



**June 16, 2016**

Colleges of Acupuncture and Oriental Medicine

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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](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](mailto: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](http://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](mailto: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