

ACUPUNCTURE BOARD

1747 North Market Boulevard, Suite 180, Sacramento, CA 95834 (916) 515-5200 FAX (916) 928-2204 www.acupuncture.ca.gov



NOTICE OF ACUPUNCTURE BOARD RESEARCH COMMITTEE MEETING

WEDNESDAY, DECEMBER 14, 2016 9:00 AM until completion of business

LOCATION: ELIHU M. HARRIS STATE OFFICE BUILDING **1515 CLAY STREET MEETING ROOM #2** OAKLAND, CA 94612

AGENDA

RESEARCH COMMITTEE MEETING

Call to Order and Establishment of a Quorum

Research Committee Members

Dr. Michael Corradino L.Ac., Ph.D., Chair, Licensed Member Kitman Chan, Public Member Jeannie Kang, Licensed Member Jamie Zamora, Public Member

- 2. Regulation of the Sale of Acupuncture Needles – Discussion (Corradino)
- Regulation of the Practice of "Dry Needling" or Unlicensed Individuals Applying a Needle 3. to the Human Body - Discussion (Corradino)
- **Future Research Committee Agenda Items**
- **Public Comment for Items Not on the Agenda** 5.

The Committee may not discuss or take any action on any item raised during this public comment section, except to decide whether to place the matter on the agenda of a future meeting (Government Code Sections 11125, 11125.7(a))

Adjournment

Public Comment on items of discussion will be taken during each item. Time limitations will be determined by the Chairperson. Times are approximate and subject to change. Action may be taken on any item listed on the Agenda.

THE FULL BOARD AGENDA, AS WELL AS COMMITTEE MEETING MINUTES, CAN BE FOUND ON THE ACUPUNCTURE BOARD'S WEBSITE AT

www.acupuncture.ca.gov

Please Note: Committee meetings are open to the public and are held in barrier free facilities that are accessible to those with physical disabilities in accordance with the Americans with Disabilities Act (ADA). If you need additional reasonable accommodations, please make your request no later than five (5) business days before this meeting. Please direct any questions regarding this meeting to the Board Liaison, Tammy Graver at (916) 515-5204; FAX (916) 928-2204

#2 – Regulation of the Sale of Acupuncture Needles



CALIFORNIA ACUPUNCTURE BOARD





DATE	December 14, 2016
то	Board Members
FROM	Marc Johnson, Policy Coordinator
SUBJECT	History of Acupuncture Needle Sales in California

The purpose of this memo is to provide a brief history and background on the sale of Acupuncture Needles in California. The sale and distribution of Acupuncture Needles is solely regulated by the California Board of Pharmacy (BOP).

Overview of the California Board of Pharmacy

The California Board of Pharmacy was formed in 1891 to function as a state health regulatory agency. In 1971, the BOP became part of the Department of Consumer Affairs. The Board regulates the pharmacy practice of pharmacists, interns, pharmacy technicians, and exemptees (those who are involved with the wholesale or manufacturer of drugs and medical devices, but not required to hold a pharmacist license). The Board also regulates all types of firms that distribute prescription drugs and devices in California, including community pharmacies and those located in hospitals, clinics, home and community support services facilities, and out-of-state mail order pharmacies that fill prescriptions and deliver them in California. BOP was originally given the authority in 1972 under California Business and Professions Code (BPC) Section 4141.

Acupuncture Needle Sales in California

In California, acupuncture needles are classified under federal and state law as "dangerous devices" under CA BPC Section 4022. As such, they are deemed unsafe for use except under the supervision of a practitioner licensed by law to direct the use of such device, and federal law restricts them to sale by or on the order of a licensed acupuncturist.

Since they are labeled as such, entities involved in the distribution and sale of the needles are required licensure pursuant to CA BPC Section 4160 (wholesaler) and CA BPC Section 4161 (out-of-state distributer). Therefore, any person or entity wishing to sell acupuncture needles must obtain a wholesaler license from the California Board of Pharmacy (Federal Code 21 C.F.R. §§ 880.5580, 801.109; CA BPC §§ 4022, subd. (b), 4023.) Further, any person or entity who sells for resale, or negotiates for distribution, or takes possession of, any dangerous drug or device, or otherwise acts as a wholesale

BUSINESS, CONSUMER SERVICES, AND HOUSING AGENCY . GOVERNOR EDMUND G, BROWN JR



CALIFORNIA ACUPUNCTURE BOARD

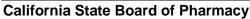
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merchant, broker, jobber, customs broker, reverse distributor, or agent for California patients must be licensed by the Board as a wholesaler (resident or non-resident) before doing so. This includes any persons or entities doing any of these activities with regard to acupuncture needles. (California BPC §§ 4043, 4160, 4161.)

Acupuncture Needle Sales by Schools

In California, Acupuncture Schools can provide needles to enrolled students as part of their approved training program. However, without a Pharmacy Board wholesaler licensee, Acupuncture Schools cannot sell acupuncture needles; to licensees or students. Notwithstanding the federal limitations on use of acupuncture needles by licensed practitioners, acupuncture students who are engaged in an approved acupuncture training program or tutorial program in acupuncture, or who are graduates of an approved educational and training program and participating in a post-graduate review course that does not exceed one (1) year in duration at the approved educational and training program, are not prohibited from administering acupuncture treatment as part of their training provided the practice of acupuncture is supervised by a licensed acupuncturist. Acupuncture students, under supervised practice, may also purchase acupuncture needles provided that they show proof of enrollment in an approved Acupuncture Training Program to the licensed wholesaler or FDA registered manufacturer. (CA BPC, §§ 4935, subd. (d), 4937, subd. (a); Cal. Code Regs., tit. 16, § 1399.436, subd. (b).)



1625 N. Market Blvd, N219, Sacramento, CA 95834 Phone: (916) 574-7900 Fax: (916) 574-8618 www.pharmacy.ca.gov

June 16, 2016

Colleges of Acupuncture and Oriental Medicine

To whom it may concern,

The Board received a complaint alleging that Colleges of Acupuncture and Oriental Medicine are selling acupuncture needles to students at school bookstores. The Board reminds Acupuncture and Oriental Medicine Training Programs of following requirements:

- Acupuncture needles are classified under federal and state law as dangerous devices. (21 C.F.R. §§ 880.5580, 801.109; Bus. & Prof. Code, §§ 4022, subd. (b), 4023.) As such, they are deemed unsafe for use except under the supervision of a practitioner licensed by law to direct the use of such device, and federal law restricts them to sale by or on the order of a licensed acupuncturist. (21 C.F.R. § 801.109.)
- Any person or entity who sells for resale, or negotiates for distribution, or takes possession of, any dangerous drug or device, or otherwise acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, or agent for California patients must be licensed by the Board as a wholesaler (resident or non-resident) before doing so. This would include any persons or entities doing any of these activities with regard to acupuncture needles. (Bus. & Prof. Code, §§ 4043, 4160, 4161.)
- Acupuncture Training Programs interested in applying for a wholesaler license may
 obtain an application from the following link to the California State Board of Pharmacy
 website http://www.pharmacy.ca.gov/forms/wls_main.shtml. For questions regarding
 the status of a pending application or licensing requirements, email your questions to
 wlsstatus@dca.ca.gov.
- For verification of whether a company is a licensed wholesaler in California, visit the California State Board of Pharmacy's website at www.pharmacy.ca.gov, License Verification System. (Bus. & Prof. Code, § 4106.)
- Manufacturers registered with the Federal Food and Drug Administration or the California Department of Public Health, Food and Drug Branch, who only sell dangerous devices for which they are the registered manufacturer are exempt from obtaining a wholesaler license from the Board. (Bus. & Prof. Code, § 4160, subd. (h).)

• Notwithstanding the federal limitations on use of acupuncture needles by licensed practitioners, acupuncture students who are engaged in a course or tutorial program in acupuncture, or who are graduates of an approved educational and training program and participating in a post-graduate review course that does not exceed one (1) year in duration at the approved educational and training program, are not prohibited from administering acupuncture treatment as part of their training provided the practice of acupuncture is supervised by a licensed acupuncturist. Acupuncture students, under supervised practice, may also purchase acupuncture needles provided that they show proof of enrollment in an approved Acupuncture Training Program to the licensed wholesaler or FDA registered manufacturer. (Bus. & Prof. Code, §§ 4935, subd. (d), 4937, subd. (a); Cal. Code Regs., tit. 16, § 1399.436, subd. (b).)

Accordingly, all persons or entities engaged in distribution of acupuncture needles, including Acupuncture Training Program bookstores or other sellers, must be licensed by the Board as a wholesaler to participate in distribution of these dangerous devices.

Thank you for your cooperation. If you have any questions, please contact Inspector Sarah Bayley at <u>sarah.bayley@dca.ca.gov</u> or call her at (626) 355-6984.

Sincerely,

Virginia Herold Executive Officer

By

Sarah Bayley

Sarah Bayley, Pharm. D. Inspector

#3 – Regulation of the Practice of "Dry Needling" or Unlicensed Individuals Applying a Needle to the Human Body