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www.nj.gov/health

JUDITH M. PERSICHILLI, RN, BSN, MA

Commissioner

March 22, 2023

Laura St. John, Administrator Surgery Center of Cherry Hill 408 Route 70 East Cherry Hill, NJ 08034

VIA EMAIL: LSTJohn@willseye.org, jweissman@willseye.org

RE: Curtailment of Services
Facility ID # NJ31C0001070
License #31C0001070

Dear Ms. St. John:

This will confirm our telephone conversation on March 17, 2023, during which the Department of Health (Department) ordered the Surgery Center of Cherry Hill (Facility) to curtail all services involving the use of sterilized instruments. The Curtailment applies to services involving the use of sterilized instruments for all primary care services, ophthalmologic services, orthopedic services, and otolaryngologic services **effective March 17, 2023**. This order shall remain in place until formally lifted by the Department.

This action is being taken in accordance with <u>N.J.A.C.</u> 8:43E-3.6 based on a recommendation from Health Facility, Survey and Field Operations (Survey) staff. During a federal recertification and state re-licensure survey on March 17, 2022, Survey identified deficient practices relating to serious breaches of infection control with the processing of sterile instruments. See <u>N.J.A.C.</u> 8:43A-14.2(b) and 14.4(a) and (g).

The following deficiencies were identified during the survey conducted on March 17, 2023:

1. The Facility failed to ensure that all Instructions for Use (IFU) were readily accessible, reviewed, and followed according to Association for the Advancement of Medical Instrumentation (AAMI) guidelines. Facility staff stated that the Facility did not have all the IFUs for the instruments used in the Facility. Therefore, Survey could not determine if the Facility's instruments are accurately reprocessed in accordance with manufacturer's instructions for use. See N.J.A.C. 8:43A-14.4(a) and 14.4(g)

- 2. The facility reprocessed all instruments using the same temperature of 273-degrees Fahrenheit, exposure time of 5 minutes, and dry time of 30 minutes, instead of following the specific instrument's instructions for use (IFUs). During an observation of reprocessing a "Small Cataract Tray," the facility failed to produce the manufacturer's IFU. Without the manufacturer's IFU, Survey could not determine if the instruments were reprocessed in accordance with AAMI guidelines. See N.J.A.C. 8:43A-14.4(a) and 14.4(g)
- 3. The facility failed to follow the IFU for Mckesson Enzymatic Detergent solution in which the facility was found to use 1 pump of the solution in a quarter of gallon of water. The IFU for the solution states that, for all manual cleaning, one must use ½ to 1 ounce of cleaner per (1) gallon of water. See N.J.A.C. 8:43A-14.4(a)
- 4. The facility failed to develop and implement policies and procedures addressing reprocessing of reusable surgical instruments in accordance with nationally recognized guidelines. See N.J.A.C. 8:43A-14.2(b) and 14.4(a).
- 5. Upon interview on March 16, 2023 at 10:00 AM, the facility Administrator stated that the facility followed AAMI guidelines to reprocess surgical instruments. However, the facility failed to produce the policies as requested and the Director of Nursing and Administrator stated that the facility did not have such policies. See N.J.A.C. 8:43A-14.2(b) and 14.4(a).

Please be advised that only after the Department receives confirmation from Survey that the Facility has corrected the deficiencies will the Department consider lifting the curtailment.

FORMAL HEARING

The Surgery Center of Cherry Hill is entitled to contest the curtailment by requesting a formal hearing at the Office of Administrative Law (OAL). Surgery Center of Cherry Hill may request a hearing to challenge the factual survey findings and the curtailment. Surgery Center of Cherry Hill must advise this Department within 30 days of the date of this letter if it requests an OAL hearing regarding the curtailment.

Please forward your OAL hearing request to:

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

Corporations are not permitted to represent themselves in OAL proceedings. Therefore, if the Surgery Center of Cherry Hill is owned by a corporation, representation by counsel is required. In the event of an OAL hearing regarding the curtailment, the Surgery Center of Cherry Hill is further required to submit a written response to each and

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every charge as specified in this notice, which shall accompany its written request for a hearing.

Due to the immediate and serious risk of harm posed to the patients, please be advised that the Department will not hold the curtailment in abeyance during any appeal of the curtailment.

Failure to submit a written request for a hearing within 30 days from the date of this notice will render this a final agency decision. The final agency order shall thereafter have the same effect as a judgment of the court. The Department also reserves the right to pursue all other remedies available by law.

Additionally, <u>N.J.A.C.</u> 8:43E-3.4(a)(2) provides for a penalty of \$250 per day for each patient serviced in violation of this curtailment order.

Thank you for your attention to this important matter and for your anticipated cooperation. Should you have any questions concerning this order, please contact Lisa King, Office of Program Compliance at (609) 376-7742.

Sincerely,

Lisa King, Regulatory Officer
Office of Program Compliance
Division of Certificate of Need and

Division of Certificate of Need and

Licensing

New Jersey Department of Health

GR:mt Control # AX23005

C: Laura St. John, Administrator
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