



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**

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*

AGENDA

RESEARCH COMMITTEE MEETING

- 1. Call to Order and Establishment of a Quorum**
- 2. Regulation of the Sale of Acupuncture Needles – Discussion (Corradino)**
- 3. Regulation of the Practice of “Dry Needling” or Unlicensed Individuals Applying a Needle to the Human Body – Discussion (Corradino)**
- 4. Future Research Committee Agenda Items**
- 5. Public Comment for Items Not on the Agenda**
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))
- 6. 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

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



DATE	December 14, 2016
TO	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 distributor). 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

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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).)



California State Board of Pharmacy

1625 N. Market Blvd, N219, Sacramento, CA 95834

Phone: (916) 574-7900

Fax: (916) 574-8618

www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

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 sarah.bayley@dca.ca.gov 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**