TITLE 16. MEDICAL BOARD OF CALIFORNIA

Notice of Proposed Regulatory Action
Change of Location for Public Hearing

The California Regulatory Notice Register dated June 5, 2009 indicated that the Medical Board of California (Board) was proposing a regulation that would amend Section 1314.1 to update and add specificity to the existing standards and methodology that the Board uses to **review international medical schools** in order to determine their compliance with Business and Professions (B&P) Code Sections 2089 and 2089.5. The Board will conduct a public hearing on this proposed regulation on July 24, 2009, at a different location than stated in the original notice.

The new hearing location is:

Medical Board of California

2005 Evergreen St, Hearing Room

Sacramento, CA 95815

As originally noticed, the hearing will begin at 9:00 a.m.

For additional information, please contact:

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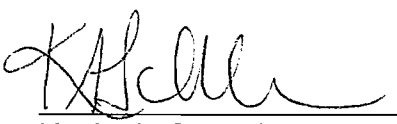
DATED: July 6, 2009



Kevin A. Schunke
Regulations Manager
Medical Board of California

TITLE 16. Medical Board of California

NOTICE IS HEREBY GIVEN that the Medical Board of California (hereinafter referred to as the "Board") is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments orally or in writing relevant to the action proposed at the hearing to be held at the Sacramento Convention Center, 1400 J Street, Sacramento, California 95814, at 9:00 a.m. on July 24, 2009. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the Board at its office not later than 5:00 p.m. on July 20, 2009 or must be received at the hearing. The Board, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Pursuant to the authority vested by Section 2018 of the Business and Professions Code, and to implement, interpret or make specific Sections 2089, 2089.5, 2102, 2103, 2135 and 2135.5 of said Code, the Board is considering changes to Division 13 of Title 16 of the California Code of Regulations as follows:

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW
Amend Section 1314.1.

Existing regulations have not been updated since their adoption in 2003. These regulations describe the process that the Board uses to review the educational programs of international medical schools to determine if they satisfy the minimum standards specified in statute. Over the past six years, Board staff and the expert Medical Consultants who assist the Board in reviewing international medical schools have identified deficiencies in the current regulations as well as additional provisions that, if adopted, would add greater specificity to the Board's process for reviewing international medical schools. Also, the Liaison Committee on Medical Education (LCME), on whose standards the regulation is based, has updated its standards for reviewing U.S. and Canadian medical schools. Several of the LCME's new standards are relevant to international medical schools and should be adopted into the Board's regulation.

This proposal would augment the regulation with provisions recommended by staff and the Board's Medical Consultants, based on their experiences in utilizing the existing regulation to review international medical schools and with relevant standards adopted by the LCME. In addition, this proposal would replace the word "division" with "board" throughout the regulation to conform to a recent statutory amendment, and would make non-substantive, editorial and grammatical revisions.

Specifically, the proposed amendments would:

- Correct an oversight to subsection (a)(1) by adding language specifying that the board may grant recognition to non-profit privately-owned medical schools registered in the country in which they are located, and that medical schools shall be affiliated with a university. The amendment would also repeal the current requirement that the country must be a member of the Organization for Economic Cooperation and Development.

- Add language to subsection (a)(2) to further differentiate medical schools in subsection (a)(1) from those in subsection (a)(2) by explaining that the primary purpose of subsection (a)(2) schools is to educate non-citizens to practice medicine in other countries.

- Clarify in subsection (b)(1)(B) that a medical school's educational program shall teach students how research applies to patient care.

- Specify in subsection (b)(3) that medical schools shall state in outcome-based terms what students are expected to learn. Require medical schools to demonstrate that their students receive comparable educational experiences if students complete clinical clerkships at multiple teaching sites.

- Add subsection (b)(4) to require medical schools to have a system for central oversight of the clinical experiences that students shall receive. Also, the system shall ensure that the faculty monitors and verifies the students' clinical experiences and modifies the system as necessary to ensure that the objectives of the clinical education program are met.

- Add subsection (b)(5) to require medical schools to promote the development of professional attributes in medical students and define those professional attributes that they expect students to develop, including the promotion of the safe practice of medicine.

- Amend subsection (b)(8) to require medical schools to document how their admitted students generally meet entrance requirements equivalent to those utilized by U.S. and Canadian medical schools and to document how the medical school conducted a background check of admitted medical students.

- Specify in subsection (b)(9) that pressure for institutional self-financing must not compromise the institution's educational mission or cause it to enroll more students than its total resources can accommodate.

- Specify in subsection (b)(13)(B) that institutions shall disclose affiliations or relationships with other institutions in which either institution agrees to grant a doctor of medicine degree to students of the other institution for coursework completed at the affiliated institution.

- Add subsection (b)(14) to require medical schools to collect a variety of outcome data and utilize that data to demonstrate that their program is meeting its educational objectives. The amendment provides examples of relevant outcome data that medical schools shall collect.

- Add language to (f)(1)(A) to require medical schools to disclose to the Board the addition or termination of any branch campus.

- Further clarify in subsection (f)(1)(D) that medical schools shall disclose to the Board any major change in their curriculum, including a curriculum change that would affect its focus, design, requirements for completion or mode of delivery.

- Add a requirement in subsection (f)(1)(F) that a medical school must disclose to the Board an increase in its enrollment above 10% or 15 students in one year, whichever is less, or a 20% increase in enrollment in three years.

- Specify in subsection (g) that the Board may require a site visit as part of the reevaluation required in subsection (f)(2) or anytime during the seven-year period if the Board becomes aware of circumstances that warrant a site visit, such as any of the changes to the school's educational program described in subsection (f).

- In subsection (h), specify three additional circumstances under which the Board may determine that a medical school is no longer in compliance with this section: 1) The institution submits false or misleading documentation regarding its compliance with section (b); 2) The institution submits fraudulent documentation concerning a former student's medical curriculum; or 3) The institution permits students to engage in clinical training in California facilities that are not defined as approved teaching sites in statute or regulation.

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None

Nondiscretionary Costs/Savings to Local Agencies: None

Local Mandate: None

Cost to Any Local Agency or School District for Which Government Code Sections 17500 - 17630 Require Reimbursement: None

Business Impact:

The Board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

The following studies/relevant data were relied upon in making the above determination:

The proposed amendments affect medical schools located outside the United States and will have no impact on California businesses or institutions.

Impact on Jobs/New Businesses:

The Board has determined that this regulatory proposal will not have any impact on the creation of jobs or new businesses or the elimination of jobs or existing businesses or the expansion of businesses in the State of California.

Cost Impact on Representative Private Person or Business:

The Board is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Effect on Housing Costs: None

EFFECT ON SMALL BUSINESS

The Board has determined that the proposed regulations would not affect small businesses. The proposed amendments affect educational institutions located outside the United States.

CONSIDERATION OF ALTERNATIVES

The Board must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would either be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposal described in this Notice.

Any interested person may present statements or arguments orally or in writing relevant to the above determinations at the above-mentioned hearing.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Board has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based. Copies of the initial statement of reasons and all of the information upon which the proposal is based may be obtained from the person designated in the Notice under Contact Person or by accessing the Board's website: http://www.medbd.ca.gov/laws/regulations_proposed.html.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained at the hearing or prior to the hearing upon request from the person designated in this Notice under Contact Person or by accessing the Board's website: http://www.medbd.ca.gov/laws/regulations_proposed.html.

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below, or by accessing the Board's website: http://www.medbd.ca.gov/laws/regulations_proposed.html.

CONTACT PERSON

Inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name:	Deborah Pellegrini, Chief of Licensing
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The backup contact person is:

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Website Access : Materials regarding this proposal can be found at http://www.medbd.ca.gov/laws/regulations_proposed.html.

MEDICAL BOARD OF CALIFORNIA

INITIAL STATEMENT OF REASONS

Hearing Date: Friday, July 24, 2009

Subject Matter of Proposed Regulations: Amendments to the Standards and Methodology for the Review of International Medical Schools

Section(s) Affected: Title 16, Section 1314.1

Specific Purpose of each adoption, amendment, or repeal:

The specific purpose of amending Section 1314.1 is to update and add specificity to the existing standards and methodology that the Medical Board of California (hereinafter referred to as the Board) uses to review international medical schools in order to determine their compliance with Business and Professions (B&P) Code Sections 2089 and 2089.5.

Factual Basis/Rationale

B&P Code Section 2084 authorizes the Medical Board of California to approve medical schools that comply with the medical education requirements in B&P Code Sections 2089. Section 2089 requires medical schools to provide a curriculum of a certain length that includes training in the basic sciences and clinical sciences course areas listed in the section. Section 2089.5 further specifies the minimum length and content of the required clinical training and the types of facilities approved to provide the clinical training. Section 2089.5 (d)(10) provides that the medical school shall bear the cost of any site inspection that the Board finds necessary to determine if the school's clinical training program complies with this subdivision.

In reference to the Board's authority to approve medical schools, Title 16, California Code of Regulations, Section 1314 provides that those medical schools accredited by the Liaison Committee on Medical Education (LCME) are deemed to be approved by the Board. The LCME accredits medical schools located in the United States and Canada. No agency accredits international medical schools worldwide. Therefore, the Board's approval efforts apply to medical schools located outside the United States and Canada.

Between 1983 and 2003, the Board had conducted individual reviews of several international medical schools to determine their compliance with the minimum

requirements in B&P Code Sections 2089 and 2089.5. The Board followed a standard process in reviewing these schools. On December 13, 2003, the Board adopted a standard review process in Section 1314.1 of Title 16, Section 1314.1, which informs consumers and international medical school administrators of the minimum standards expected of medical schools whose graduates wish to apply for licensure in California.

Since Section 1314.1 took effect in 2003, the Board has reviewed 13 medical schools pursuant to subsection (a)(2). Two medical schools involved site inspections to the schools' campuses and clinical training sites. The Board granted recognition to one of these two schools and disapproved the other. The Board reviewed 11 other schools for which site inspections were not deemed necessary. Ten of these schools were granted recognition and one was disapproved.

In the course of conducting these reviews, the Board gained experience and knowledge of the strengths and shortcomings of the existing regulation. Working with Medical Consultants and medical school officials over the past six years, the Board has identified multiple areas where the regulation could be clarified to better explain to affected parties the type of data they need to compile regarding their educational program and resources to facilitate the Board's review process.

Specifically, the proposed amendments to Section 1314.1 would replace all references to the "Division" or "Division of Licensing" with the word "board" throughout the regulation. Assembly Bill 253, which took effect on January 1, 2008, abolished the two divisions in the Board. The full Board now handles all functions that the Division of Licensing previously performed.

Subsection (a)(1) will clarify that the Board may grant recognition to non-profit privately-owned medical schools registered in the country in which they are located, and that these medical schools shall be affiliated with a university. When Section 1314.1 was drafted in 2003, staff intended subsection (a)(1) to encompass the vast majority of the world's medical schools whose purpose is to educate their own citizens to practice in those countries. The current wording mandates that the school be "government owned and operated." However, the world's traditional medical schools educating their own citizens are not all government owned and operated. For example, California itself has five government-sponsored medical schools in the University of California system as well as three privately-owned medical schools, Stanford, Loma Linda and the University of Southern California.

California licenses a significant amount of graduates of international medical schools. India's and Pakistan's medical schools may be government-owned or privately-owned, run by societies or trusts with government oversight. Philippine medical schools are either government owned or are owned and operated by religious orders with government approval. Belgian medical schools are run by non-profit private foundations, independent from the Belgian government. To train more physicians to

meet the needs of their growing populations, more countries with government-owned schools are also approving privately-owned medical schools to open for the sole purpose of training their own citizens to practice medicine in their countries. The United Kingdom, Israel, Nigeria and Egypt are recent examples of this trend. The Board has no basis to require medical schools in these countries to undergo review pursuant to subsection (a)(2) simply because they are privately-owned and operated, but serve the same purpose of training "in-country" physicians.

If subsection (a)(1) is not amended to reflect the prevailing governance of the world's medical schools and conform to the Board's original intent in 2003, the Board would need to review privately-owned medical schools on an individual basis pursuant to subsection (a)(2). This would prove to be a hardship and an unnecessary expense to the Board and the medical school, and would cause unreasonable delays in their graduates' obtaining licensure in California.

The Board will repeal the requirement in subsection (a)(1) that the country must be a member of the Organization for Economic Cooperation and Development (OECD). When the Board promulgated Section 1314.1 in 2003, there was an expectation that many more countries would seek membership in the OECD. Six years later, OECD membership stands at approximately 30 countries, almost all of whom are in Europe. The Board receives licensing applications from physicians who graduate from medical schools around the world. Therefore, this requirement has not proved to be relevant to the Board's review process and cannot be enforced. The requirement for OECD membership will be repealed and replaced by the more generic requirement that medical schools must be part of a "university offering other graduate and professional degree programs that contribute to the academic environment of the medical school." This requirement more closely reflects the true model of medical schools in the United States and around the world, where the medical school is part of a larger university that offers graduate and professional degree programs in other fields and offers administrative and financial support to the medical school.

Currently, subsection (a)(1) states that the primary purpose of a subsection (a)(1) medical school is to educate citizens of the country where the school is located to practice medicine in that country. Although not explicitly stated, schools in the subsection (a)(2) category differ from (a)(1) schools because their purpose is to educate non-citizens who will then leave the country to practice elsewhere. This has been the mission of all of the medical education programs that the Board has reviewed pursuant to subsection (a)(2). The addition of the statement, "the primary purpose of the medical school program is to educate non-citizens to practice medicine in other countries," to subsection (a)(2) will add further clarity and balance to the regulation. This amendment will better define the type of medical school that is subject to the Board's review process and that the medical school must demonstrate that it meets the standards set forth in subsection (b) of the regulation.

The addition of the words "the medical school" in subsection (a)(2) is a non-substantive, grammatical change.

The amendment to subsection (b)(1)(B) will replace the vague term "practice" with the more specific term "including its application to patient care." This will clarify that a medical school's educational program should teach students how research applies to patient care or, in other words, the process by which research findings in the laboratory translate into improved diagnoses and treatments available to patients.

The amendment to subsection (b)(3) will require medical schools to state in outcome-based terms what students are expected to learn. Based on the Board's experiences over the past six years, greater clarity is needed in the regulation. The Board's Medical Consultants have found that additional communications with medical school officials are needed because school officials do not initially submit information in a useable format. Advising medical school officials to express curriculum information in outcome-based terms will assist the medical school and the Board in determining if the school's educational program is meeting its stated mission. Such clarity will presumably lead to quicker recognition.

The second amendment to subsection (b)(3) will require medical schools to demonstrate that their students receive comparable educational experiences if students complete clinical clerkships at multiple teaching sites. This is especially relevant because most of the medical schools that the Board has reviewed pursuant to subsection (a)(2) do not own teaching hospitals. Instead, after their students complete their basic sciences coursework at the school's campus, the students disperse to the United States and other countries where they train in multiple teaching sites pursuant to a written affiliation agreement between their school and the teaching hospitals. The students' clinical training is supervised by hospital attending physicians who may or may not serve as teaching faculty in the local medical schools. Therefore, it is reasonable to expect medical school officials to demonstrate how their students receive a comparable educational experience; for example, in a surgery clerkship, some students may train at a university teaching hospital in one state alongside medical school students from that state, some students may complete the same clerkship in a small community hospital in another state that does not train medical students, and a few students may elect to complete the surgery clerkship in a hospital outside the United States. These varying teaching sites may offer different levels of clinical exposure to inpatient or outpatient populations or a mixture of both. Adding greater clarity to the regulation will advise medical school officials that the Board expects them to demonstrate how they provide a reasonably uniform and consistent clinical experience to their medical students across multiple teaching sites.

The amendment to subsection (b)(4) will require medical schools to have a system for central oversight of their students' clinical experiences. Also, faculty shall monitor the students' clinical experiences and modify the system as necessary to ensure that the

objectives of the clinical education program are being met. Medical school officials will be prepared to document their system for monitoring and assessing students' clinical experiences to ensure that students are gaining the expected skills. They will be able to provide examples of any modifications they made to the system if they determined that the objectives of the clinical education program were not being met. This is especially important for medical schools in subsection (a)(2) whose students may be geographically disbursed in hospitals across the United States and other countries. In the Board's experience, some schools address this monitoring need by having a clinical coordinator who visits the affiliated hospitals periodically and evaluates the faculty and students. By adding this clarity to the regulation, medical school officials will be advised of the level of information that the Board expects them to provide.

The addition of subsection (b)(5) will require medical schools to promote the development of professional attributes in medical students and define those professional attributes that they expect students to develop. Professionalism among medical students commonly includes attributes such as taking accountability for one's actions, showing altruism toward patients, behaving cooperatively with other members of the healthcare team, complying with the ethical standards of the medical profession, and so forth. The importance of professionalism in the medical field has been substantiated by several studies published in peer reviewed medical journals.[1] These studies demonstrate the positive correlation between failures in professionalism during medical school with disciplinary action against practicing physicians. For medical schools in the subsection (a)(2) category, it is especially important to determine how they develop professionalism in their students because of the geographical disconnect inherent in their educational program. For the most part, their students complete their two years of clinical training on a separate continent from the medical school under the supervision of hospital staff who are not faculty members of the students' medical school. Medical school officials are relying on distantly-located individuals to train, guide and evaluate their students. Adding clarity to the regulation will notify medical school officials that the Board will review their system for teaching professionalism to their students and addressing deficiencies identified in certain students such that these students have the opportunity to provide optimum care and not violate California's Medical Practice Act.

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[1]Papadakis MA, Hodgson CS, Teherani A, Kohatsu ND. Unprofessional behavior in medical school is associated with subsequent disciplinary action by a state medical board. Academic Medicine 79 (3): 244-249, 2004.

Teherani A, Hodgson CS, Banach M, Papadakis MA. Domains of unprofessional behavior during medical school associated with future disciplinary action by a state medical board. Academic Medicine 80 (10 Suppl): S17-20, 2005.

Subsection (b)(6) will be renumbered (b)(8), and further specificity will be added to the admission and promotion standards. The amendment will require medical schools to document how their admitted students meet entrance requirements equivalent to those utilized by United States and Canadian medical schools and to document how the medical school conducts appropriate background checks of admitted medical students. Medical school administrators must document whether they require candidates to pass a standardized aptitude test to demonstrate their fitness to begin medical education or what equivalent process they utilize to select their student body. This will allow the Board to assess the rigorousness of the medical school's selection criteria in admitting students who will be equipped to provide safe medical care to the public in California. The clarification is not intended to interfere with the medical schools' authority or to impose United States admission standards on international schools.

Subsection (b)(7) will be renumbered (b)(9). Further specificity will be added to the financial resources section. Subsection (b)(9) will state that pressure for institutional self-financing must not compromise the institution's educational mission or cause it to enroll more students than its total resources can accommodate. This is especially relevant to medical schools in the subsection (a)(2) category which are mainly proprietary, for-profit medical schools whose only financial revenue source may be student tuition fees.

Subsection (b)(11) will be renumbered (b)(13), and the section will be subdivided into (A) and (B). Subsection (b)(13)(B) will further clarify that institutions shall disclose affiliations or relationships with other institutions in which either institution agrees to grant a doctor of medicine degree to students of the other institution for coursework completed at the affiliated institution. This clarification is necessary because of new trends in medical education involving so-called "twinning" programs, whereby two medical schools execute agreements that allow students to complete a significant part of their medical education in another medical school. Adding specificity to subsection (b)(13) will allow affected parties to better understand that they are required to disclose any affiliations with other institutions where their students are permitted to train toward the doctor of medicine degree. The Board will use its discretion to determine if a site visit is necessary to other campuses involved in the school's medical education program.

Subsection (b)(14) will be added to require medical schools to collect a variety of outcome data to demonstrate that their program is meeting its educational objectives. The amendment provides examples of relevant outcome data that medical schools shall collect. If a medical school's mission is to train physicians to practice in other countries, school officials shall have a system for tracking their graduates' success in gaining training or licensure in other countries. Without such a tracking system, school officials cannot evaluate the effectiveness of their program and make needed adjustments to ensure that graduates can satisfy the licensing requirements in their chosen country. While conducting medical school reviews recently, the Board's Medical Consultants

found that they frequently need to request this data from medical school officials in subsequent correspondence. Some of the schools have had no systems in place to track their alumni's success in gaining licensure. Adding this level of specificity to the regulation will require medical school officials to develop tracking systems to demonstrate to the Board and document that their educational program is meeting its stated mission.

Subsection (f)(1)(A) will be amended to advise medical school officials that they must notify the Board not only of a change in the school's main campus location but also the addition or termination of any branch campus. This reflects a recently-observed trend for medical schools to expand their enrollment by opening branch campuses in other countries. This information will assist the Board in determining if the action affects the school's continued compliance with regulation and statute and in ensuring the consistency of the medical education provided at the branch campus(es).

The Board will add specificity to subsection (f)(1)(D) by giving further examples of curriculum changes that medical schools should disclose to the Board. A "major" change in curriculum includes a change that would affect its "focus, design, requirements for completion or mode of delivery." Changes in these areas could affect the institution's compliance with California statute and regulation. For example, if a medical school were to drastically reduce the number of weeks of clinical training required for graduation, its curriculum may no longer comply with the 72-week minimum requirement in B&P Code Section 2089.5. If a medical school were to begin delivering the curriculum required in B&P Code Section 2089 to its students via a "distance learning" format, the school's curriculum would no longer comply with the "resident course of instruction" requirement in B&P Code Sections 2036 and 2089. Adding specificity to the notification requirement in this subsection will help medical schools understand the Board's expectations, will allow the Board and affected medical school officials to communicate about changes in their curriculum in a timely fashion, and will minimize medical schools reporting trivial alterations in their programs.

The addition of subsection (f)(1)(F) will require that affected medical schools must disclose to the Board significant increases in their enrollment. The proposed language will define a disclosable increase in enrollment as an increase above 10 percent or 15 students in one year, whichever is less, or a 20 percent increase in enrollment in three years. This amendment is desirable because increasing enrollment without increasing the appropriate supporting resources could cause a medical school to fall out of compliance with the regulation. For example, if a medical school steeply increases its first-year class without increasing its clinical training sites, those students may experience inordinate wait times to be placed in hospitals for clinical rotations or they may be placed in marginal facilities that provide cannot an acceptable training experience to meet course objectives.

Subsection (g) will be amended to specify that the Board may require a site visit as part of the reevaluation required in subsection (f)(2) or anytime during the seven-year period if the Board becomes aware of circumstances that warrant a site visit, such as any of the changes to the school's educational program described in subsection (f). The Board's authority to conduct site visits derives from Sections 2089 and 2089.5. This amendment will clarify to affected medical schools that in addition to conducting an initial site visit when a medical school applies for recognition in California, the Board may also conduct site visits as part of the seven-year reevaluations required in subsection (f)(2). The same discretion to require a site visit applies if a recognized school notifies the Board of changes to the school's program as described in subsection (f). Since the Board is preparing to conduct the first series of medical school reevaluations pursuant to subsection (f)(2) in 2010, it is important to ensure that medical school officials understand that the process of retaining recognition in California may entail subsequent site visits.

Specificity will be added to subsection (h) in the form of three examples of circumstances under which the Board may determine that a medical school is no longer in compliance with this section: 1) The institution submits false or misleading documentation regarding its compliance with section (b); 2) The institution submits fraudulent documentation concerning a former student's medical curriculum; 3) The institution permits students to engage in clinical training in California facilities that are not defined as approved teaching sites in statute or regulation. With respect to the latter point, the Board has encountered repeated instances over the last 20 years where recognized medical schools permitted students to train illegally in unapproved training sites in California, despite repeated warnings to the medical school and hospital. Unlawful clinical training experiences constitute the unlicensed practice of medicine. These amendments will serve to caution recognized medical schools and schools that contemplate applying for recognition in the future. The amendments will establish the ethical standard and cooperation that the Board expects of medical school officials who desire to retain their schools' recognized status in California.

Underlying Data

The Board's process for reviewing international medical schools is based on the process and standards employed by the LCME to review U.S. and Canadian medical schools. The LCME's publication, "Functions and Structure of a Medical School," describes the LCME's standards for accrediting medical education programs. This publication is available on the LCME's web site at: www.lcme.org.

In proposing the addition of subsection (b)(8), the Board relied on studies reported in the medical literature, including the following:

Papadakis MA, Hodgson CS, Teherani A, Kohatsu ND. Unprofessional behavior in medical school is associated with subsequent disciplinary action by a state medical board. Academic Medicine 79 (3): 244-249, 2004.

Teherani A, Hodgson CS, Banach M, Papadakis MA. Domains of unprofessional behavior during medical school associated with future disciplinary action by a state medical board. Academic Medicine 80 (10 Suppl): S17-20, 2005.

In formulating the amendments proposed in this rulemaking, the Board relied on the hands-on experiences gained in reviewing 11 international medical schools since Section 1314.1 took effect in December 2003. Board staff also invited input from affected parties at an "interested parties" meeting on March 25, 2009. The Board mailed meeting agendas to all known interested parties and noticed the meeting on the Board's web site. Representatives from several international medical schools attended the meeting and provided feedback. The proposed amendments were presented to the Board and the public again at a regularly-scheduled Board meeting on May 8, 2009. One comment was received from a member of the public at that meeting. After receiving and considering that comment, the Board voted to set these proposed regulations for public hearing.

Business Impact

This regulation will not have a significant adverse economic impact on businesses. This initial determination is based on the following facts or evidence/documents/testimony:

The proposed amendments affect educational institutions located outside the United States. Additionally, these proposed changes relate to recordkeeping and notice requirements.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative to the regulation would be either more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed regulation.

Set forth below are the alternatives which were considered and the reasons each alternative was rejected:

The alternative to this proposal is to maintain the regulation in its current form. However, without the amendments proposed in this rulemaking, affected parties would forego the benefits to be gained from clarifying the meaning of the existing language. Greater clarity in the language should lead to greater efficiency in the Board's review process for reviewing international medical schools. Affected medical schools will know in advance the types of information that the Board requires of them. They will have more time to compile the necessary information, and the Board should spend less time requesting followup information from school officials. Additionally, the existing regulation does not reflect the changing status of medical education outside of the United States and Canada.

MEDICAL BOARD OF CALIFORNIA
International Medical Schools
Specific Language of Proposed Changes

Amend section 1314.1 in Article 4 of Chapter 1, Division 13, Title 16 CCR 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 *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.

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 meet 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.