



State of New Jersey
DEPARTMENT OF HEALTH

PO BOX 358
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www.nj.gov/health

PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

JUDITH M. PERSICHILLI, RN, BSN, MA
Commissioner

January 20, 2023

Lauren Terrarosa, Administrator
Menlo Park Surgery Center
10 Parsonage Road, Suite 204
Edison, NJ 08837

VIA FACSIMILE (732) 243-9501 & CERTIFIED MAIL:
VIA EMAIL: admin@menloparkasc.com

RETURN RECEIPT REQUESTED

RE: **Curtailment of Surgical Procedures and Services**
Facility ID # 31C0001308
License # NJ24829

Dear Ms. Terrarosa:

This will confirm the telephone conversation on January 19, 2023, between you and Marquis Jones, Regulatory Officer, during which the Department of Health (Department) ordered Menlo Park Surgery Center (facility) to curtail all orthopedic and spinal surgical procedures and services requiring the use of reusable instruments at the ambulatory surgical center **effective immediately**. This order shall remain in place until formally lifted by the Department. The Department's order does not curtail the provision of pain management services requiring only single-use, disposable instruments.

This action is being taken based on a recommendation from the 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 January 18, 2023, 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(a)1, 14.4(g).

The Survey team identified several violations of N.J.A.C. 8:43A-14.4(a)1 during the complaint survey conducted on January 18, 2023. Survey staff inspected a wrapped Acumed Wrist Tray and observed the following:

More than six instruments had stains, residue buildups, and sticky residue;
Segments of the tray holders were observed to be peeling and chipped, which can compromise the sterility of the instruments;
A wrapped cervical tray had residue, debris, and stains on the instruments;
A wrapped cervical retractor tray had red-colored stains on the instruments and whitish residue in the instrument tray. There was also a black colored film on some of the instruments;
and

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A foot tray had brownish colored residue in the crevices of the instrument and residue in the instrument tray.

The Survey team determined that the facility failed to comply with N.J.A.C. 8:43A-14.4(g) because it failed to ensure that all reusable surgical instruments were reprocessed in accordance with the manufacturer's instructions for use (IFUs). The facility also failed to ensure the IFUs were readily accessible, reviewed, and followed according to the Association for Advancement of Medical Instrumentation (AAMI) sterilization guidelines. Further, N.J.A.C. 8:43A-14.4(a) requires ambulatory care facilities to comply with the AAMI sterilization guidelines. At the survey on January 18, 2023, the facility was unable to provide the Survey team with the manufacturer's instructions for the following surgical instruments:

All surgical instruments contained in the "Hand Tray";
The surgical instruments contained in a peel pouch labeled, "Screwdriver and .45 wires; dated 1/10/23";
The surgical instruments contained in an unlabeled peel pouch dated 12/8/22;
The surgical instruments labeled, "2.5 mm Hex; dated 6/22/22";
The surgical instruments contained in an unlabeled peel pouch dated 6/22/22;
The surgical instruments contained in a peel pouch labeled, "Small Screwdriver" dated 10/13/22;
The container used for reprocessing scopes sets using a Sterrad system; and
An Acumed Wrist Tray containing implants.

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

Menlo Park Surgery Center is entitled to a prompt formal hearing at the Office of Administrative Law (OAL) to challenge this curtailment pursuant to N.J.S.A. 26:2H-13. Menlo Park Surgery Center may request a hearing to challenge either the factual survey findings or the curtailment, or both.

Menlo Park 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 Menlo Park Surgery Center is owned by a corporation, representation by counsel is required.

In the event of an OAL hearing regarding this matter, Menlo Park 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.

Menlo Park Surgery Center

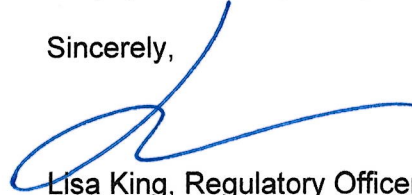
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In addition, N.J.A.C. 8:43E-3.4(a)(2) provides for a penalty of \$250 per day for each patient admitted in violation of this curtailment order.

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

Sincerely,



Lisa King, Regulatory Officer
Office of Program Compliance
Division of Certificate of Need and Licensing
New Jersey Department of Health

WCK:

Control # AX23001

C: Stefanie Mozgai
Lisa King
Kimberly Hansen
Lisa Kiernan