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Governor

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JUDITH M. PERSICHILLI, RN, BSN, MA Commissioner

March 17, 2022

Suzanne Bruno, Administrator Horizon Laser and Eye Surgery Center 9701 Ventnor Avenue, Suite 301 Margate, NJ 08402

VIA FACSIMILE (609) 822-3229 & CERTIFIED MAIL: 7007 1490 0003 1530 4860 VIA EMAIL: sbruno@horizoneyecare.com and kspencer@horizoneyecare.com

RETURN RECEIPT REQUESTED

RE: Curtailment of Surgical Procedures and Services

Facility ID # NJ31C0001066 License # R24590

Dear Ms. Bruno:

This will confirm our telephone conversation yesterday during which the Department ordered you to curtail all surgical procedures and services at Horizon Laser and Eye Surgery Center **effective immediately**. This order shall remain in place until formally lifted by the Department.

This action is being taken based on a recommendation from Health Facility, Survey and Field Operations (Survey) staff and in accordance with N.J.A.C. 8:43E-3.6 during an on-site recertification survey on March 15, 2022, in which deficient practices were identified related to serious breaches of infection control with the sterile processing of instrumentation. See N.J.A.C. 8:43A-14.4(g). The deficiencies found include but may not be limited to:

1. The facility failed to ensure that surgical eye instruments were reprocessed in accordance with the manufacturer's instructions for use (IFUs).

Upon interview, the facility reprocessed all instruments using the same temperature of 273-degree Fahrenheit, exposure time of 7 minutes, and dry time of 30 minutes, instead of following the specific instrument's IFUs. During an observation of reprocessing a "Cataract Tray," the following instruments were contained in the "Cataract Tray," and the corresponding manufacturer's IFUs were reviewed. The following was identified:

a. Phaco Hanpiece IFU stated, "Steam Sterilization Cycles: Prevacuum Cycle 270 degrees Fahrenheit; Exposure time of 4 minutes.

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- b. Phaco AMO LAMINAR Flow Phaco Tips, Curved, and Infusion Sleeves IFU stated, ""Steam Sterilization Cycles: Prevacuum Cycle 270 degrees Fahrenheit; Exposure time of 4 minutes.
- 2. The facility failed to ensure that IFUs were readily accessible, reviewed, and followed.

The facility was not able to provide a complete list of items contained in the "Cataract Tray." During an observation of reprocessing a "Cataract Tray," the following IFUs were requested and not received:

- a. Balance Salt Solution bottle
- b. The blue wrap used to sterilize the Cataract Tray
- c. 19 Gauge Cannula
- 3. The facility failed to ensure that the Biological Indicator (BI) to monitor the sterilization processes, was used in accordance with the IFU.

The facility utilized 3M Attest 1262 BI with the sterilization parameters of 273 degrees Fahrenheit, 3 minutes of exposure time. Review of the corresponding IFU stated, "... run at 270 degrees Fahrenheit for 4 or more minutes..."

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

FORMAL HEARING

Horizon Laser and Eye Surgery Center is entitled to a prompt formal hearing at the Office of Administrative Law (OAL) to challenge this assessment of penalties pursuant to N.J.S.A. 26:2H-13. Horizon Laser and Eye Surgery Center may request a hearing to challenge either the factual survey findings or the curtailment, or both. Please note that facility rights to IDR (Informal Dispute Resolution) and administrative law hearings are not mutually exclusive, and both may be invoked simultaneously.

Horizon Laser Eye and Surgery Center must advise this department within 30 days of receipt of this letter to request an OAL hearing regarding this matter.

Please forward your OAL hearing request to:

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

Corporations are not permitted to represent themselves in OAL proceedings. Therefore, if Horizon Laser and Eye Surgery Center of South Jersey is owned by a corporation, representation by counsel is required.

In the event of an OAL hearing regarding this matter, Horizon Laser and Eye Surgery Center is further required to submit a written response to each and every charge as specified in this order, which shall accompany your written request for a hearing.

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In addition, N.J.A.C. 8:43E-3.4(a)(2) provides for a penalty of \$250 per day for each patient admitted in violation of this curtailment order.

Please call Lisa King at (609) 376-7751 if you have any questions regarding this curtailment.

Sincerely,

Jean Markey, Regulatory Officer Office of Program Compliance

Division of Certificate of Need and Licensing

New Jersey Department of Health

JLM:ms Control # AX21010

C: Stefanie Mozgai Maria Christensen Gene Rosenblum Lisa King Kimberly Hansen Lisa Kiernan Denise.Gorski-Galla