

DEPARTMENT OF HEALTH

TRENTON, N.J. 08625-0358

www.nj.gov/health

JUDITH M. PERSICHILLI, RN, BSN, MA Commissioner

Governor
SHEILA Y. OLIVER
Lt. Governor

PHILIP D. MURPHY

June 20, 2022

Bridget Hogan, Acting Administrator Newark Community Health Center 741 Broadway Newark, NJ 07104

CERTIFIED MAIL:

VIA EMAIL: coo@nchfqhc and cmo@nchfqhc.org

RETURN RECEIPT REQUESTED

RE: Curtailment of Surgical Procedures and Services

Facility ID # NJ311806 License # 70777

Dear Ms. Hogan:

This will confirm our telephone conversation on June 16, 2022, with Doctor Nelson Aluya, Chief Medical Officer, during which the Department of Health (Department) ordered Newark Community Health Center to curtail gynecological and podiatric surgical procedures and services requiring the use of reusable instruments at the federally qualified health center **effective immediately**. This order shall remain in place until formally lifted by the Department. The Department's order does not curtail the performance of services requiring only single-use, disposable instruments.

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 complaint survey on June 16, 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-14.1(b) and (c), 14.4(a), (e) and (g), and 14.5(b)5.

The following deficiencies were identified during the complaint investigation conducted on June 16, 2022:

- a. The facility failed to comply with $\underline{N.J.A.C.}$ 8:43A-14.4(g) because was it unable to provide manufacturer's instructions for the use and sterilization (IFU) of gynecological instruments.
- 1. The facility could not provide IFUs for the Premier, PSS Select, and MedGyn Instruments.

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- 2. The facility could not provide IFUs for the following instruments from an unknown manufacturer: six speculums; one surgical straight nose scissor; and two regular straight forceps.
- b. The facility failed to comply with <u>N.J.A.C.</u> 8:43A-14.4(g) because it was unable to provide the manufacturer's Instructions for the use and sterilization (IFU) of podiatry Instruments. The facility could not provide IFUs for the use of the Vantage Podiatry Clippers.
- c. The facility failed to comply with <u>N.J.A.C.</u> 8:43A-14.1(c) because it does not have a certified infection control professional or a contract with one.
- d. The facility failed to comply with <u>N.J.A.C.</u> 8:43A-14.1(b) because its infection control plan does not provide infection control training.
- e. The facility failed to comply with <u>N.J.A.C.</u> 8:43A-14.5(b)5 because the three individuals it employed for the reprocessing of obstetric/gynecological reusable surgical instruments do not have sterile processing certifications or any documented training.
- d. The facility failed to comply with N.J.A.C. 8:43A-14.4(a)(1) because the survey team found eighteen (18) peel-packaged instruments crammed into a MidMark M11, Ultraclave Steam flush Pressure Pulse table-top sterilizer. The peel-packs were bent, crushed and punctured, compromising the contents within the package. Three speculums had brownish discoloration/markings on multiple surfaces, one speculum peel-pack contained a hole in its packaging, and one tenaculum was found sterilized in the closed position.
- e. The facility failed to comply with <u>N.J.A.C.</u> 8:43A-14.4(e)(2) because its sterilization records do not contain a list of the specific contents of the sterilization/disinfection load.

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

Newark Community Health 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. Newark Community Health 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.

Newark Community 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

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Corporations are not permitted to represent themselves in OAL proceedings. Therefore, if Newark Community Health Center is owned by a corporation, representation by counsel is required.

In the event of an OAL hearing regarding this matter, Newark Community Health 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.

In addition, <u>N.J.A.C.</u> 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,

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

WCK:ms Control # AX22002

C: Stefanie Mozgai
Lisa King
Kimberly Hansen
Lisa Kiernan
Denise Gorski-Galla