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TOWN OF DEDHAM

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**Town of Dedham
Board of Health Regulations
Cryogenic Chamber Therapy
Part VIII**

Authority

This Regulation is promulgated pursuant to the authority granted to the Dedham Board of Health by Chapter 111, Section 31 of the Massachusetts General Laws that "Boards of Health may make reasonable health regulations".

Statement of Purpose

The purpose of this Regulation is to protect the customers and employees within the Town of Dedham so they may make informed decisions about using the cryogenic chamber therapy and to allow local enforcement to ensure requirements are being met.

Definitions

Agent- means any duly authorized agent of the Board of Health as specified under MGL c. 111 sec. 30

Board of Health- Town of Dedham Board of Health and its designated agents.

Employee- Any individual who performs services for an employer

Employer- Any individual, partnership, association, corporation, trust or other organized group or individuals that uses the services (1) of one or more employees.

Establishment- Place where cryogenic chamber therapy takes places

Permit – to show establishment is permitted through the Board of Health

Cryotherapy- enveloping the body with hyper-cooled air (using liquid nitrogen) ranging from negative 184 to negative 256 within time frame of 1 to 3 minutes.

Certifications and Training: comprehensive training to show proof of Knowledge

Consent Form- A form that must have establishments name, address, phone number, clients name, address, phone number, date of service, time of service, length of time in sauna, show that a review of the screening process with employee of establishment has been done, both client and employee sign consent form.

A. General Provisions for customers

1. Must be 18 years or older (no minor's even with parental permission)
2. One session per day (for max of 3 minutes)
3. No jewelry
4. Protective Clothing- customers must wear the appropriate protective clothing (no moisture or dampness)
5. Must be in good health

B. Screening

1. Any person considering using a cryogenic chamber should consult their medical provider prior to use. Customers should not use machine if they currently have, or have recently had, any of the previous health conditions:
 - Heart attack or stroke
 - High blood pressure
 - Pregnancy
 - Seizure Disorder
 - Reynaud's Syndrome
 - Cold Allergies
 - Vein Thrombosis or Clotting Issues
 - An infection or fever
 - Pacemaker and other implanted medical devices
 - Certain medications
 - Claustrophobia
 - Or any serious medical condition not already mentionedList of medical conditions must be on the consent form that the customer is signing.
2. Consent form must be supplied to Health Department prior to opening for approval
3. Full description of the cryotherapy process along with a short video of explanation which clearly states there are no proven medical benefits to cryotherapy.
4. Cryotherapy is not an FDA approved medical device

C. Physical Facility:

1. Defibrillator- on premises of establishment and staff trained on how to use.
2. Emergency Phone with Emergency phone numbers listed directly beside it and phone clearly marked as Emergency Phone Only.
3. Warning signs which must list health conditions in Screening part A; Cryotherapy is not an approved FDA medical device nor is there any proven health benefits to cryotherapy and be posted in screening area along with cryotherapy room.
4. Permits must be visible at all times to patrons
5. Oxygen Deficiency Monitors as needed to properly monitor in each area separated by walls and on each sauna
6. Oxygen Deficiency Monitors shall be tested periodically as manufacturer calls for but no less than four times in a twelve month period
7. Automatic shut-off when oxygen levels fall below 20%
8. OSHA Requirements: The facility must meet all OSHA requirements along with proper signage (All Warning Signs Posted Red with White lettering 2" letters)
9. Standing Operating Procedures for facility must be kept up to date and available for review at all times (cleaning of machines, maintenance records, service calls etc.)

D. Employee Training:

1. All employees and owners must have proof of Basic Life Support CPR and defibrillator class based training and must be kept valid at all times
2. All employees and owners must be trained by manufacturers guidelines and show proof of such
3. Establishment Owner must have periodic training reviews with all staff at a minimum of two times within a twelve month period and documented

E. Enforcement and Inspection

1. The Board of Health shall enforce the provisions of this regulation. Any agent of the Board of Health may, according to law, enter upon any premises at any reasonable time to inspect for compliance.
2. Upon request by an agent of the Board of Health, an owner or operator shall furnish all information required to enforce and monitor compliance with this Regulation, including but not limited to, a complete inventory of all product that are purchased by the establishment along with receipts.
3. The Board of Health may, after providing opportunity for a hearing, order the revocation of a Permit to Operate a Cryogenic Chamber Therapy type facility of one or more particular operations for:

- a. Serious or repeated violations of this regulation
 - b. Interference with the Board of Health in the performance of its duty.
 - c. For keeping or submitting any misleading or false records or documents required by the regulation.
4. Standard Operating Procedure Log must be maintained and up to date
5. Employee records must have copies of all trainings and certifications

F. Application and Fees:

1. Application, plans, equipment spec sheets must be submitted for review prior to approval
2. Once approved maintenance agreements must be submitted with application and updated annually with permit to operate
3. Application must be filled out annually for renewal
4. Fees are as follows;
 - a. Review of new or upgraded facility \$100.00
 - b. Application for establishment \$350.00 annually
 - c. Per sauna per person \$ 50.00 additional

G. Effective Date:

This regulation shall take effect on _____,2016.
Town of Dedham Board of Health

Sara Rosenberg-Scott MD, MPH, Chairperson

Leanne Jasset B.S.P., RPh, Vice-Chairperson

Jason Brogan, MSM, Member