

MEDICAL BOARD STAFF REPORT

DATE REPORT ISSUED: May 8, 2009
 ATTENTION: Medical Board of California
 SUBJECT: International Medical School Regulations

STAFF CONTACT: Deborah Pellegrini, Chief

REQUESTED ACTION:

Direct staff to schedule a public hearing at the July 23-24, 2009 Board meeting to review proposed amendments to Section 1314.1 of Title 16, California Code of Regulations.

STAFF RECOMMENDATION:

Staff recommends that the Board set for regulatory hearing the amendments indicated on the attached copy of Section 1314.1, along with any edits or additional provisions that the Board may suggest for inclusion in the regulation.

BACKGROUND:

At the Board's meeting on July 25, 2008, Ms. Anita Scuri, Senior Legal Counsel, proposed that staff research whether the Liaison Committee on Medical Education (LCME) had changed its standards for accrediting U.S. and Canadian medical schools in any area that would be relevant to the Board's standards and process for reviewing international medical schools in Section 1314.1. The Board approved this proposal. Subsequently, staff reviewed changes that the LCME made to its accreditation standards as well as amendments proposed by staff and Board medical consultants. The resulting proposed amendments were incorporated into a working draft.

On March 25, 2009, staff hosted a meeting for interested parties at the Board's headquarters to allow parties, who will be affected by the amendments, an opportunity to provide feedback on the suggested amendments. Please refer to the attached list of attendees. Representatives of several international medical schools attended and provided helpful feedback, which was considered and incorporated in part into the attached proposed regulatory language.

ANALYSIS:

The attached proposed amendments to Section 1314.1 will satisfy the Board's intent to update its international medical school regulations to conform with relevant changes and improvements that the LCME has made in its standards since Section 1314.1 took effect in December 2003.

FISCAL CONSIDERATIONS:

No fiscal impact.



MEDICAL BOARD OF CALIFORNIA
Licensing Program

Interested Parties Meeting
International Medical Schools Regulation

Medical Board of California Headquarters
2005 Evergreen Street, Suite 1200
Sacramento, CA 95815

March 25, 2009

MINUTES

The meeting opened on March 25, 2009 at 1:30 p.m.

Participants Present:

Leonard Sclafari, Vice President and General Counsel, American University of Antigua
Tom Monahan, Consultant, Government of Grenada
John Wilbur, Office of Regulations, Data and Information, St. George's University
Frank Cali, Associate General Counsel, St. George's University
Ted Wait, Legislative Consultant, Golden State Advocacy
Cynthia Holden, Counsel, American University of the Caribbean
David Gonzalez, Counsel, American University of the Caribbean

Staff Present:

Deborah Pellegrini, Chief of Licensing
Kathryn Taylor, Licensing Manager
Anita Scuri, Senior Legal Counsel, DCA Legal Office
Harold Simon, M.D., Ph.D., Medical Consultant
James Nuovo, M.D., Medical Consultant
Patricia Park, Associate Governmental Program Analyst
Therese Kelly, Associate Governmental Program Analyst
Caroline Barrozo, Staff Services Analyst
Jean Arendt, Staff Services Analyst
Kevin Schunke, Regulations Coordinator
K. Demos, Regulations Coordinator

Deborah Pellegrini, Chief of Licensing, the medical consultants, and legal counsel reviewed proposed amendments to the Board's international medical schools regulation in Section 1314.1 of Title 16, California Code of Regulations. Based on feedback received from medical school representatives, the proposed regulations will be amended and presented to the Board members for review at their next meeting on May 8, 2009.

The meeting ended at 2:29 p.m.

MEDICAL BOARD OF CALIFORNIA
International Medical Schools
Specific Language of Proposed Changes
Draft—4/9/09

Amend section 1314.1 in Article 4 of Chapter 1, Division 13, Title 16 Cal. Code Regs. to read as follows:

§ 1314.1. International Medical Schools.

(a) For purposes of Article 5 of Chapter 5 of Division 2 of the code (commencing with Section 2100), a medical school's resident course of instruction that leads to an M.D. degree shall be deemed equivalent to that required by Sections 2089 and 2089.5 of the code if the medical school offers the curriculum and clinical instruction described in those sections and meets one of the following:

(1) The medical school is owned and operated by the government of the country in which it is located, ~~the country is a member of the Organization for Economic Cooperation and Development,~~ the medical school is a component of a university offering other graduate and professional degree programs that contribute to the academic environment of the medical school, and the medical school's primary purpose is educating its own citizens to practice medicine in that country; or

(2) the medical school is chartered by the jurisdiction in which it is domiciled and meets the standards set forth in subsection (b) below.

(b)(1) Mission and Objectives.

The institution shall have a clearly stated written purpose or mission statement and objectives that include:

(A) The institution's broad expectations concerning the education students will receive;

(B) The role of research as an integral component of its mission, including the importance, nature, objectives, processes and evaluation of research in medical education including its application to patient care and practice; and

(C) Teaching, patient care, and service to the community.

The institution shall have institutional objectives that are consistent with preparing graduates to provide competent medical care.

(2) Organization.

The institution shall be organized as a definable academic unit responsible for a resident educational program that leads to the M.D. degree. The manner in which the institution is organized shall be set forth in writing.

(3) Curriculum.

The structure and content of the educational program shall provide an adequate foundation in the basic and clinical sciences and shall enable students to learn the fundamental principles of medicine, to acquire critical judgment skills, and to use those principles and skills to provide competent medical care. The objectives of the educational program shall state, in outcome-based terms, what students are expected to learn. When an institution provides clinical clerkships at multiple teaching sites, the institution shall demonstrate comparability of educational experiences for all students across instructional sites.

(4) Clinical Oversight

The institution shall have a system with central oversight to assure that the faculty define the types of patients and clinical conditions that students must encounter, the appropriate clinical setting for the educational experiences, and the expected level of student responsibility. The system shall ensure that the faculty monitor and verify student experience and modify it as necessary to ensure that the objectives of the clinical education program will be met.

(5) Professionalism

The learning environment shall promote the development of appropriate professional attributes in medical students. The institution shall define the professional attributes it expects students to develop, in the context of the institution's mission and of promoting the safe practice of medicine.

~~(4)~~ (6) Governance.

The administrative and governance system shall allow the institution to accomplish its objectives (i.e. its statements of the items of knowledge, skills, behavior and

attitude that students are expected to learn). An institution's governance shall give faculty a formal role in the institution's decision-making process. A student enrolled in the program shall not serve as an instructor, administrator, officer or director of the school.

~~(5)~~ (7) Faculty.

The faculty shall be qualified and sufficient in number to achieve the objectives of the institution. A "qualified" faculty member is a person who possesses either a credential generally recognized in the field of instruction or a degree, professional license, or credential at least equivalent to the level of instruction being taught or evaluated. The institution shall have a formal ongoing faculty development process that will enable it to fulfill its mission and objectives.

~~(6)~~ (8) Admission and promotion standards.

The institution shall have and adhere to standards governing admission requirements and student selection and promotion that are consistent with the institution's mission and objectives. The institution shall document that its admitted students generally meets entrance requirements equivalent to those utilized by U.S. and Canadian medical schools, including an appropriate background check of all applicants admitted to the institution.

~~(7)~~ (9) Financial Resources.

The institution shall possess sufficient financial resources to accomplish its mission and objectives. Pressure for institutional self-financing must not compromise the educational mission of the institution nor cause it to enroll more students than its total resources can accommodate.

~~(8)~~ (10) Facilities.

The institution shall have, or have access to, facilities, laboratories, equipment and library resources that are sufficient to support the educational programs offered by the institution and to enable it to fulfill its mission and objectives. If an institution utilizes affiliated institutions to provide clinical instruction, the institution shall be fully responsible for the conduct and quality of the educational program at those affiliated institutions.

~~(9)~~ (11) Quality Assurance System.

If the institution provides patient care, it shall have a formal system of quality assurance for its patient care program.

~~(10)~~ (12) Records.

The institution shall maintain and make available for inspection any records that relate to the institution's compliance with this section for at least five years, except, however, that student transcripts shall be retained indefinitely.

~~(11)~~ (13) Branch Campuses.

(A) An institution with more than one campus shall have written policies and procedures governing the division and sharing of administrative and teaching responsibilities between the central administration and faculty, and the administration and faculty at the other locations. These policies shall be consistent with the institution's mission and objectives. The institution shall be fully responsible for the conduct and quality of the educational program at these sites. If an institution operates a branch campus located within the United States or Canada, instruction received at that branch campus shall be deemed to be instruction received and evaluated at that institution. For purposes of this section, the term "branch campus" means a site other than the main location of the institution but does not include any hospital at which only clinical instruction is provided.

(B) For purposes of this section, an institution shall disclose any affiliation or other relationship that it has with another institution in which either institution agrees to grant a doctor of medicine degree or its equivalent to students of the other institution who complete coursework at the affiliated institution.

(14) Evaluation of Program Effectiveness

An institution shall collect and use a variety of outcome data to demonstrate the extent to which it is meeting its educational program objectives. For purposes of this subsection, "outcome data" means specific and measurable outcome-based

performance measures of knowledge, skills, attitudes, and values (for example, measures of academic progress, program completion rates, performance of graduates in residency training and on licensing and certification examinations). ..

(c) The division board may, on its own or at the request of an institution, determine whether that institution meets the requirements of subsections (a) and (b). The division board shall have the sole discretion to determine whether a site visit is necessary in order to verify the accuracy and completeness of the data provided and to conduct an in-depth review of the program to determine whether the institution is in compliance with this regulation.

(d) An institution's failure to provide requested data regarding its educational program or to cooperate with a site team shall be grounds for disapproval of its educational program.

(e) If the division board determines that a site visit is necessary, it shall appoint a site inspection team to conduct a comprehensive, qualitative onsite inspection and review of all aspects of the institution's operations to determine whether the institution complies with the requirements of subsections (a) and (b).

The fee for a site visit is all reasonable costs incurred by the board staff and the site team, payable in estimated form in advance of the site visit. If the cost of the site visit exceeds the amount previously paid, the board shall bill the institution for the remaining amount and shall not take action to determine the institution's equivalency until such time as the full amount has been paid. If the amount paid exceeds the actual costs incurred, the board shall remit the difference to the institution within 60 days.

The site team shall prepare and submit to the division board a report that includes

(1) Its findings regarding the institution's compliance with the requirements of the law and this regulation;

(2) Its assessment of the quality of the institution as a whole and the quality of the institution's educational program, including any deficiencies; and

(3) Its recommendation whether or not the institution's resident course of instruction leading to an M.D. degree should be deemed equivalent to that required by Sections 2089 and 2089.5 of the code, including a recommendation regarding the correction of any deficiencies identified in the report. A copy of the report shall be provided to the institution, which shall have 60 days following the date of the report in which to respond to board staff as to any errors of fact or erroneous findings.

(f) If an institution wishes to retain the ~~division's~~ board's determination that its resident course of instruction leading to an M.D. degree is equivalent to that required by Sections 2089 and 2089.5 of the code, or if it is currently being evaluated for such equivalency, it shall do the following:

(1) It shall notify the ~~division~~ board in writing no later than 30 days after making any change in the following:

(A) Location including addition or termination of any branch campus;

(B) Mission, purposes or objectives;

(C) Change of name;

(D) Any major change in curriculum, including but not limited to, a change that would affect its focus, design, requirements for completion, or mode of delivery, or other circumstance that would affect the institution's compliance with subsections (a) and (b).

(E) Shift or change in control. A "shift or change in control" means any change in the power or authority to manage, direct or influence the conduct, policies, and affairs of the institution from one person or group of people to another person or group of people, but does not include the replacement of an individual administrator with another natural person if the owner does not transfer any interest in, or relinquish any control of, the institution to that person.

(F) An increase in its entering enrollment above 10% of the current enrollment or 15 students in one year, whichever is less, or 20% in three years.

(2) Every seven years, it shall submit documentation sufficient to establish that it remains in compliance with the requirements of this section and of Sections 2089 and 2089.5 of the code.

(g) The documentation submitted pursuant to subsection (f)(2) shall be reviewed by the ~~division~~ board or its designee to determine whether the institution remains in compliance with the requirements of these regulations and of Sections 2089 and 2089.5 of the code. The board may require a site visit as part of this review. It may also require a site visit at any other time during the seven-year period if it becomes aware of circumstances that warrant a site visit, including any change described in subsection (f).

(h) The ~~division~~ board may at any time withdraw its determination of equivalence when any of the following occur:

(1) ~~an~~ An institution is no longer in compliance with this section;

(2) The institution submits false or misleading information or documentation regarding its compliance with this section;

(3) Institution officials submit fraudulent documentation concerning a former student's medical curriculum; or

(4) The institution permits students to engage in clinical training in California facilities that do not satisfy the requirements of section 2089.5(c) and (d) and, where applicable, section 1327.

Prior to withdrawing its determination of equivalence, the ~~division~~ board shall send the institution a written notice of its intent to withdraw its determination of equivalence, identifying those deficiencies upon which it is proposing to base the withdrawal and giving the institution 120 days from the date of the notice within which to respond to the notice. The ~~division~~ board shall have the sole discretion to determine whether a site visit is necessary in order to ascertain the institution's compliance with this section. The ~~division~~ board shall notify the institution in writing of its decision and the basis for that decision.

(i) The ~~division~~ board may evaluate any institution described in subsection (a)(1) to determine its continued compliance with Sections 2089 and 2089.5 of the code if, in its sole discretion, the ~~division~~ board has reason to believe that the institution may no longer be in compliance.

Note: Authority cited: Section 2018, Business and Professions Code. Reference: Sections 2018, 2089, 2089.5, 2102 and 2103, Business and Professions Code.

ADDENDUM

MEDICAL BOARD STAFF REPORT

DATE REPORT ISSUED: May 8, 2009
ATTENTION: Medical Board of California
SUBJECT: International Medical School Regulations

STAFF CONTACT: Deborah Pellegrini, Chief

Attached is a revised copy of Section 1314.1 of Title 16 of the California Code of Regulations for your review on May 8, 2009. The attached proposed version dated April 23, 2009 contains new proposed modifications that further refines the language that differentiates subsection (a)(1) medical schools from subsection (a)(2) medical schools.

When Section 1314.1 was drafted, staff intended subsection (a)(1) to encompass the vast majority of the world's medical schools whose purpose is to educate the citizens of their own country to practice medicine in those countries. As Section 1314.1 (a)(1) was drafted in 2003, language was included for "government owned and operated" medical schools only, given the difficulty in trying to differentiate between the various types of medical schools. However, the world's traditional medical schools educating their own citizens are not all government owned and operated. For example, India's and Pakistan's medical schools may be government owned or private, run by societies or trusts. Philippine medical schools are either government-owned or owned and operated by religious orders with government approval. This change would clarify staffs' intent.

Please use the attached version of Section 1314.1 in place of the April 9, 2009 version that was bound into your meeting packet. Thank you.

MEDICAL BOARD OF CALIFORNIA
International Medical Schools
Specific Language of Proposed Changes
Draft—4/23/09

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(1) The medical school is owned and operated by the government of the country in which it is located or by a bona fide nonprofit institution registered with or otherwise approved by the country in which it is domiciled, ~~the country is a member of the Organization for Economic Cooperation and Development, the~~ medical school is a component of a university offering other graduate and professional degree programs that contribute to the academic environment of the medical school, and the medical school's primary purpose is educating its own citizens to practice medicine in that country; or

(2) the medical school is chartered by the jurisdiction in which it is domiciled, the primary purpose of the medical school program is to educate non-citizens to practice medicine in other countries, and the medical school meets the standards set forth in subsection (b) below.

(b)(1) Mission and Objectives.

The institution shall have a clearly stated written purpose or mission statement and objectives that include:

(A) The institution's broad expectations concerning the education students will receive;

(B) The role of research as an integral component of its mission, including the importance, nature, objectives, processes and evaluation of research in medical education including its application to patient care and practice; and

(C) Teaching, patient care, and service to the community.

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(c) The ~~division~~ board may, on its own or at the request of an institution, determine whether that institution meets the requirements of subsections (a) and (b). The ~~division~~ board shall have the sole discretion to determine whether a site visit is necessary in order to verify the accuracy and completeness of the data provided and to conduct an in-depth review of the program to determine whether the institution is in compliance with this regulation.

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(D) Any major change in curriculum, including but not limited to, a change that would affect its focus, design, requirements for completion, or mode of delivery, or other circumstance that would affect the institution's compliance with subsections (a) and (b).

(E) Shift or change in control. A "shift or change in control" means any change in the power or authority to manage, direct or influence the conduct, policies, and affairs of the institution from one person or group of people to another person or group of people, but does not include the replacement of an individual administrator with another natural person if the owner does not transfer any interest in, or relinquish any control of, the institution to that person.

(F) An increase in its entering enrollment above 10% of the current enrollment or 15 students in one year, whichever is less, or 20% in three years.

(2) Every seven years, it shall submit documentation sufficient to establish that it remains in compliance with the requirements of this section and of Sections 2089 and 2089.5 of the code.

(g) The documentation submitted pursuant to subsection (f)(2) shall be reviewed by the ~~division~~ board or its designee to determine whether the institution remains in compliance with the requirements of these regulations and of Sections 2089 and 2089.5 of the code. The board may require a site visit as part of this review. It may also require

a site visit at any other time during the seven-year period if it becomes aware of circumstances that warrant a site visit, including any change described in subsection (f).
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(1) an An institution is no longer in compliance with this section;

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Note: Authority cited: Section 2018, Business and Professions Code. Reference: Sections 2018, 2089, 2089.5, 2102 and 2103, Business and Professions Code.