (3) new glucometers were purchased, and the older units were discarded...</p>	{Q 241}			

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NAME OF PROVIDER OR SUPPLIER BERGEN-PASSAIC EYE SURGERY			STREET ADDRESS, CITY, STATE, ZIP CODE 18-01 POLLITT DRIVE, SUITE 4 FAIR LAWN, NJ 07410		
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{Q 241}	<p>Continued From page 5</p> <p>2. Facility Policies and Procedures... and ongoing checks and rounds will be implemented to ensure systemic changes... The US FOIA (b)(6) are responsible to monitor compliance with the systemic changes at least monthly... Monitoring has been ongoing since the date of the survey, August 4, 2021."</p> <p>2. During the entrance conference at 10:00 AM, a request was made to Staff #1 and Staff #2 for the monthly monitoring rounds regarding the use of tape in the facility and the cleaning and disinfecting of glucometers. No evidence of monthly monitoring was provided.</p> <p>3. Upon interview at 11:30 AM, Staff #3 confirmed that there was no evidence of monthly monitoring regarding the use of tape in the facility and the cleaning and disinfecting of glucometers.</p> <p>E. Based on document review and staff interviews, it was determined the facility failed to conduct staff education on the discontinued use of the supplemental air cooling system in the clean workroom, as indicated on the facility's PoC.</p> <p>Findings include:</p> <p>1. The facility's PoC, dated 9/30/21, states, "Immediate Action Taken: 1. The individual split room air handling unit that was observed and being used as a supplemental air cooling for the clean workroom was immediately disconnected and removed from use. ... Systemic Change... 3. All clinical staff have been educated about the discontinued use of the supplemental air cooling for the clean workroom."</p>	{Q 241}			

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NAME OF PROVIDER OR SUPPLIER BERGEN-PASSAIC EYE SURGERY			STREET ADDRESS, CITY, STATE, ZIP CODE 18-01 POLLITT DRIVE, SUITE 4 FAIR LAWN, NJ 07410		
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{Q 241}	<p>Continued From page 6</p> <p>2. During the entrance conference at 10:00 AM, a request was made to Staff #1 and Staff #2 for staff education conducted regarding the discontinued use of the split room air handling unit. No staff education was provided.</p> <p>3. Upon interview at 11:30 AM, Staff #3 confirmed that there was no evidence of staff education conducted regarding the discontinued use of the split room air handling unit.</p> <p>F. Based on document review and staff interviews, it was determined the facility failed to monitor compliance with the discontinued use of the supplemental air cooling system in the clean workroom, as indicated on the facility's PoC.</p> <p>Findings include:</p> <p>1. The facility's PoC, dated 9/30/21, states, "Immediate Action Taken: 1. The individual split room air handling unit that was observed and being used as a supplemental air cooling for the clean workroom was immediately disconnected and removed from use. ... The US FOIA (b)(6) are responsible to monitor compliance with the systemic change daily and report to the COC which will report to the Board. ... Monitoring began as of September 16, 2021."</p> <p>2. During the entrance conference at 10:00 AM, a request was made to Staff #1 and Staff #2 for evidence of monitoring for compliance regarding the discontinued use of the supplemental air cooling system in the clean workroom. No evidence of monitoring was provided.</p> <p>3. Upon interview at 11:30 AM, Staff #3 confirmed that there was no evidence of monitoring</p>	{Q 241}			

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NAME OF PROVIDER OR SUPPLIER BERGEN-PASSAIC EYE SURGERY			STREET ADDRESS, CITY, STATE, ZIP CODE 18-01 POLLITT DRIVE, SUITE 4 FAIR LAWN, NJ 07410		
(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) COMPLETION DATE	
{Q 241}	Continued From page 7 regarding the discontinued use of the supplemental air cooling system in the clean workroom.	{Q 241}			
{Q 242}	INFECTION CONTROL PROGRAM CFR(s): 416.51(b) The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevent program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines. This STANDARD is not met as evidenced by: A. Based on document review and staff interviews, it was determined the facility failed to conduct staff education regarding adherence to manufacturer's instructions for use regarding contact time for <small>NJ Exec Order 26.4b1</small> germicidal wipes, as indicated on the facility's PoC. 1. The facility's PoC, dated 9/30/21, states, "Systemic Change... 2. All staff will be educated on following manufacturer's instructions for proper use of <small>NJ Exec Order 26.4b1</small> cleaners, including dry time. ... Re-education was completed as of September 15, 2021." 2. During the entrance conference at 10:00 AM, a request was made to Staff #1 and Staff #2 for evidence of staff education regarding following manufacturer's instructions for use for contact time for <small>NJ Exec Order 26.4b1</small> germicidal wipes. No staff education was provided.	{Q 242}			

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NAME OF PROVIDER OR SUPPLIER BERGEN-PASSAIC EYE SURGERY			STREET ADDRESS, CITY, STATE, ZIP CODE 18-01 POLLITT DRIVE, SUITE 4 FAIR LAWN, NJ 07410		
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{Q 242}	<p>Continued From page 8</p> <p>3. Upon interview at 11:30 AM, Staff #3 confirmed that there was no evidence of staff education regarding following manufacturer's instructions for use for contact time for [REDACTED] germicidal wipes.</p> <p>B. Based on document review and staff interviews, it was determined the facility failed to monitor compliance with the manufacturer's instructions for use for contact time when using [REDACTED] germicidal wipes, as indicated on the facility's PoC.</p> <p>Findings include:</p> <p>1. The facility's PoC, dated 9/30/21, states, "Systemic Change... 2. All staff will be educated on following manufacturer's instructions for proper use of [REDACTED] cleaners, including dry time. ... The [REDACTED] is responsible to monitor compliance with the systemic change by visual observation daily and report to the COC quarterly, which will report to the Board."</p> <p>2. During the entrance conference at 10:00 AM, a request was made to Staff #1 and Staff #2 for evidence of monitoring for compliance with following manufacturer's instructions for use for contact time when using [REDACTED] germicidal wipes. No evidence of monitoring was provided.</p> <p>3. Upon interview at 11:30 AM, Staff #3 confirmed that there was no evidence of monitoring for compliance with following manufacturer's instructions for use for contact time when using [REDACTED] germicidal wipes.</p>	{Q 242}			

POST-CERTIFICATION REVISIT REPORT

PROVIDER / SUPPLIER / CLIA / IDENTIFICATION NUMBER 31C0001023	MULTIPLE CONSTRUCTION A. Building B. Wing	DATE OF REVISIT 10/18/2021
NAME OF FACILITY BERGEN-PASSAIC EYE SURGERY	STREET ADDRESS, CITY, STATE, ZIP CODE 18-01 POLLITT DRIVE, SUITE 4 FAIR LAWN, NJ 07410	

This report is completed by a qualified State surveyor for the Medicare, Medicaid and/or Clinical Laboratory Improvement Amendments program, to show those deficiencies previously reported on the CMS-2567, Statement of Deficiencies and Plan of Correction, 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 CMS-2567 (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 Q0083	Correction	ID Prefix Q0181	Correction	ID Prefix Q0225	Correction
Reg. # 416.43(d)	Completed	Reg. # 416.48(a)	Completed	Reg. # 416.50(d)(4),(5), & (6)	Completed
LSC	10/18/2021	LSC	10/18/2021	LSC	10/18/2021
ID Prefix Q0266	Correction	ID Prefix	Correction	ID Prefix	Correction
Reg. # 416.52(c)(2)	Completed	Reg. #	Completed	Reg. #	Completed
LSC	10/18/2021	LSC		LSC	
ID Prefix	Correction	ID Prefix	Correction	ID Prefix	Correction
Reg. #	Completed	Reg. #	Completed	Reg. #	Completed
LSC		LSC		LSC	
ID Prefix	Correction	ID Prefix	Correction	ID Prefix	Correction
Reg. #	Completed	Reg. #	Completed	Reg. #	Completed
LSC		LSC		LSC	
ID Prefix	Correction	ID Prefix	Correction	ID Prefix	Correction
Reg. #	Completed	Reg. #	Completed	Reg. #	Completed
LSC		LSC		LSC	

REVIEWED BY STATE AGENCY <input checked="" type="checkbox"/>	REVIEWED BY (INITIALS) [REDACTED]	DATE 10/22/21	SIGNATURE OF SURVEYOR [REDACTED] NJ Exec Order 26.4b1	DATE 10/22/21
REVIEWED BY CMS RO <input type="checkbox"/>	REVIEWED BY (INITIALS)	DATE	TITLE	DATE

FOLLOWUP TO SURVEY COMPLETED ON
8/4/2021

☐ CHECK FOR ANY UNCORRECTED DEFICIENCIES. WAS A SUMMARY OF UNCORRECTED DEFICIENCIES (CMS-2567) SENT TO THE FACILITY?

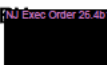

☐ YES ☐ NO

STATE FORM: REVISIT REPORT

PROVIDER / SUPPLIER / CLIA / IDENTIFICATION NUMBER 24208	MULTIPLE CONSTRUCTION A. Building B. Wing	DATE OF REVISIT 10/18/2021
NAME OF FACILITY BERGEN-PASSAIC EYE SURGERY		STREET ADDRESS, CITY, STATE, ZIP CODE 18-01 POLLITT DRIVE, SUITE 4 FAIR LAWN, NJ 07410

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 A2334	Correction	ID Prefix A3224	Correction	ID Prefix A4532	Correction
Reg. # 8:43A-9.3(b)(9)	Completed	Reg. # 8:43A-12.9(a)(3)	Completed	Reg. # 8:43A-16.1(b)	Completed
LSC	10/18/2021	LSC	10/18/2021	LSC	10/18/2021
ID Prefix	Correction	ID Prefix	Correction	ID Prefix	Correction
Reg. #	Completed	Reg. #	Completed	Reg. #	Completed
LSC		LSC		LSC	
ID Prefix	Correction	ID Prefix	Correction	ID Prefix	Correction
Reg. #	Completed	Reg. #	Completed	Reg. #	Completed
LSC		LSC		LSC	
ID Prefix	Correction	ID Prefix	Correction	ID Prefix	Correction
Reg. #	Completed	Reg. #	Completed	Reg. #	Completed
LSC		LSC		LSC	
ID Prefix	Correction	ID Prefix	Correction	ID Prefix	Correction
Reg. #	Completed	Reg. #	Completed	Reg. #	Completed
LSC		LSC		LSC	

REVIEWED BY STATE AGENCY <input checked="" type="checkbox"/>	REVIEWED (INITIALS) 	DATE 10/22/21	SIGNATURE OF SURVEYOR 	DATE 10/22/21
REVIEWED BY CMS RO <input type="checkbox"/>	REVIEWED BY (INITIALS)	DATE	DATE	DATE
FOLLOWUP TO SURVEY COMPLETED ON 8/4/2021		<input type="checkbox"/> CHECK FOR ANY UNCORRECTED DEFICIENCIES. WAS A SUMMARY OF UNCORRECTED DEFICIENCIES (CMS-2567) SENT TO THE FACILITY? <input type="checkbox"/> YES <input type="checkbox"/> NO		

POST-CERTIFICATION REVISIT REPORT

PROVIDER / SUPPLIER / CLIA / IDENTIFICATION NUMBER 31C0001023	Y1	MULTIPLE CONSTRUCTION A. Building B. Wing	Y2	DATE OF REVISIT 11/4/2021	Y3
NAME OF FACILITY BERGEN-PASSAIC EYE SURGERY			STREET ADDRESS, CITY, STATE, ZIP CODE 18-01 POLLITT DRIVE, SUITE 4 FAIR LAWN, NJ 07410		

This report is completed by a qualified State surveyor for the Medicare, Medicaid and/or Clinical Laboratory Improvement Amendments program, to show those deficiencies previously reported on the CMS-2567, Statement of Deficiencies and Plan of Correction, 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 CMS-2567 (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 Q0240	Correction	ID Prefix Q0241	Correction	ID Prefix Q0242	Correction
Reg. # 416.51	Completed	Reg. # 416.51(a)	Completed	Reg. # 416.51(b)	Completed
LSC	11/04/2021	LSC	11/04/2021	LSC	11/04/2021
ID Prefix	Correction	ID Prefix	Correction	ID Prefix	Correction
Reg. #	Completed	Reg. #	Completed	Reg. #	Completed
LSC		LSC		LSC	
ID Prefix	Correction	ID Prefix	Correction	ID Prefix	Correction
Reg. #	Completed	Reg. #	Completed	Reg. #	Completed
LSC		LSC		LSC	
ID Prefix	Correction	ID Prefix	Correction	ID Prefix	Correction
Reg. #	Completed	Reg. #	Completed	Reg. #	Completed
LSC		LSC		LSC	
ID Prefix	Correction	ID Prefix	Correction	ID Prefix	Correction
Reg. #	Completed	Reg. #	Completed	Reg. #	Completed
LSC		LSC		LSC	
REVIEWED BY STATE AGENCY <input type="checkbox"/>	REVIEWED BY (INITIALS)	DATE	SIGNATURE OF SURVEYOR	DATE	
REVIEWED BY CMS RO <input type="checkbox"/>	REVIEWED BY (INITIALS)	DATE	TITLE	DATE	
FOLLOWUP TO SURVEY COMPLETED ON 8/4/2021		<input type="checkbox"/> CHECK FOR ANY UNCORRECTED DEFICIENCIES. WAS A SUMMARY OF UNCORRECTED DEFICIENCIES (CMS-2567) SENT TO THE FACILITY? <div style="float: right;"> <input type="checkbox"/> YES <input type="checkbox"/> NO </div>			

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 08/20/2024
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 31C0001023		(X2) MULTIPLE CONSTRUCTION A. BUILDING 01 B. WING _____		(X3) DATE SURVEY COMPLETED 08/04/2021	
NAME OF PROVIDER OR SUPPLIER BERGEN-PASSAIC EYE SURGERY				STREET ADDRESS, CITY, STATE, ZIP CODE 18-01 POLLITT DRIVE, SUITE 4 FAIR LAWN, NJ 07410			
(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) COMPLETION DATE
E 000	Initial Comments This is a Federal Recertification Survey conducted on 8/4/2021. Bergen-Passaic Eye Surgery is in compliance with Emergency Preparedness regulation 416.54, Condition for Coverage for Ambulatory Surgical Centers (ASCs) for this Federal Recertification Survey only.			E 000			
K 000	INITIAL COMMENTS This is a Federal Recertification Survey conducted on 8/4/2021. Bergen-Passaic Eye Surgery is in compliance with the National Fire Protection Association's 2012 Life Safety Code for this Federal Recertification Survey only.			K 000			

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.