TO: The Professional Practice Committee
FROM: Douglas E. Lentivech
SUBJECT: Proposed Amendment of Section 29.2 of the Rules of the Board of Regents and Addition of Section 52.47 and Subpart 79-19 to the Regulations of the Commissioner of Education Relating to the Licensure of Perfusionists
DATE: June 6, 2016
AUTHORIZATION(S):

SUMMARY

Issue for Discussion

Should the Board of Regents amend section 29.2 of the Rules of the Board of Regents and add a new section 52.47 and a new Subpart 79-19 to the Regulations of the Commissioner of Education relating to the licensure of licensed perfusionists?

Reason for Consideration

Required by State statute (L. 2013, Ch. 409).

Proposed Handling

The proposed rule will be presented to the Professional Practice Committee for discussion at the June 2016 meeting of the Board of Regents.

Procedural History

It is anticipated that a Notice of Proposed Rule Making will be published in the State Register on June 29, 2016. A copy of the proposed rule is attached. Supporting materials for the proposed rule are available upon request from the Secretary to the Board of Regents.
Background Information

A perfusionist is a highly specialized and highly skilled health care professional whose primary responsibility is to operate a heart-lung machine during open-heart surgery. In this capacity, a perfusionist is the only health professional with specialized training on the machinery and with the technology used to replace and support the patient’s circulatory and respiratory functions. During surgery, at the direction of the cardiac surgeon, the perfusionist redirects the circulation of a patient’s blood outside of his or her body and through artificial organs (heart, lung, and kidney) to temporarily relieve the patient of his or her dependence of his or her own organs. Perfusionists administer medications to stop the patient’s heartbeat and protect the heart while it is stopped. Perfusionists also reanimate the heart and are skilled at transferring the vital life-sustaining circulatory responsibilities back to the patient when the surgery is complete. Perfusionists are also experts in ventricular assist devices, artificial hearts, and membrane lungs. Perfusionists are skilled at interpreting patient data and managing patient circulatory and respiratory functions. Because the skills of the perfusionist are so specialized, they are an essential member of the surgical team and play a key role during transport of patients and organs supported by extracorporeal and intracorporeal technologies.

Chapter 409 of the Laws of 2013 amended the Education Law by adding Article 134, which establishes and defines the practice of the profession of perfusion, effective October 21, 2016. Previously, changes to the Education Law that required certain laboratory tests to be performed by licensed professionals had the unintended consequence of prohibiting perfusionists from independently performing tests essential to the proper operation of machines they operate during surgery. This forced perfusionists to get another licensed professional (a clinical laboratory technologist) to perform tests that they had previously performed independently while monitoring their machines. This situation created a risk of error in the operating room, and led to delays in surgery. To address this situation, Chapter 479 of the Laws of 2012, amended the Education Law by adding a new subdivision (9) to section 8609 of the Education Law, which allows perfusionists, through a temporary permit structure, to independently perform laboratory tests necessary to their job of running machines essential to certain procedures, including, but not limited to, open heart surgery and organ transplants. This temporary permit structure was set to expire on July 1, 2014. However, Chapter 409 extends this authorization to October 21, 2018. At that time, perfusionists will be able to apply to become licensed by the Department and, once licensed, they will be authorized by law to conduct the appropriate tests and use the equipment necessary to perform said tests.

The purpose of Chapter 409 is to establish the new profession of perfusion and to establish the licensure requirements for licensed perfusionists to perform perfusion services. Chapter 409 defines the practice of perfusion as the provision of extracorporeal or intracorporeal patient care services to support or replace the circulatory or respiratory function of a patient, including the administration of pharmacological and therapeutic agents, and blood products, and the management, treatment and monitoring of the physiological status of a patient during the operation of extracorporeal circulation equipment or intracorporeal equipment that replaces or support circulatory or respiratory functions. Chapter 409 further provides that all
perfusion services must be performed pursuant to the order and direction of a physician. In addition, Chapter 409 provides that perfusion services may be performed in a general hospital licensed pursuant to Article 28 of the Public Health Law or during the transport of patients or organs supported by extracorporeal or intracorporeal equipment.

Chapter 409 establishes the education, experience, examination, age, moral character and fee requirements for applicants seeking licensure as a licensed perfusionist. It also provides a grandparenting licensure pathway for individuals who meet the requirements for licensure as a licensed perfusionist except for examination, experience and education, if they submit an application to the Department on or before October 20, 2018 and meet one of the following sets of requirements: (1) they have practiced as a perfusionist for five years in the past 10 years in an inpatient unit that provides cardiac surgery services in a hospital approved by the Department of Health or a substantially equivalent accrediting body acceptable to the State Committee for Perfusion and the Department at least three of such years of experience having occurred during the past five years; or (2) they possess certification from a national certification organization acceptable to the State Committee for Perfusion and the Department and have been employed as a perfusionist for three of the past five years. Although this pathway will expire on October 20, 2018, the licenses issued under it will not.

The proposed amendment to subdivision (a) of section 29.2 of the Rules of the Board of Regents adds the profession of perfusion to the list of health care professions that are subject to its unprofessional conduct provisions.

The proposed addition of section 52.47 to the Regulations of the Commissioner of Education establishes the program registration requirements for professional education programs. These requirements include registration and curriculum requirements for programs offered in New York State that lead to licensure as a licensed perfusionist. The proposed amendment requires professional perfusionist education programs to be a program in perfusion or a substantially equivalent program as determined by the Department leading to a baccalaureate or higher degree; or a credit bearing certificate program in perfusion acceptable to the Department which ensures that each student holds a baccalaureate or higher degree; and which must include course content in each of the following subjects or their equivalent as determined by the department: (1) heart-lung bypass for patients undergoing heart surgery; (2) long-term supportive extracorporeal circulation; (3) monitoring of the patient undergoing extracorporeal circulation; (4) autotransfusion; and (5) special applications of the technology related to the practice of perfusion. The proposed amendment also requires licensure qualifying programs to include a supervised clinical experience, which is appropriate to the practice of perfusion, as such practice is defined in subdivision (3) of section 6630 of the Education Law, and incorporates and requires performance of an adequate number and variety of circulation procedures.

Additionally, the proposed addition of Subpart 79-19 to the Regulations of the Commissioner of Education establishes the requirements for licensure as a licensed perfusionist, which include, but are not limited to, education, experience, examination, fee and limited permit requirements, as well as the requirements for the grandparenting licensure pathway.
Timetable for Implementation

It is anticipated that the proposed rule will be presented for adoption at the September 2016 Regents meeting. If adopted at the September meeting, the proposed amendment will become effective October 21, 2016, which is the effective date of the statute.
AMENDMENT TO THE RULES OF THE BOARD OF REGENTS AND THE REGULATIONS OF THE COMMISSIONER OF EDUCATION

Pursuant to sections 207, 212, 6504, 6507, 6509, 6630, 6631, 6632, 6633, 6634, 6635, and 6636 of the Education Law, Chapter 409 of the Laws of 2013, and Chapter 479 of the Laws of 2012

1. Subdivision (a) of section 29.2 of the Rules of the Board of Regents is amended, effective October 21, 2016, as follows:

   (a) Unprofessional conduct shall also include, in the professions of: acupuncture, athletic training, audiology, certified behavior analyst assistant, certified dental assisting, chiropractic, creative arts therapy, dental hygiene, dentistry, dietetics/nutrition, licensed behavior analyst, licensed perfusionist, licensed practical nursing, marriage and family therapy, massage therapy, medicine, mental health counseling, midwifery, occupational therapy, occupational therapy assistant, ophthalmic dispensing, optometry, pharmacy, physical therapist assistant, physical therapy, physician assistant, podiatry, psychoanalysis, psychology, registered professional nursing, respiratory therapy, respiratory therapy technician, social work, specialist assistant, speech-language pathology (except for cases involving those professions licensed, certified or registered pursuant to the provisions of article 131 or 131-B of the Education Law in which a statement of charges of professional misconduct was not served on or before July 26, 1991, the effective date of chapter 606 of the Laws of 1991):

   (1) . . .
   (2) . . .
   (3) . . .
   (4) . . .
   (5) . . .
2. Section 52.47 of the Regulations of the Commissioner of Education is added, effective October 21, 2016, as follows:

§52.47 Licensed Perfusionist.

In addition to meeting all the applicable provisions of this Part, to be registered as a program recognized as leading to licensure as a licensed perfusionist, which meets the requirements of section 79-19.1 of this Title, the program shall:

(a) either:

(1) be a program in perfusion or a substantially equivalent program as determined by the department, which leads to a baccalaureate or higher degree; or

(2) be a credit bearing certificate program in perfusion acceptable to the department which ensures that each student holds a baccalaureate or higher degree;

(b) include course content in each of the following subjects or their equivalent as determined by the department:

(1) heart-lung bypass for patients undergoing heart surgery;

(2) long-term supportive extracorporeal circulation;

(3) monitoring of the patient undergoing extracorporeal circulation;
(4) autotransfusion; and

(5) special applications of the technology related to the practice of perfusion; and

(c) include a supervised clinical experience, which is appropriate to the practice of perfusion, as such practice is defined in subdivision (3) of section 6630 of the Education Law, and incorporates and requires performance of an adequate number and variety of circulation procedures.

3. Subpart 79-19 of the Regulations of the Commissioner of Education is added, effective October 21, 2016, to read as follows:

SUBPART 79-19

LICENSED PERFUSIONISTS

§79-19.1 Professional study for licensed perfusionists.

(a) As used in this section, an acceptable accrediting body for perfusion education programs shall mean an organization acceptable to the department as a reliable authority for the purpose of accreditation of perfusion education programs at the postsecondary level, which applies its criteria for granting accreditation of programs in a fair, consistent, and nondiscriminatory manner.

(b) To meet the professional educational requirement for licensure as a perfusionist, the applicant shall present satisfactory evidence of:

(1) holding a baccalaureate or higher degree in perfusion awarded upon the successful completion of a baccalaureate or higher degree program in perfusion registered as leading to licensure pursuant to section 52.47 of this Title or accredited by an acceptable accrediting body for perfusion education programs, or a baccalaureate or higher degree program that is substantially equivalent to such a registered program as determined by the department; or

(2) both:
(i) holding a baccalaureate or higher degree awarded upon the successful completion of a baccalaureate or higher degree program; and

(ii) completing a credit bearing certificate program in perfusion acceptable to the department which is accredited by an acceptable accrediting body for perfusion education programs or its equivalent as determined by the department; or

(3) completing, on or before October 20, 2018, a baccalaureate or higher degree and an accredited training program in perfusion acceptable to the department. Such training program must be accredited by an acceptable accrediting body for perfusion education programs but need not be a credit bearing program.

§79-19.2 Licensing examinations for licensed perfusionists.

(a) Content. The licensing examination shall consist of an examination designed to test knowledge, skills and judgment relating to all areas of perfusion, including, but not limited to, the basic science of perfusion, clinical applications of perfusion, and the practice of perfusion as defined in subdivision (3) of section 6630 of the Education Law.

(b) The department may accept a passing score on an examination determined by the department to be acceptable for licensure as a licensed perfusionist.

§79-19.3 Fees.

(a) Applicants shall pay a fee of $50 for an initial license and a fee of $150 for the first registration period.

(b) Licensees shall pay a fee of $150 for each triennial registration period.

§79-19.4 Limited permits.

As authorized by section 6635 of the Education Law, the department may issue a limited permit to practice perfusion in accordance with the requirements of this section.

(a) An applicant for a limited permit to practice as a licensed perfusionist shall:
(1) file an application with the department on a form prescribed by the department together with a fee of $105 for the limited permit;

(2) meet all the requirements for licensure as a licensed perfusionist, except the examination requirement; and

(3) practice as a perfusionist only under the supervision of a licensed perfusionist and pursuant to the order and direction of a physician.

(b) The limited permit in perfusion shall be valid for a period of not more than 12 months, provided that a limited permit may be extended for an additional 12 months at the discretion of the department for good cause as determined by the department. The time authorized by such limited permit and subsequent extension shall not exceed 24 months in total.

§79-19.5 Special provisions.

(a) An individual who meets the requirements for a license as a licensed perfusionist except for examination, experience and education and who meets the requirements enumerated under paragraphs (1) or (2) of this subdivision may be licensed without meeting additional requirements provided that such individual submits an application to the department on or before October 20, 2018:

(1) applicants may be licensed if they have been practicing as a perfusionist, as defined in subdivision (3) of section 6630 of the Education Law, for five years in the past ten years in an inpatient unit that provides cardiac surgery services in a hospital approved by the department of health or a substantially equivalent accrediting body acceptable to the State Committee for Perfusion and the department. At least three of such years of experience shall have occurred during the past five years; or

(2) applicants who possess certification from a national certification organization acceptable to the State Committee for Perfusion and the department may be licensed if
they have been employed as a perfusionist, as defined in subdivision (3) of section 6630 of the Education Law, for three of the past five years.