



TO: The Honorable the Members of the Board of Regents

FROM: Douglas E. Lentivech


SUBJECT: Proposed Amendment to Regulations of the Commissioner of Education Relating to the Approval of International Medical Schools for Long-Term Clinical Clerkship Placements

DATE: July 9, 2012

AUTHORIZATION(S):


SUMMARY

Issue for Consent

Should the Board of Regents approve the addition of a new section 60.10 of the Regulations of the Commissioner relating to the standards and process for the approval of international medical schools to place students in long-term clinical clerkships in New York State?

Reason(s) for Consideration

Review of Policy.

Proposed Handling

This question will come before the full Board at its July 2012 meeting where it will be voted on and action taken.

Procedural History

At its April 2012 meeting, the Board of Regents approved the proposed amendment as an emergency measure, effective April 24, 2012. A Notice of Proposed Rule Making and Emergency Adoption was published in the State Register on May 9, 2012.

Background Information

During the November and December 2010 meetings of the PPC, former Deputy Commissioner Muñoz, Executive Secretary Ramos, and Roger M. Oskvig, M.D., Chair of the New York State Board for Medicine, presented a rationale for reviewing and amending the Commissioner's regulations regarding the oversight of international medical schools seeking approval to place students in long-term clinical clerkships in New York State hospitals. The presentations before the Committee followed a series of discussions with the Study Group on International Medical Schools. At the January 2011 meeting of the PPC, options and recommendations for future action were presented for Regents consideration.

In April 2011, the Board of Regents approved regulations to establish an Advisory Committee on Long-Term Clinical Clerkships (Advisory Committee). The members of the Committee were subsequently appointed, effective July 1, 2011. The Committee, which was appointed by the Chancellor after consultation with the Board of Regents, includes representatives from the Board of Regents, the State Education Department, the Department of Health, registered New York State medical schools, dual-campus international medical schools, hospitals that serve as clinical clerkship sites and physicians experienced in evaluating medical education. The regulations adopted in April 2011 define the duties of the Committee, including the development of standards and processes by which dual-campus international medical schools seeking authorization to operate in New York State would be evaluated.

The Advisory Committee met on several occasions and developed standards and processes for the approval of international medical schools to place students in long-term clinical clerkships. Those standards and processes were approved in concept by the Professional Practice Committee at its meeting in December 2011, and they provide the basis for the proposed amendments to the Regulations of the Commissioner.

At its April 2012 meeting, the Board of Regents approved, as an emergency measure, the proposed amendments which establish the standards for the approval of international medical schools to place students in long-term clinical clerkships in New York. The standards require that the school be recognized by the appropriate civil authorities in the country in which it is located as an acceptable education program for physicians in that country. In addition, the school must have in place institutional policies and leadership to prepare students effectively for the practice of medicine and must have sufficient resources to achieve its goals. The school must provide at least 130 weeks of instruction, and the curriculum must incorporate the fundamental principles of medicine, promote the development of skills of critical judgment, and develop the ability of students to use such principles and skills effectively. The proposed regulation requires schools to provide clinical, as well as didactic instruction, and the clinical experiences must provide for students to undertake appropriate and progressive responsibilities. To be approved, a school must also provide instruction in ethics and human values and must have in place systems for the effective assessment of student achievement. The school must also have a sufficient number of qualified faculty members and provide appropriate assessment and development opportunities for them. With regard to clinical clerkships, the school must have affiliation agreements with the

facilities providing such clerkships, and the clerkships must be provided at facilities where there is appropriate oversight and supervision. The medical school is required to inform the Department of the facilities with which it has affiliation agreements and of anticipated changes in its agreements.

The proposed amendment also establishes the application and approval process for these schools. Schools seeking approval would be required to submit to the Department an application, on a form prescribed by the Commissioner, which shall include a self-study. Once a determination is made that the application adequately addresses the approval standards, a site visit would be conducted. The school would be provided with a copy of the site visit report and have an opportunity to respond. The Advisory Committee would then make findings with respect to compliance with the approval standards and submit a report and recommendation to the Board of Regents. The report shall include a recommendation to approve or deny the application and provide the rationale for the recommendation, reflecting majority and minority opinions. The Board of Regents would then make a final determination on the application. Any approvals may be subject to certain limitations and restrictions imposed by the Board of Regents.

Schools would be required to submit an annual report. Upon receipt of the annual report, if the Advisory Committee determines that there has been a substantial change in the approved medical program that is not in compliance with the approval standards set forth in this section, the Advisory Committee may recommend corrective action which may include a site visit, additional reporting requirements, submission of a new application and/or self-study, or revocation by the Board of Regents or placement in probationary status.

The proposed amendment would also authorize the Advisory Committee or the Department to recommend to the Board of Regents at any time the revocation of a medical school's approval to place students in New York clinical clerkships and/or placement of the medical school in probationary status and establishes procedures for such actions.

A Notice of Emergency Action and Proposed Rule Making was published in the State Register on May 9, 2012. Following a 45-day public comment period, no comments were received on the proposed amendment.

Recommendation

VOTED: That section 60.10 of the Regulations of the Commissioner of Education be added, as submitted, effective July 22, 2012, as an emergency measure upon a finding by the Board of Regents that such action is necessary for the preservation of the public health and general welfare to ensure that the emergency rule adopted at the April 2012 Regents meeting remains continuously in effect until it can be adopted as a permanent rule; and it is further

VOTED: That section 60.10 of the Regulations of the Commissioner of Education be added, as submitted, effective August 1, 2012.

Timetable for Implementation

If approved at the July 17, 2012 meeting of the Board of Regents, the emergency action will be effective on July 22, 2012, and the effective date of the approval of the regulation as a permanent rule will be August 1, 2012.

STATEMENT OF FACTS AND CIRCUMSTANCES WHICH NECESSITATE
EMERGENCY ACTION

The proposed amendments to the Regulations of the Commissioner of Education are necessary to establish a process and standards for the approval of international medical schools to place students in long-term clinical clerkships in New York.

Emergency action is necessary for the preservation of the public health and general welfare in order to enable the Advisory Committee on Long-Term Clinical Clerkships to evaluate pending applications by international medical schools to place students in long-term clinical clerkships in New York State in a timely manner. Such applications have been on hold pending a review of the process and standards used to approve such applications, and it is now necessary to formally approve the new process and standards, which are designed both to protect the health and safety of patients in the facilities in which the clinical clerkships will be conducted and to assure that the students in the international medical schools placing students in such clerkships are receiving an appropriate medical education before and during their participation in such clerkships.

The proposed amendment was adopted as an emergency measure at the April Regents meeting and became effective April 24, 2012. Pursuant to the State Administrative Procedure Act, the emergency rule is effective for 90 days and will expire on July 22, 2012. Therefore, emergency action is needed at the July Regents meeting to ensure that the emergency rule adopted at the April 2012 Regents meeting remains continuously in effect until it can be take effect as a permanent rule.

AMENDMENT TO THE REGULATIONS OF THE COMMISSIONER OF EDUCATION

Pursuant to Education Law sections 207, 6506, 6507 and 6508.

Sections 60.10 of the Regulations of the Commissioner of Education is added, effective July 22, 2012, to read as follows:

§60.10 Standards and process for the approval of international medical schools to place students in long-term clinical clerkships in New York State.

(a) General requirements. To meet the requirements for approval to place students in long-term clinical clerkships in New York State, an international medical school shall meet the requirements in this section.

(b) Duration of approval. Based upon a review conducted pursuant to this section, initial and subsequent approvals of a school shall be for a term of 7 years unless otherwise limited to a lesser period for good cause, and such approvals may be subject to certain limitations and restrictions as determined by the Board of Regents. The term of approval may be extended by the Board of Regents on one or more occasions for a period not to exceed 12 months on each occasion for good cause.

(c) Approval standards. In addition to any applicable requirements in section 60.2 of this Part, in order to be approved to place students in long-term clinical clerkships in New York State, the institution shall meet the following requirements:

(1) Recognition by appropriate authorities of country. The international medical school shall be recognized by the appropriate civil authorities of the country in which the school is located as an acceptable educational program for physicians, and graduates of the program shall be eligible to pursue licensure or other authorization to practice medicine in such country.

(2) Institutional mission and objective.

(i) The medical school shall be organized and have in place a planning process that sets forth the responsibilities of all sectors of the school community and that sets the direction for its program and results in measurable outcomes.

(ii) The medical school shall have in place a system with central oversight to define the objectives of its program in outcome-based terms that facilitate assessment of student progress in developing essential physician competencies, and such objectives shall be made available to all medical students and to the faculty, residents, and others with direct responsibilities for medical student education and assessment.

(3) Faculty. The medical school shall have a sufficient number of appropriately qualified faculty members to meet the needs and missions of the program. The school shall provide for each faculty member regularly scheduled assessments of his or her academic performance. All faculty members shall be provided with opportunities to develop their skills as medical educators.

(4) Curriculum.

(i) The medical education program shall provide at least 130 weeks of instruction, and the curriculum of the medical school shall provide a general professional education and prepare medical students for entry into graduate medical education in any discipline.

(ii) The curriculum of the medical school shall incorporate the fundamental principles of medicine and its underlying scientific concepts; promote the development of skills of critical judgment based on evidence and experience; and develop medical students' abilities to use such principles and skills in solving problems of health and disease.

(iii) The medical school curriculum shall include didactic and clinical instruction necessary for students to become competent practitioners of contemporary medicine, including communication skills as they relate to physician responsibilities.

(iv) The medical school curriculum shall include clinical experience in a broad cross-section of areas, including, but not limited to, primary care. All clinical experiences shall be designed and implemented in such a manner as to ensure that students perform appropriate and progressive clinical responsibilities, and, regardless of the setting in which they are undertaken, shall be supervised by individuals appointed to the faculty of the medical school.

(v) The medical school shall provide instruction in medical ethics and human values, including, but not limited to, ethical principles in caring for patients and in relating to patients' families and to others involved in patient care.

(vi) The medical school shall demonstrate that there is integrated institutional responsibility for the overall design, management, and evaluation of a coherent and coordinated curriculum. The medical school faculty shall design, monitor, and periodically review and revise the objectives, content, and pedagogy of each segment of a medical school's curriculum, as well as of the curriculum as a whole.

(vii) The medical school shall demonstrate that it provides comparable educational experiences and equivalent methods of assessment across all instructional sites within a given discipline.

(5) Assessment of student performance. The medical school shall have a system in place for the effective assessment of medical student performance throughout the program. The system of student assessment shall employ a variety of measures of knowledge, skills, behaviors, and attitudes.

(6) Administration.

(i) Responsibilities.

(a) The chief academic officer of the medical school shall be responsible for the conduct and quality of the educational program and for ensuring the adequacy of resources, including faculty, at all instructional sites, and shall be given explicit authority to facilitate change in the medical program and to otherwise carry out his or her responsibilities for management and evaluation of the curriculum.

(b) Within the authority of the governing entity, the medical school shall collect and use a variety of outcome data, including accepted norms of accomplishment, to demonstrate the extent to which its educational objectives are being met, and shall engage in an ongoing systematic process to assess student achievement, program effectiveness, and opportunities for improvement.

(c) At least every other year, the medical school shall publish, either in print or online, information on policies and procedures on academic standards, grading, attendance, tuition and fees, refund policy, student promotion, retention, graduation, academic freedom, students' rights and responsibilities including a grievance policy and appeal procedures, the school's criteria for selecting students for admission, the application and admission processes, and other information pertinent to the student body.

(d) The medical school shall provide clinical clerkships in accordance with affiliation agreements that define the responsibilities of each party related to the educational program for medical students and section 60.2(d) of this Part. Such clerkships shall be conducted at health care settings in which there is appropriate oversight and supervision. The educational program for medical students shall remain under the control of the school's faculty at each instructional site, and such faculty shall monitor medical student experiences and modify them as necessary to ensure that the

objectives of the medical school are met. The medical school shall inform the Department of the clinical facilities with which it has affiliation agreements and of anticipated changes in its affiliation agreements or the affiliation status the clinical facilities.

(ii) Qualifications.

(a) The chief official of the medical school and the other members of the school administration shall be qualified by education and experience to provide leadership in medical education, scholarly activity, and patient care.

(b) The medical school shall have a sufficient number of appropriately qualified administrators to meet the needs and missions of the program.

(7) Admission. The medical school shall develop criteria, policies, and procedures for the selection of medical students that are readily available to potential and current applicants and their collegiate advisors. Such criteria, policies, and procedures shall be developed to select students who possess the intelligence, integrity, and personal and emotional characteristics necessary for them to become effective physicians.

(8) Student support services. The medical school shall have an effective system of academic advising and personal and career counseling for medical students that integrates the efforts of faculty members, course directors, and student affairs officers with its counseling and tutorial services.

(9) Published policies.

(i) The medical school shall establish, and make available to all sectors of the school community, policies regarding the standards of conduct for the faculty-student relationship, the standards and procedures for the assessment, advancement, and

graduation of its medical students, and the standards and procedures for disciplinary action.

(ii) Medical student educational records shall be confidential and shall be maintained in a manner that will ensure confidentiality as well as the accuracy of such records. Such records shall only be made available to those members of the faculty and administration and other administrative bodies or committees with a need to know, unless released by the medical student or as otherwise governed by laws concerning confidentiality. A medical student enrolled in the medical school shall be allowed to review the content and challenge information contained in his or her records if he or she considers the information contained therein to be inaccurate, misleading, or inappropriate.

(10) Resources. The medical school shall have sufficient resources, including, but not limited to, buildings, equipment, and didactic and clinical instructional resources, to achieve its educational and other goals.

(d) Procedures for approval.

(1) Application.

(i) In order to obtain approval by the Board of Regents to place students in long-term clinical clerkships in New York State, an international medical school shall submit an application, on a form prescribed by the Department. Applications shall remain in active status for three years from the date of receipt of such application. If the school fails to complete all requirements for approval within three years from the date of receipt of such application, the application may be deemed expired. If the school subsequently wishes to re-apply for approval, the school shall submit a new application with the required documentation. Institutions seeking renewal of approval shall submit a letter of intent to seek such renewal at least 18 months prior to the end date of the current

approval period, provided, however, that, for good cause shown, the Department may accept a letter of intent at a later time.

(ii) Self-study. A school shall be required to conduct and submit with its application for approval a self-study, substantiating compliance with the standards for approval set forth in this section and plans for improvements pertinent to such standards. Upon request from the Department, the institution shall submit supplemental materials.

(2) Site visit.

(i) When the Advisory Committee has made a preliminary determination that the application has adequately addressed the standards for approval set forth in this section, a site visit will be scheduled, and the Advisory Committee will designate a site visit team of no less than three members, selected from a list of qualified medical education program evaluators developed and maintained by the Department.

(ii) During the site visit, the medical school and its program will be reviewed to verify, clarify and update the representations contained within the application and any supporting documents. The medical school will bear the burden of demonstrating satisfactory compliance with the approval standards set forth in this section.

(3) Site visit report and recommendation. The site visit team shall prepare a site visit report and recommendation and provide a copy to the medical school prior to review by the Advisory Committee. The school shall be provided with an opportunity to respond to such report and recommendation and shall submit its response within 30 days after its receipt of the report. The response to the site visit report and recommendation shall be delivered to the Department no less than 60 days prior to the Advisory Committee meeting at which the medical school's application is scheduled to be considered. Unless good cause is shown, failure to file a timely response as

prescribed herein may result in forfeiture of the school's right to respond. In the case of new applications, failure to comply may result in the postponement of the consideration of the school's application.

(4) Advisory Committee.

(i) The Advisory Committee shall review the site review team's report and recommendation and any written submission by the school and the record upon which the site review team made its recommendation, including, but not limited to, the institution's self-study, the institution's application for approval, and any additional documentation submitted by the institution in support of the application. The Advisory Committee shall base its determination only upon the record before it.

(ii) Upon completion of its review, the Advisory Committee shall forward a report and recommendation to the Board of Regents. The Advisory Committee shall send a copy of its report and recommendation to the school by first class mail, return receipt requested and to the Board of Regents. The report shall include a recommendation to approve or deny the authority of the school to place students in long-term clinical clerkships in New York State and provide the rationale for the recommendation, reflecting majority and minority opinions.

(6) Board of Regents.

(i) The Board of Regents may review:

(a) the report and recommendation of the Advisory Committee;

(b) the record upon which the Advisory Committee made its recommendation, including, but not limited to, the site visit report and recommendation, the self study, the school's application for approval, and any additional documentation submitted by the institution in support of the application;

(c) any response submitted by the school to the report and recommendation of the Advisory Committee, provided that such submission shall be limited to a discussion of the documentary material already submitted and shall not contain new documentary material.

(ii) Based on the record described in subparagraph (i) of this paragraph, the Board of Regents will make a final determination on the application.

(e) Annual Report. No later than September 30 of each year, an international medical school that has been approved to place its students in long-term clinical clerkships in New York shall submit an annual report in a form prescribed by the Department. Upon receipt of the annual report, if the Advisory Committee determines that there may be a substantial change in the approved medical education program that could result in non-compliance with any of the approval standards set forth in this section, the Advisory Committee may recommend corrective action which may include a site visit, additional reporting requirements, submission of a new application and/or self-study, or revocation of approval or placement in probationary status by the Board of Regents.

(f) Revocation of approval or placement in probationary status. Upon a finding of substantial non-compliance with the approval standards set forth in this section, the Department or Advisory Committee may at any time during the approval period recommend to the Board of Regents that the approval be revoked or that the school be placed in probationary status in accordance with the following procedure:

(1) The Department or the Advisory Committee shall provide written notice to the school of its recommendation to revoke the school's approval or place the school in probationary status and the reasons therefor.

(2) The school may reply to such notification within 30 days. If no reply is received, the recommendation shall be forwarded to the Board of Regents for action.

(3) If a reply is received, such reply and the Department's or Advisory Committee's recommendation shall be forwarded to the Board of Regents for action thereon. Based on such recommendation and/or reply, the Board of Regents may:

(i) revoke the school's approval, subject to any conditions set by the Board of Regents;

(ii) continue its approval;

(iii) modify the time period for approval; and/or

(iv) place the school in probationary status.

(4) For purposes of this section, placement in probationary status shall mean the continued approval of the school by the Board of Regents for a specified period of time and subject to certain limitations, restrictions and/or remediation action as prescribed by the Board of Regents.

(g) Reporting requirements.

(1) The institution and /or school shall submit any reports requested by the Department, the Advisory Committee and/or the Board of Regents.

(2) The institution and/or school shall notify the Department of any denial, withdrawal, suspension, revocation, or termination of recognition, approval, accreditation or any other adverse action by any other body against the institution and/or school within 72 hours after receiving official notification of that action by providing to the Department a copy of such action.