CALIFORNIA ACUPUNCTURE BOARD
FINAL STATEMENT OF REASONS
IMPLEMENTATION OF SB 1246

HEARING DATE: June 6, 2016

SUBJECT MATTER OF PROPOSED REGULATIONS:; Criteria for Approval of Acupuncture and Oriental Medicine Curriculum; Criteria for Approval of Acupuncture Training Program; Requirements for Board Approval of Curriculum.

SECTIONS AFFECTED: Amend Section 1399.434, repeal Section 1399.436, and amend Section 1399.437 of Division 13.7 of Title 16 of the California Code of Regulations (CCR).

UPDATED INFORMATION
The Initial Statement of Reasons submitted as part of the rulemaking package is included in the file. The information contained therein is updated as follows:

1. The California Acupuncture Board (hereafter 'Board') currently regulates a total of 16,126 licensees, all of whom have been issued a license to practice Acupuncture in California.

2. On page 2, under discussion of Business and Professions Code (BPC) Section 4927.1, the full section is added for reference:

   "(3) Meets any of the following:
   (A) Is accredited by the Accreditation Commission for Acupuncture and Oriental Medicine.
   (B) Has been granted candidacy status by the Accreditation Commission for Acupuncture and Oriental Medicine.
   (C) Has submitted a letter of intent to pursue accreditation to the Accreditation Commission for Acupuncture and Oriental Medicine within 30 days of receiving full institutional approval pursuant to paragraph (2), and is granted candidacy status within three years of the date that letter was submitted."

3. Document incorporated by reference – change of revision date. This change was approved by the Board at the August 31, 2016 public meeting. This form was available to the public as part of the initial notice and the text has not changed:
   - "Application for Board Approval of Curriculum" ~~(rev 1/1/17)~~ (rev 04/15)

4. New document incorporated by reference in CCR Section 1399.434b(2)(K): "Clean Needle Technique manual, 7th edition" (rev. January 2016), published by the Council of Colleges of Acupuncture and Oriental Medicine. This document is available to the public at their website: http://www.ccaom.org/cntmanual.asp

5. During the course of this rulemaking, the Board made several revisions to the proposed text in response to the comments received during the initial 45-day comment period, which was held from April 22, 2016 through June 6, 2016. The changes approved by the Board at the August 31, 2016 public Board meeting are as follows:

    - 1399.434 – revised the meaning of 'curriculum' to include 'coursework that contains the following criteria' which provides a clearer definition to the reader. Added an authority and reference section at the end of the section.
    - 1399.434b (2)(K) – updated the reference to the 'Clean Needle Technique' to the most current January 2016 version, as the previous version is no longer current. Removed the words 'as its primary reference', which makes the regulation more specific.
    - 1399.434h (4) – added additional language and total number of hours needed to better define direct 'line-of-site' observation and clinical supervision of the student.
    - 1399.437a – changed the revision date of proposed "Application for Board Approval of Curriculum (rev 04/15)".
    - 1399.437a (5) – added the words 'all information and documentation submitted under this section shall be in English', in order to clarify the application must be in English.
    - 1399.437b – better definition of what a complete application is, and listing what information and documentation is required for a complete application. This provides better clarity to a training program as to how applications are defined as complete by spelling out exactly what must be included.

    - 1399.437c – changed how the Board would notify a training program that an application may be incomplete and the reasons why. Also, the Board will now include instructions for how to address the incomplete application. This will provide better guidance for approved training programs how to rectify an incomplete application and help to streamline the approval process.

    - 1399.437e – defined further to include coursework as listed in 1399.434. This provides clarity to the training program as to what constitutes a new curriculum by referring it to the relevant regulatory section and how it requires Board approval.

Additionally, an authority and reference section was added for each proposed section as part of the modified text.

6. A 15-day public comment period was held from September 1, 2016 through September 15, 2016. As a result of public comment, the Board approved changes to the proposed text at the September 21, 2016 public meeting, which reverts to the original text as initially approved by the Board on November 17, 2015:

- 1399.434(h) – removed language defining line-of-sight observation and total number of hours a supervisor must observe the student during clinical instruction.

7. The Notice of Public Hearing, under the authority and reference sections, incorrectly listed the Board making changes to Division 13.5 of Title 16 of the California Code of Regulations. The correct Division is 13.7.

8. The Initial Statement of Reasons, under the 'underlying data' section on page 7, incorrectly listed the date for approved minutes and meeting materials for the November 13, 2015 Acupuncture Board meeting. The corrected date of the meeting is November 17, 2015.

9. On page 7 of the ISOR, it is noted that any applications which are submitted incomplete are considered abandoned by the Board. If applications are not submitted complete, no deadline extension is available as the proposed text does not allow for such an extension.

10. On page 8 of the ISOR, the proposed "Application for Board Approval of Curriculum (rev 1/1/17)" form is listed as underlying data. This listing is incorrect. The proposed form is incorporated by reference into the proposed text for CCR Section 1399.437 and therefore does not need to listed as underlying data.
11.

LOCAL MANDATE

A mandate is not imposed on local agencies or school districts.

SMALL BUSINESS IMPACT

The proposed California Code of Regulations (CCR) Section 1399.433, which sets the requirements for foreign applicants to apply to take the California Acupuncture Licensing Exam (CALE), would only affect individuals or companies based outside of the United States. Therefore, the economic impact to those individuals or companies is not applicable for the purposes of this analysis.

Acupuncture Schools in the State of California will incur minor administrative costs when applying for curriculum approval or re-approval of curriculum due to a change. These administrative costs may include filling and completing the proposed form "Application for Board Approval of Curriculum" (rev 04/15), providing copies of syllabus and course catalogs, and additional administrative costs such as postage and shipping. However, these schools, under current regulations, already are required to inform the Board about any curriculum changes, and therefore the proposed CCR Section 1399.437 would not impose any additional costs on them.

The proposed CCR Sections 1399.434 and 1399.436 would have no small business impact.

BENEFITS

This regulatory proposal benefits the health and welfare of California residents by ensuring that licensed acupuncturists continue to meet the same educational training and clinical experience standards the Board has been consistently applying to those beginning education and training since 2005. This will also benefit the public protection by ensuring that from January 1, 2017, forward those educated outside of the United States are held to the same requirements as those educated within the United States. Hence, all licensed acupuncturists will meet an appropriate minimum standard.

CONSIDERATION OF ALTERNATIVES

No other reasonable alternative to the regulatory proposal exists which would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome to affected private persons. Additionally, no other reasonable alternative to the regulatory proposal exists which would be more cost-effective to affected private persons and as effective in implementing the statute required.

Another possible alternative would be to delay or not promulgate these regulations. This alternative was rejected. The statute provides that the Board is required to comply with the requirements of BPC section 4927.5 and 4939 by January 1, 2017. A delay is unreasonable due to the express statutory requirement of compliance by January 1, 2017. The Board must act to implement the statutory requirement as soon as possible.

SUMMARY OF COMMENTS RECEIVED DURING THE 45-DAY COMMENT PERIOD (April 12, 2016 – May 31, 2016)

The following comments were made regarding this proposal:

Letter received via mail dated April 27, 2106 from Dr. Bob Damone, Doctor of Acupuncture and Oriental Medicine (DAOM), Dean of Southern California University of Health Sciences, College of Eastern Medicine.

1. Dr. Damone notes: *"However, beginning January 1, 2017, per BPC Section 4927.5 an approved educational and training program will be one that, among other things, is accredited by the Accreditation Commission for Acupuncture and Oriental Medicine (ACAOM), approved by the Bureau of Private Postsecondary Education (BPPE), and offers curriculum that includes at least 3,000 hours of which at least 2,050 hours are didactic and laboratory training, and at least 950 hours are supervised clinical instruction. Has submitted that curriculum to the board, and has received approval of the curriculum. (BPC 4927.5(a)(1). The language of SB 1246 states that an approved training program may either be accredited by ACAOM, be in candidacy status with ACAOM, or have submitted a letter of intent to pursue ACAOM accreditation within one-month of receiving Board curriculum approval, and become accredited within three years."*

The Board accepts this comment. The Final Statement of Reasons will reflect the correct language as set out in California BPC Section 4927.5:

"(3) Meets any of the following:
(A) Is accredited by the Accreditation Commission for Acupuncture and Oriental Medicine.
(B) Has been granted candidacy status by the Accreditation Commission for Acupuncture and Oriental Medicine.
(C) Has submitted a letter of intent to pursue accreditation to the Accreditation Commission for Acupuncture and Oriental Medicine within 30 days of receiving full institutional approval pursuant to paragraph (2), and is granted candidacy status within three years of the date that letter was submitted."

Letter received via mail dated April 28, 2106 from Dr. Bob Damone, Doctor of Acupuncture and Oriental Medicine (DAOM), Dean of Southern California University of Health Sciences (SCUHS), College of Eastern Medicine.

1. Dr. Damone notes that "A*s long as 'curriculum' pertains only to the courses listed among Title 16, California Code of Regulations Article 3.5 Acupuncture training programs, Section 1399.433, CEM at SCU is full agreement. However, we feel that 'curriculum' should be further defined in its narrow sense as 'coursework listed in 1399.433'. Otherwise, CAB approved schools may appear to be expected to acquire CAB approval at least 30 days in advance of even minor curriculum changes, even to those courses which do not affect CAB-required coursework. This could potentially interfere with a given program's ability to meet with agility the evolving needs of its student, accreditors, and regulatory bodies. Many acupuncture training programs have courses within their curricula in excess of CAB requirements. While board members and then EO, Ms. Thorfinson reassured those present at the Education Committee meeting that the spirit of section (e) was not intended to be aimed at 'elective' courses, further clarification would not dilute the Board's oversight yet would communicate with greater clarity the intended purpose."*

The reference to CCR Section 1399.433 (Criteria for International Training and Clinical Experience) is assumed to refer to the proposed CCR Section 1399.434 (Criteria for Approval of Acupuncture and Oriental Medicine). SCUHS would not be subject to 1399.433 since it is an Acupuncture school located in the United States.

The Board accepts this comment. The language originally approved was vague and requires clarification. Thus, the Board approved updated language to 1399.434(e) at the August 31, 2016 Board meeting which was released as a 15-day modified text. This new language clarifies what constitutes a new curriculum and that any new curriculum requires Board approval:

> (e) Any changes to ~~curriculum~~ *coursework as listed in California Code of Regulations Title 16, Chapter 13.7, Article 3.5, Section 1399.434* after Board

approval constitutes a new curriculum and requires Board approval pursuant to Business and Professions Code Section 4927.5. The approval shall be attained prior to implementing the new curriculum.

Letter received via mail dated May 25, 2016 from Dr. Steven Given, DAOM, L.Ac, Associate Academic Dean of the California Institute of Integral Studies.

Dr. Given's letter had four distinct comments.

1. *"It is not likely that an institution in California that began the accreditation process after SB 1246 was signed into law will be fully accredited by January 1, 2017. The language of SB 1246, "(C) is accredited of granted candidacy status by the Accreditation Commission for Acupuncture and Oriental Medicine, or has submitted a letter of intent to pursue accreditation to that commission, as specified." Institutions that have achieved candidacy with ACAOM by January 1, 2017 should be considered in compliance with CAB regulations on that date."*

The Board accepts this comment. The Final Statement of Reasons will reflect the correct language as set out in California BPC Section 4927.5:

"(3) Meets any of the following:
(A) Is accredited by the Accreditation Commission for Acupuncture and Oriental Medicine.
(B) Has been granted candidacy status by the Accreditation Commission for Acupuncture and Oriental Medicine.
(C) Has submitted a letter of intent to pursue accreditation to the Accreditation Commission for Acupuncture and Oriental Medicine within 30 days of receiving full institutional approval pursuant to paragraph (2), and is granted candidacy status within three years of the date that letter was submitted."

2. *"Beyond the initial approval of the curriculum of an institution, it is unclear when or how an institution would be required to resubmit curriculum to CAB. Under the accreditation process institutions are constantly reflecting on and making changes to improve curriculum."*

The Board accepts this comment. The language originally approved was vague and requires clarification. Thus, the Board approved updated language to CCR Section 1399.437e at the August 31, 2016 Board meeting which was subsequently released for public comment as a 15-day modified text. This new language clarifies what constitutes a new curriculum and that any new curriculum requires Board approval:

(e) Any changes to ~~curriculum~~ coursework as listed in California Code of Regulations Title 16, Chapter 13.7, Article 3.5, Section 1399.434 after Board approval constitutes a new curriculum and requires Board approval pursuant to Business and Professions

Code Section 4927.5. The approval shall be attained prior to implementing the new curriculum.

3. "*We believe that so long as any improvements to an institution's curriculum leaves the institution fully in compliance with CA regulations, no further review by CAB is necessary. Conversation with prior CAB staff suggested that CAB is considering reviewing virtually all changes to curriculum. This would be burdensome and result in making it harder for institutions to make positive changes to their program of study."*

The Board rejects this comment. In order to protect the public and ensure that California standards apply to all acupuncture training programs, it is necessary to require approved training programs submit changes to their coursework as defined as above to the Board.

4. "*Cautions CAB regarding attempting to ensure that licensed acupuncturists continue to meet the same educational training and clinical experience standards (sb1246_isr.pdf). It is hoped that CAB staff and commissioners will create an environment where an institution may meet or exceed the standards set out in regulation."*

The Board rejects this comment. The Board is setting minimum standards for Approved Training Program curriculum, not making the program exceed the standards as proposed. Exceeding these standards remains the program's decision.

Comments received at the June 6, 2016 public hearing on in Sacramento:

Dr. Steven Given, DAOM, L.Ac, Associate Academic Dean of the California Institute of Integral Studies had six distinct comments set out below.

1. *Dr. Given suggested a correction on proposed CCR Section 1399.433(b) (1) (G) – 'Jin Gui' is listed. Dr. Given feels 'Yaolae' should be added to further define the term.*

The Board rejects this comment. 'Jin Gui' is a significant enough identifier and is consistent with other classical acupuncture references within the section. The full textual name of each technique and modality listed in the proposed language would add additional length to the proposed language.

2. *Dr. Given noted the 'Clean Needle Technique' manual as referred in the proposed CCR Section 1399.433b (2)(K) is no longer published by the National Acupuncture Foundation. It is now published by the Council of Colleges of Acupuncture and Oriental Medicine – and is distributed free at the website: ccaaom.org.*

The Board accepts this comment. The reference to the 'Clean Needle Technique' manual is out of date and will be updated. The Board approved updated language to CCR Section 1399.433b(2)(K) and CCR Section 1399.434b(2)(K) at the August 31, 2016 Board meeting which was subsequently released for public comment as a 15-day modified text:

> (K) Hygienic standards, including clean needle techniques. The clean needle technique portion of this subject shall use as its primary reference the most ~~current edition of the "Clean Needle Technique Manual" published by the National Acupuncture Foundation,~~ current edition of the "Clean Needle Technique Manual 7th edition, (2015)", published by the Council of Colleges of Acupuncture and Oriental Medicine, which is hereby incorporated by reference, ~~or an equivalent standard which has been approved by the Board.~~ Students shall successfully complete the clean needle technique portion of the hygienic standards subject prior to performing any needling techniques on human beings;

The CCAOM's Clean Needle Technique manual, 7th edition (2015), incorporated by reference above, is available on their website: http://www.ccaom.org/cntmanual.asp

3. There is language Dr. Given believes is outdated: *"In subsection H - clinical practice hours – nine hundred fifty hours" and the "statement in subsection 4 – thereafter two hundred seventy five hours the clinical supervisor shall be physically present at the needling of the patient".* Dr Given believes *"that is outdated and should be deleted... California is the only state which requires this. Virtually no evidence that is necessary or enhances the training of the intern." He then notes "here is the following sentence…that the clinic supervisor shall be in close proximity, and is true for all stages of clinical stages and continues to be true."*

The Board rejects this comment. The intention of this section is for direct 'line-of-sight' observation and clinical supervision of the student. Needling and the instruction thereof is a precise and sensitive procedure. A supervisor's physical presence assures public protection through the thorough training of the intern. In order to better define the presence of a supervisor, the Board approved the following changes to CCR Section 1399.433 h (4) and CCR Section 1399.434h (4) at the August 31, 2016 public Board meeting which was subsequently released for public comment as 15-day modified text:

> The curriculum in clinical practice shall consist of at least 950 hours in clinical instruction, 75% of which shall be in a clinic owned and operated by the school, which includes direct patient contact ~~where appropriate~~ in the following:
> (1) Practice Observation (minimum 150 hours)--supervised observation of the clinical practice of acupuncture and Oriental medicine with case presentations and discussion;
> (2) Diagnosis and evaluation (minimum 275 hours)--the application of Eastern and Western diagnostic procedures in evaluating patients;

(3) Supervised practice (minimum 275 hours)--the clinical treatment of patients with acupuncture and oriental medicine treatment modalities listed in the Business and Professions Code Section 4927(d) and 4937(b).
(4) During the initial 275 hours of diagnosis, evaluation and clinical practice, the clinic supervisor shall be physically present at all times during the diagnosis and treatment of the patient. Thereafter, for a second period of 275 hours the clinic supervisor shall be physically present at the needling of the patient. During the initial 700 hours of clinical instruction, the student shall remain in the direct line of sight of the clinic supervisor at all times when the patient is being diagnosed and/or treated. After 700 hours of clinical instruction, ~~The~~ the clinic supervisor shall ~~otherwise~~ be in close proximity to the location at which the patient is being treated ~~during the clinical instruction~~. The student shall also consult with the clinic supervisor before and after each treatment.

4. *Similar to comment #1 in his letter (as referenced above), Dr. Given notes a statement in the SB 1246 ISR referring to approved training programs seeking ACAOM status does not refer to the full text of the statute.*

The Board accepts this comment. The Final Statement of Reasons will reflect the correct language as set out in California BPC Section 4927.5.

5. Dr. Given feels *"the Board should have complete authority first 30 days as per SB 1246, but thereafter the review of curriculum needs to be ended as far as CAB is concerned." He states "that under the accreditation process, schools are constantly improving and changing curriculum – and if an institution were required to go back to CAB for every time they made improvement to their curriculum, institutions would have a disincentive to continue to improve their curriculum as is required by accreditation, and believes that CAB would be inundated with minor changes, when in fact it is not necessary for CAB to approve that."*

   Dr. Given then said *"that a past CAB president made the statement at a past CAB meeting that this may include an ongoing review of all curriculum. It is very important for CAB to know that that review needs to be ended after that 30 day period. CAB will continue to have the opportunity to review transcripts to make sure they comply with California law and that should be considered follow up review as needed."*

The Board rejects this comment. In order to protect the public and ensure that California standards apply to all acupuncture training programs, it is necessary to require approved training programs submit changes to their coursework as defined to the Board.

6. Dr. Given notes *"a statement made in documents forwarded to me that licensed acupuncturists continue to meet the same training and clinical experience standards. More in the spirit of education under accreditation should meet or*

exceed those standards." He feels "it is in fact not appropriate for a Board to say that everybody must meet the same standards…we should be able to meet or exceed those standards according to the review of faculty and the academic leadership of the individual institution…that is in fact what is happening now, institutions do have an opportunity to exceed those standards as they see fit."

The Board rejects this comment. The Board is setting minimum standards for Approved Training Program curriculum, not making the program exceed the standards as proposed. Exceeding these standards remains the program's decision.

SUMMARY OF COMMENTS RECEIVED DURING THE 15-DAY MODIFIED TEXT PERIOD (September 1, 2016 – September 15, 2016)

Written letter received via email (acupuncture@dca.ca.gov mailbox) on September 14, 2016 from Ron Zaidman, President and CEO, Five Branches University in Santa Cruz, CA and San Jose, CA.

1. Mr. Zaidman feels that *"the proposed new clinic training regulation seriously undermines the quality of clinical education and the safety of the patient by forcing faculty to stand by and observe students needling when the students have already been trained in needling. Most importantly, this takes the faculty away from the imperative responsibility of meeting with the student to analyze and discuss the diagnosis and treatment plan of the patient. By the time students are needling patients, they have had over 250 hours of direct acupuncture training, and extensive experience in how to needle every point on the curriculum. During the 250 hours of acupuncture education and in-class practical training, students have been observed and examined to assure the student is skillful in needling, including CNT, point location, needle angle and needle depth. Students are not allowed to needle patients until they have acquired these skills."*

   As you know, the California standards for acupuncture and Traditional Chinese Medicine education were written over 35 years ago when the acupuncture committee assumed that clinical training would be done in the same structure as in China where acupuncture was practiced in large rooms where the supervisor, patients and students were physically present in the same space. Today, in the U.S. and more and more in China, acupuncture is practiced in private rooms, and the supervisor can only be present with one student and patient. To continue with high quality supervision, faculty need to visit the patient to help in making the correct diagnosis, then meet with the student to discuss and agree on the diagnosis, and acupuncture and herbal formula treatment plan. Faculty normally revisit the patient to observe the accuracy of the student's acupuncture. The proposed regulation has the unintended effect of taking the faculty member away from this fundamental and indispensable aspect of clinical training – to meet with the student to discuss and agree on the diagnosis, and acupuncture and herbal formula treatment plan – and require that the faculty instead observe the student needling.

To require that, 'during the initial 700 hours of clinical instruction, the student shall remain in the direct line of sight of the clinic supervisor at all times when the patient is being diagnosed and/or treated' assumes that patients in America are okay being treated in a large, common treatment room, community clinic style. While some patients may accept this, the majority of patients want privacy and a private room."

The Board accepts this comment. In response to concerns about additional direct line-of-sight requirements and supervision hours, the Board decided at its September 21, 2016 public meeting to remove the requirements by reverting to the previously approved text in CCR Sections 1399.433h and 1399.434h:

(h) Clinical Practice 950 hours

The curriculum in clinical practice shall consist of at least 950 hours in clinical instruction, 75% of which shall be in a clinic owned and operated by the school, which includes direct patient contact ~~where appropriate~~ *where appropriate* in the following:

(1) Practice Observation (minimum 150 hours)--supervised observation of the clinical practice of acupuncture and Oriental medicine with case presentations and discussion;

(2) Diagnosis and evaluation (minimum 275 hours)--the application of Eastern and Western diagnostic procedures in evaluating patients;

(3) Supervised practice (minimum 275 hours)--the clinical treatment of patients with acupuncture and oriental medicine treatment modalities listed in the Business and Professions Code Section 4927(d) and 4937(b).

(4) During the initial 275 hours of diagnosis, evaluation and clinical practice, the clinic supervisor shall be physically present at all times during the diagnosis and treatment of the patient. Thereafter, for a second period of 275 hours the clinic supervisor shall be physically present at the needling of the patient. ~~*During the initial 700 hours of clinical instruction, the student shall remain in the direct line of sight of the clinic supervisor at all times when the patient is being diagnosed and/or treated*~~. ~~*After 700 hours of clinical instruction,*~~ ~~The~~ ~~*the*~~ *The* clinic supervisor shall ~~otherwise~~ *otherwise* be in close proximity to the location at which the patient is being treated ~~during the clinical instruction~~ *during the clinical instruction*. The student shall also consult with the clinic supervisor before and after each treatment.

2. Mr. Zaidman further comments, "*In brief, striking, 'Thereafter, for a second period of 275 hours the clinic supervisor shall be physically present at the needling of the patient' would, in the view of our academic leadership and faculty, assure the highest education and clinical training, and would maximize patient safety."*

The Board rejects this comment. Removal of the requirement of a second period of 275 hours that the clinic supervisor shall be physically present would reduce the Board's ability to protect the public by way of thorough training of the student, and may increase the possibility of public harm by requiring less supervised clinical training and instruction for acupuncture students.

SUMMARY OF COMMENTS RECEIVED DURING THE SECOND 15-DAY MODIFIED TEXT PERIOD (October 1, 2016 – October 15, 2016)

Letter received via mail dated October 5, 2016 from Dr. Bob Damone, Doctor of Acupuncture and Oriental Medicine (DAOM), Dean of Southern California University of Health Sciences, College of Eastern Medicine.

1. Regarding the proposed language for 1399.433h and 1399.434h, he feels *"it is our contention that the practice of acupuncture needling is an 'Entrustable Professional Activity' that can be performed safely, effectively, and independently by well-trained Acupuncture interns fairly early in their training, and certainly well before a 700-hour minimum supervisory period."*

The Board rejects this comment. The proposed changes to CCR Section 1399.433(h) and 1399.434(h) do not alter any of the current clinical requirements that have been in regulation since 2005. Needling is a precise and sensitive procedure and there exists a difference between the didactic instruction in the practice and the clinical application of needling. The Acupuncture Board's primary purpose is to protect the public and reduce the risk of public harm. Therefore, supervision is necessary to ensure that the skills learned didactically continue to develop when transitioning to patient care.

2. Dr. Damone points out the difference between clinical supervision regulations for acupuncture tutorials and acupuncture training programs by referring to the Board's CCR Section 1399.426, which reads as follows:

   1399.426. Supervising Acupuncturist's Responsibilities
   "The supervisor shall only assign those patient treatments which can be safely and effectively performed by the trainee and which are consistent with the level of training received by the trainee. The supervisor shall provide continuous direction and immediate supervision of the trainee when patient services are provided. The supervisor shall be in the same facility as and in proximity to the location where the trainee is rendering services and shall be readily available at all times to provide advice, instruction and assistance to the trainee."

   He states that "*the regulatory language above reflects a reasonable approach to safe and pedagogically sound clinical supervision for both acupuncture tutorials and acupuncture training programs. We support immediate adoption of this standard for all acupuncture education in California."*

The Board rejects this comment. The proposed changes to CCR Section 1399.433(h) and 1399.434(h) do not alter any of the existing clinical requirements that have been in regulation since 2005. A tutorial candidate works in very close proximity at all times with the supervisor in an environment much different from an acupuncture school. In a Tutorial Program, the Tutorial Supervisor works with only one, or, at most, two trainees, in a small clinic setting. This presents a drastically different learning environment and level of supervision when compared to a Board approved acupuncture training program (at educational institutions) where common practice assigns a minimum of four clinical student interns per clinic supervisor, and in some cases exceeding that number, in a larger clinical facility setting. In addition, the Tutorial Training Program requires the successful completion of a minimum of 3,798 hours to be eligible for the licensing exam whereas Board Approved acupuncture training programs (at institutions) require a minimum of 3,000 hours. Therefore, the requirements from CCR Section 1399.426 would not be applicable here.

3. Dr. Damone cites the "*the resident clinical supervision standards from the Accreditation Commission for Graduate Medical Education (ACGME), Common Program Requirements. In decreasing order of supervisorial intensity, the ACGME guidelines identify three levels of clinical supervision. They are: 1) direct supervision; 2) indirect supervision and; 3) oversight. Depending on the educational level of the resident, and the relative complexity and associated risk of a given medical procedure, the appropriate degree of supervisorial oversight can be implemented using this model. A similar model would fit perfectly within the clinical supervision regulations for Acupuncture Training programs. We urge the Board to seriously consider these guidelines."*

The Board rejects this comment. The ACGME standards reflect the Entrustabale Professional Activity (EPA) used within the education models for physicians and osteopaths. Those standards do not readily translate to acupuncture education models. Medical students may have more supervisory independence sooner than acupuncture students but the same western medical education requirements and hours, pre-requisites (Bachelor's degree) and qualification testing (MCAT, at the very least) are not required of acupuncture students. Moreover, there are no established national acupuncture training supervision standards, therefore the Board is emboldened to adhere to the system presently in place to ensure public protection.

4. Dr. Damone notes the "*interpretation of 'Immediate and Direct Supervision' by the California Chiropractic Board", and* states that "*the California Chiropractic Board defines the terms "immediate and direct" supervision in a more liberal fashion than does the California Acupuncture Board, as is evidenced below:*

   'Immediate and direct supervision' means the licensed Doctor of Chiropractic shall be at all times on the premises where the examinations are being conducted. The licensed Doctor of Chiropractic shall be responsible for the verification of the recorded findings and will be solely responsible for rendering a conclusion based on the findings."

The Board rejects this comment. Chiropractic education and practice has a different type of learning and clinical training than Acupuncture. For example, Chiropractic treatment does not involve the use of needles. Therefore utilizing language that works for chiropractic education does not translate to the educational regulations proposed.

5. Finally, Dr. Damone asks "*that the Board will consider placing on its future agenda the issue of updating and modernizing the California acupuncture clinical supervision regulations to reflect current scientific evidence and best practices within health profession education, including those used by the medical profession."*

The Board rejects this comment. The Board is currently restoring the proposed regulations regarding clinical supervision so that there will be no proposed changes to what is currently in place. In the future, the Board may look into reviewing the acupuncture training program clinical supervision requirements in light of any changes to the profession. At this time, however, the Board is opting to keep the requirements as is for the reasons outlined above.

Letter received via mail dated October 10, 2016 from Dr. Gregory Lane, Doctor of Acupuncture and Oriental Medicine (DAOM), Director of Clinical Services, Pacific College of Oriental Medicine.

Dr. Lane thanked the Board and acknowledged all of the hard work and time invested by the Board in deliberating the issues and seeking feedback leading up to the public meeting. He feels that the Board has demonstrated a commitment to uphold the highest standards of the profession, as well as solicit and consider feedback from professionals in the field, including quality training institutions.

Dr. Lane's letter had three comments regarding the proposed regulatory action:

1. Dr. Lane feels *"that there remains work to be done in further revision of the regulatory language as relates to clinical supervision in acupuncture programs. We respectfully request that in a future agenda the CAB consider recommendations for regulation modification that would serve ideal clinical supervision in acupuncture training programs. We propose that any future changes would take into consideration current evidence and best practices in clinical teaching effectiveness in other health professions education."*

The Board rejects this comment. The Board is currently restoring the proposed regulations regarding clinical supervision so that there will be no proposed changes to what is currently in place. In the future, the Board may look into reviewing the acupuncture training program clinical supervision requirements in light of any changes to the profession. At this time, however, the Board is opting to keep the requirements as is for the reasons outlined above.

2. Dr. Lane also cites ACGME common program requirements, writing that *"The current evidence and best practices in health professions education supports a tiered approach, which aims towards a higher level of autonomy of the clinical student utilizing competency-based assessments on the part of the supervisors. As you can see there is a clearly delineated tier structure providing for the appropriate level of oversight balanced with self-directed learning with the goal of developing well-trained future practitioners and protecting public safety. We believe this model also fits our profession."*

The Board rejects this comment. The ACGME standards reflect the Entrustabale Professional Activity (EPA) used within the education models for physicians and osteopaths. Those standards do not readily translate to acupuncture education models. Medical students may have more supervisory independence sooner than acupuncture students but the same western medical education requirements and hours, pre-requisites (Bachelor's degree) and qualification testing (MCAT, at the very least) are not required of acupuncture students. Moreover, there are no established national acupuncture training supervision standards, therefore the Board is emboldened to adhere to the system presently in place to ensure public protection.

3. Finally, Dr. Lane further states that *"…we would also like to bring attention to the CAB that there are inconsistencies in the regulations governing clinical supervision in acupuncture tutorials and in acupuncture training programs. We respectfully request that these regulations be considered in a future agenda for re- wording to close disparity and bring into alignment the regulations."* He is referring to the Board's CCR Section 1399.426, which reads as follows:

1399.426. Supervising Acupuncturist's Responsibilities
"The supervisor shall only assign those patient treatments which can be safely and effectively performed by the trainee and which are consistent with the level of training received by the trainee. The supervisor shall provide continuous direction and immediate supervision of the trainee when patient services are provided. The supervisor shall be in the same facility as and in proximity to the location where the trainee is rendering services and shall be readily available at all times to provide advice, instruction and assistance to the trainee."

The Board rejects this comment. The proposed changes to CCR Section 1399.433(h) and 1399.434(h) do not alter any of the current clinical requirements that have been in regulation since 2005. A tutorial candidate works in very close proximity at all times with the supervisor in an environment much different from an acupuncture school. In a Tutorial Program, the Tutorial Supervisor works with only one, or, at most, two trainees in a small clinic setting. This presents a drastically different learning environment and level of supervision when compared to a Board approved acupuncture training program (at educational institutions) where common practice assigns a minimum of four clinical student interns per clinic supervisor, and in some cases exceeding that number, in a larger clinical facility setting. In addition, the Tutorial Training Program requires the successful completion of a minimum of 3,798 hours to be eligible for the licensing exam

whereas Board Approved acupuncture training programs (at institutions) require a minimum of 3,000 hours. Therefore, the requirements from CCR Section 1399.426 would not be applicable here.

SUMMARY OF COMMENTS RECEIVED DURING THE 3RD 15-DAY MODIFIED TEXT PERIOD (December 14, 2016 – December 30, 2016)

No comments were received during this public comment period.

INCORPORATION BY REFERENCE:

1. "Application for Board Approval of Curriculum" (rev 04/15)
2. "Clean Needle Technique Manual 7th edition (rev. January 2016), published by the Council of Colleges of Acupuncture and Oriental Medicine. Available to the public online at: http://www.ccaom.org/cntmanual.asp

The incorporation by reference method was used for the above documents because it would be impractical and cumbersome to publish the listed documents in the California Code of Regulations (CCR). The "Application for Board Review of Curriculum (rev 04/15)" and the "Clean Needle Technique Manual, 7th edition" (rev. January 2016)" are twelve and two hundred seventy five pages, respectively, and if incorporated into the CCR it would increase the size of Division 13.7 and may cause confusion to the user. The "Application for Board Review of Curriculum (rev 04/15)" and the "Clean Needle Technique Manual, 7th edition (rev. January 2016)" were made available to the public and also posted on the Board's website.