State of New Jersey
DEPARTMENT OF HEALTH
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Commissioner

March 13, 2023

Sarah Walker, Director of Site Operations
Zufall Health Center Inc.
117 Seber Rd., Building 5
Hackettstown, NJ 07840
VIA EMAIL: **swalker@zufallhealth.org**

RE: **Curtailment of Services**
Facility ID # NJ 311900
License #24530

Dear Ms. Walker:

This will confirm our telephone conversation on March 10, 2023, during which the Department of Health (Department) ordered Zufall Health Center, Inc. (Facility) to curtail all services involving the use of sterilized instruments, to include pap smears, IUD (intrauterine device) insertions and birth control implant insertions. The Curtailment applies to services involving the use of sterilized instruments for all primary care services, gynecological services, and dental services, **effective March 10, 2023**. 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 in accordance with N.J.A.C. 8:43E-3.6 based on a recommendation from Health Facility, Survey and Field Operations (Survey) staff. During an on-site complaint survey on March 10, 2022, Survey identified deficient practices relating to serious breaches of infection control with the processing of sterile instruments. 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 survey conducted on March 10, 2023:

1. The prep and pack is being conducted immediately next to a dirty sink that is used to wash all soiled instruments, which allows for recontamination of instruments. See N.J.A.C. 8:43 A-14.4(a)

2. Dental instruments are not thoroughly being washed prior to soaking into the ultrasonic. See N.J.A.C. 8:43 A-14.4(a)

3. The Facility was not able to provide a complete list of items contained in any of the peel pouched packages. It is not the Facility's practice to document the specific contents in each load that needs sterilization. The Facility only documents the exposure time, temperature, and dry time. Therefore, the Facility is unable to determine and trace the instruments used on patients. See N.J.A.C. 8:43A-14.4(a); N.J.A.C. 8:43A-14.4(e)2

4. 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. Facility staff also stated that there was no inventory list for all the instruments used in the Facility's dental department. 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(g)

5. The Facility used two tabletop sterilizers. When questioned on the kind of cycles used with the two tabletop sterilizers, the technician stated maybe prevacuum cycles and the corporate Director of Nursing (DON) stated that it was not prevacuum cycles. Upon request, the DON was not able to provide the specific cycles on which the sterilizers are running which determines the safe sterilization parameters of the instruments. See N.J.A.C. 8:43A-14.4(a); N.J.A.C. 8:43A-14.5

6. New instruments in the Facility require high level disinfection. However, the Facility did not develop policies and procedures that address high level disinfection of instruments. See N.J.A.C. 8:43A-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

Zufall Health Center, Inc. is entitled to contest the curtailment by requesting a formal hearing at the Office of Administrative Law (OAL). Zufall Health Center, Inc. may request a hearing to challenge the factual survey findings and the curtailment. Zufall Health Center, Inc. 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 Zufall Health Center, Inc. is owned by a corporation, representation by counsel is required. In the event of an OAL hearing regarding the curtailment, Zufall Health Center, Inc. is further required to submit a written response to each and 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, N.J.A.C. 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.

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Sincerely,

Gene Rosenblum, Director
Office of Program Compliance
Division of Certificate of Need and Licensing
New Jersey Department of Health

GR:mdj:NJ
Control # AX23004

C: Kathleen Felezzola, Corporate DON
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