Jeffrey A Lutz, CMTPT
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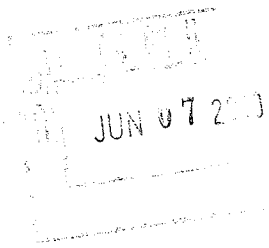
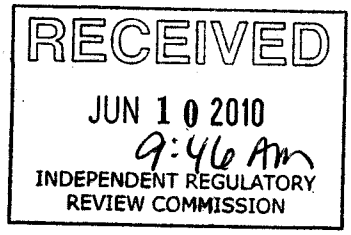
Greensburg, PA 15601
ph. 724-853-2353 fax 724-853-2354
jeff@musclepainhelp.com

2843




Judy Harner, Board Administrator
State Board of Massage Therapy
P.O. Box 2649
Harrisburg, PA 17105-2649




RE: The use of "Rx Only" medical devices by LMT's in PA

Proposed Language in Question

In 20.41(b), the Board would provide a list of some of the things that are § outside the scope of practice of massage therapists, including the diagnosis or treatment of impairment, illness, disease or disability, medical procedures, chiropractic manipulation—adjustment, physical therapy mobilization—manual therapy, therapeutic exercise, the prescription of medicines for which a license to practice medicine, chiropractic, physical therapy, occupational therapy, podiatry or other practice of the healing arts is required, the application of high velocity/low amplitude force further defined as thrust techniques directed toward joint surfaces and the use of equipment or devices that require a prescription, for example, ultrasound, diathermy, electrical neuromuscular stimulation.

**Purpose:** To amend the medical device restriction, as per the proposed rules of the PA State Massage Therapy Board, to be open ended so that medical devices which are utilized within the scope of practice of a LMT practicing in the Commonwealth are accessible by LMT's, without restriction. Please note: this is not to infringe upon the restriction of any device which is called out in the law (therapeutic ultrasound and electro neuromuscular stimulation).

**Specific Device**
Device: Gebauer's Spray and Stretch topical anesthetic skin refrigerant.
Unclassified: Rx Only

Please Note: The mention of this specific company and device is in no way meant to imply product recognition or endorsement from the board. I am mentioning the specifics because there is currently no other domestic product with these indications and the board will most likely need something to reference. Should the board move to allow these types of medical devices, it will in no way be construed as a specific exception to this company or product.

**Indications:**
- Trigger Point Therapy
- Myofascial Pain Syndromes
- Muscle spasms
- Restricted motion
- Minor sports injuries

**Important Risk and Safety Information for Gebauer's Spray and Stretch:**
- Do not spray in eyes
- Over spraying may cause frostbite
- Freezing may alter skin pigmentation
- Do not use this product on persons with poor circulation or insensitive skin
- Do not use on open wounds or abraded skin
- If skin irritation develops, discontinue use
- Rx Only



Summary of the Prescription Medical Device Regulations (A copy of 21 CFR 801.109 is located in Appendix Section 1 of this request for reference):

The FDA designates devices as prescription medical devices solely based on whether they believe if adequate directions for use can be developed for a given device. If in their perspective, adequate directions for use cannot be prepared, the device has to be labeled with the "Rx only" statement or with the statement "Caution: Federal law restricts..." which is meant to convey the same essentially restrictive meaning regarding the professional authorization required to use the product.

21 CFR 801.109 contains the regulations concerning prescription devices. These regulations clearly define exactly who can purchase prescription devices. Prescription devices can be sold to:
1. businesses engaged in the wholesale or retail distribution of the device, and;
2. a healthcare practitioner* such as physicians, dentists etc. licensed by law to use or order the use of the device, and;
3. a person who has received a prescription or other order from a healthcare practitioner (21 CFR 801.109.a2). Please note that "other order" is specifically called out in the regulations.

*A healthcare practitioner is clearly defined in the prescription device regulations (21 CFR 801.109.b1) as "any other practitioner licensed by the law of the State in which he practices to use or order the use of the device."

A Note from the Gebauer Company's Director of Regulatory Affairs

Impact of Regulations on Gebauer's Business Practices:

Our prescription products can be sold without restriction to wholesalers and retailers. Our devices can also be sold to any healthcare practitioner who is licensed by the state such as chiropractors, physical therapists, nurses, massotherapists etc. Healthcare practitioners do not need a prescription or "other order" to obtain the products from either ourselves or one of our distributors. Any healthcare professional should be able to purchase our prescription products without restriction. Our prescription products can also be sold to anyone who has received a prescription or "other order" from any licensed healthcare practitioner (physical therapist, chiropractor etc.). An "other order" is defined as an instruction from a healthcare practitioner to use a prescription device.

The key question is whether the LMT is licensed as a healthcare practitioner in the state in which they practice. Some LMT's have to be licensed in states but the licensing is strictly under a department of health who are worried about things like hygiene, cleanliness etc and they would not be considered healthcare providers. BOP licensure or Medical Board licensing indicates that they are viewed in that particular state as a healthcare provider.

**Within the Scope of Practice**

LMT's in PA, based on the proposed rules, would bear not only the ability to treat soft tissue manifestations, but will be given the proper education to do use this type of particular device as mentioned above.

20.13(b), the Board would set forth the practical skills that must be In § taught to massage therapy students, including the skills to: administer fundamental therapeutic massage techniques for the treatment of soft tissue manifestations of the human body, safely utilize topical preparations, thermal and cryogenic modalities, hydrotherapy and movements that lengthen and shorten soft tissues within the client's normal range of motion, maintain safe and effective body mechanics in the application of therapeutic massage techniques, locate and palpate muscle attachments, muscle bellies and other anatomical landmarks necessary for the practice of massage therapy, and use draping/coverage practices that address both function and safety.

[This is an indication that the spray and stretch technique has a place in the scope of practice for LMT's in PA. Please note the above highlighted areas regarding 'cryogenic modalities' and 'movements that lengthen and shorten soft tissues within the client's normal range of motion'. Based on this information a reasonable person could surmise that a skin refrigerant would be within the scope of practice for LMT's in PA, especially when used in conjunction with the spray and stretch technique.]

**Recent State Ruling in Hawaii**

At their January 28, 2010 meeting the Board of Massage Therapy ("Board") reviewed and discussed your email below and based on the information in your email, by the definition you cited in our email under 21 CFR 801.109, specifically, who can purchase prescription devices..."a healthcare practitioner such as physicians, dentists, etc. licensed by law to use or order the use of the device,..." and your "key" question, "Is whether the LMT is licensed as a healthcare practitioner in the state in which they practice.". The definition of "massage therapy" as stated in Hawaii Revised Statutes, section 452-1, states, "Massage", "massage therapy", and "Hawaiian massage" commonly known as lomilomi, means any method of treatment of the superficial soft parts of the body, consisting of rubbing, stroking, tapotement, pressing, shaking, or kneading with the hands, feet, elbow, or arms, and whether or not aided by any mechanical or electrical apparatus, appliances, or supplementary aids such as rubbing alcohol, liniments, antiseptics, oils, powder, creams, lotions, ointments, or other similar preparations commonly use in this practice. Any mechanical or electrical apparatus used as described in this chapter shall be approved by the United States Food and Drug Administration."

Consequently, based on this definition, it would appear that Hawaii licensed massage therapist are licensed by law to use such a device.

[Full transcript of communications with the State Board of Massage Therapy in Hawaii is in Appendix Section 2]

**Closing**

It is in my hopes that the board can see clear to allow, or not entirely restrict, the use of all prescription medical devices from use of LMT's in PA. The scope of practice, as put into law in PA, is a true step forward in our professional lives in the Commonwealth -- and the ability to practice to that full scope will be the aim of all future LMT's.

Thank you for affording me the opportunity to voice this concern.

Respectfully submitted,

Jeffrey A Lutz, CMTPT

# Appendix

**SECTION 1**



[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2009]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR801.109]



TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 801_LABELING--Table of Contents

Subpart D_Exemptions From Adequate Directions for Use

Sec. 801.109 Prescription devices.

A device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which ``adequate directions for use'' cannot be prepared, shall be exempt from section 502(f)(1) of the act if all the following conditions are met:

(a) The device is:

(1)(i) In the possession of a person, or his agents or employees, regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of such device; or

(ii) In the possession of a practitioner, such as physicians, dentists, and veterinarians, licensed by law to use or order the use of such device; and

(2) Is to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice.

(b) The label of the device, other than surgical instruments, bears:

(1) The statement ``Caution: Federal law restricts this device to sale by or on the order of a --------'', the blank to be filled with the word ``physician'', ``dentist'', ``veterinarian'', or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device; and

(2) The method of its application or use.

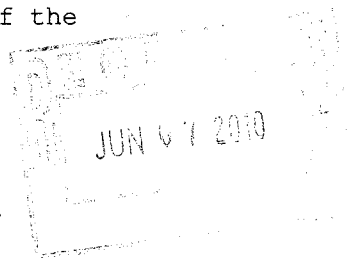
(c) Labeling on or within the package from which the device is to be dispensed bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented: Provided, however, That such information may be omitted from the dispensing package if, but only if, the article is a device for which directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device. Upon written request, stating reasonable grounds therefor, the Commissioner will offer an opinion on a proposal to omit such information from the dispensing

package under this proviso.

[[Page 23]]

(d) Any labeling, as defined in section 201(m) of the act, whether or not it is on or within a package from which the device is to be dispensed, distributed by or on behalf of the manufacturer, packer, or distributor of the device, that furnishes or purports to furnish information for use of the device contains adequate information for such use, including indications, effects, routes, methods, and frequency and duration of administration and any relevant hazards, contraindications, side effects, and precautions, under which practitioners licensed by law to employ the device can use the device safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented. This information will not be required on so-called reminder--piece labeling which calls attention to the name of the device but does not include indications or other use information.

(e) All labeling, except labels and cartons, bearing information for use of the device also bears the date of the issuance or the date of the latest revision of such labeling.




**SECTION 2**

**Communication with Hawaii State Board of Massage Therapy**

**From:** LeeAnn.N.Teshima@dcca.hawaii.gov
[mailto:LeeAnn.N.Teshima@dcca.hawaii.gov] **On Behalf Of** massage@dcca.hawaii.gov
**Sent:** Tuesday, February 02, 2010 7:21 PM
**To:** Jeffrey A Lutz, CMTPT
**Subject:** RE: Hawaii Massage Therapists and Prescription (Rx only) Medical Devices

Dear Jeffrey,

At their January 28, 2010 meeting the Board of Massage Therapy ("Board") reviewed and discussed your email below and based on the information in your email, by the definition you cited in our email under 21 CFR 801.109, specifically, who can purchase prescription devices..."a healthcare practitioner such as physicians, dentists, etc. licensed by law to use or order the use of the device,..." and your "key" question, "Is whether the LMT is licensed as a healthcare practitioner in the state in which they practice.". The definition of "massage therapy" as stated in Hawaii Revised Statutes, section 452-1, states, "Massage", "massage therapy", and "Hawaiian massage" commonly known as lomilomi, means any method of treatment of the superficial soft parts of the body, consisting of rubbing, stroking, tapotement, pressing, shaking, or kneading with the hands, feet, elbow, or arms, and whether or not aided by any mechanical or electrical apparatus, appliances, or supplementary aids such as rubbing alcohol, liniments, antiseptics, oils, powder, creams, lotions, ointments, or other similar preparations commonly use in this practice. Any mechanical or electrical

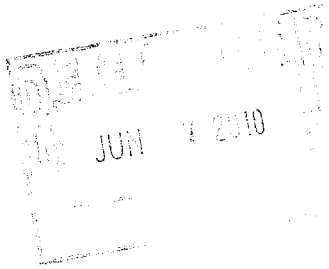
apparatus used as described in this chapter shall be approved by the United States Food and Drug Adminstration."

Consequently, based on this definition, it would appear that Hawaii licensed massage therapist are licensed by law to use use such a device.

In addition to the massage therapist issue, I also have issues as the Executive Officer for the Board of Pharmacy. If you wish to distribute this medical device into this State to the massage therapist or other healthcare practitioner, but have no facilities in this State, no license would be required.

If you wish to dispense this medical device to the end user/patient pursuant to a valid prescription, then the Board of Pharmacy would require you to have a miscellaneous permit as an out-of-state pharmacy and you would be required to comply with those requirements.

If you have any further questions, please let me know.




Lee Ann Teshima, Executive Officer
Board of Massage Therapy
P.O. Box 3469
Honolulu, Hawaii 96801
Telephone: (808) 586-2694
Fax No.: (808) 586-2874
Web page: www.hawaii.gov/dcca/areas/pvl/boards/massage/
Email: massage@dcca.hawaii.gov

"Jeffrey A Lutz, CMTPT" <jeff@learnsprayandstretch.org>

**"Jeffrey A Lutz, CMTPT" <jeff@learnsprayandstretch.org>**

10/29/2009 07:59 AM

To <massage@dcca.hawaii.gov>

cc

Subject RE: Hawaii Massage Therapists and Prescription (Rx only) Medical Devices

Hi Lee Ann,

Thank you so much for your response and I look forward to your reply. Here is some regulatory information you may find helpful from the manufacturer.

Summary of the Prescription Medical Device Regulations:
The FDA designates devices as prescription medical devices solely based on whether they believe if adequate directions for use can be developed for a given device. If in their perspective, adequate directions for use can not be prepared, the device has to be labeled with the "Rx only" statement or with the statement "Caution: Federal law restricts…" which is meant to convey the same essentially restrictive meaning regarding the professional authorization

required to use the product.
21 CFR 801.109 contains the regulations concerning prescription devices. These regulations clearly define exactly who can purchase prescription devices. Prescription devices can be sold to:

1. businesses engaged in the wholesale or retail distribution of the device, and;
2. a healthcare practitioner* such as physicians, dentists etc. licensed by law to use or order the use of the device, and;
3. a person who has received a prescription or other order from a healthcare practitioner (21 CFR 801.109.a2). Please note that "other order" is specifically called out in the regulations.

*A healthcare practitioner is clearly defined in the prescription device regulations (21 CFR 801.109.b1) as "any other practitioner licensed by the law of the State in which he practices to use or order the use of the device."

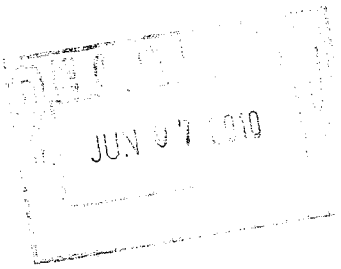
Impact of Regulations on Gebauer's Business Practices:

Our prescription products can be sold without restriction to wholesalers and retailers. Our devices can also be sold to any healthcare practitioner who is licensed by the state such as chiropractors, physical therapists, nurses, massotherapists etc. Healthcare practitioners do not need a prescription or "other order" to obtain the products from either ourselves or one of our distributors. Any healthcare professional should be able to purchase our prescription products without restriction. Our prescription products can also be sold to anyone who has received a prescription or "other order" from any licensed healthcare practitioner (physical therapist, chiropractor etc.). An "other order" is defined as an instruction from a healthcare practitioner to use a prescription device.

The key question is whether the LMT is licensed as a healthcare practitioner in the state in which they practice. Some LMT's have to be licensed in states but the licensing is strictly under a department of health who are worried about things like hygiene, cleanliness etc and they would not be considered healthcare providers. BOP licensure or Medical Board licensing indicates that they are viewed in that particular state as a healthcare provider.

Best regards,

Jeffrey A. Lutz, CMTPT
Editorial Advisor, LearnSprayAndStretch.org
www.LearnSprayAndStretch.org
(Cell) 412-760-4693




-----Original Message-----
From: LeeAnn.N.Teshima@dcca.hawaii.gov
[mailto:LeeAnn.N.Teshima@dcca.hawaii.gov] On Behalf Of massage@dcca.hawaii.gov
Sent: Wednesday, October 28, 2009 2:59 PM
To: Jeffrey A Lutz, CMTPT
Subject: Re: Hawaii Massage Therapists and Prescription (Rx only) Medical Devices

Dear Jeffrey,

I will have the Board of Massage Therapy review your email at their next scheduled meeting on December 23rd (if it is not cancelled).

Lee Ann Teshima, Executive Officer
Board of Massage Therapy
P.O. Box 3469

Honolulu, Hawaii 96801
Telephone: (808) 586-2694
Fax No.: (808) 586-2874
Web page: www.hawaii.gov/dcca/areas/pvl/boards/massage/
Email: massage@dcca.hawaii.gov

"Jeffrey A Lutz, CMTPT" <jeff@learnspraya ndstretch.org>

To <massage@dcca.hawaii.gov>

cc

10/28/2009 05:58 AM

Subject Hawaii Massage Therapists and Prescription (Rx only) Medical Devices

To Whom It May Concern of The Hawaii State Massage Therapy Board:

We are working to make aware, once again, the use of a vapocoolant in the treatment of myofascial pain and trigger points called, The Spray and Stretch Technique. This technique was first introduced by Drs. Travell and Simons in their two volume text, Myofascial Pain and Dysfunction: The Trigger Point Manuals. Because the vapocoolant which we have chosen to recommend is a prescription (Rx only) medical device, any therapist using this product would have to be licensed for its acquisition and use.

In writing to you, we are hoping to determine if the use of Gebauers Spray and Stretch as a cold modality, fits into the practice act of Massage Therapy in the state of Hawaii. Please review this material and kindly respond to jeff@learnsprayandstretch.org with your reply.

If you have any other questions about the product or technique, please do not hesitate to contact me.

Sincerely,

Jeff -

Jeffrey A. Lutz, CMTPT