

<h1>Regulatory Analysis Form</h1> <p>(Completed by Promulgating Agency)</p> <p>(All Comments submitted on this regulation will appear on IRRC's website)</p>		<p>INDEPENDENT REGULATORY REVIEW COMMISSION</p> <p>RECEIVED</p> <p>MAR 30 2023</p> <p>Independent Regulatory IRRC Number Commission 3365</p>
<p>(1) Agency Department of State, Bureau of Professional and Occupational Affairs; State Board of Medicine</p>		
<p>(2) Agency Number: 16A Identification Number: 4954</p>		
<p>(3) PA Code Cite: 49 Pa. Code § 18.604</p>		
<p>(4) Short Title: Temporary Graduate Perfusionist</p>		
<p>(5) Agency Contacts (List Telephone Number and Email Address):</p> <p>Primary Contact: Shana M. Walter, Assistant Counsel, 2601 North Third Street, P.O. Box 69523, Harrisburg, PA 17106-9523; phone (717) 783-7200; fax (717) 787-0251; shanwalter@pa.gov.</p> <p>Secondary Contact: Jacqueline A. Wolfgang, Senior Regulatory Counsel, P.O. Box 69523, Harrisburg, PA 17106-9523; phone (717) 783-7200; fax (717) 787-0251 jawolfgang@pa.gov.</p>		
<p>(6) Type of Rulemaking (check applicable box):</p> <p><input type="checkbox"/> Proposed Regulation <input type="checkbox"/> Final Regulation <input checked="" type="checkbox"/> FINAL-OMITTED REGULATION</p>		<p><input type="checkbox"/> Emergency Certification Regulation; <input type="checkbox"/> Certification by the Governor <input type="checkbox"/> Certification by the Attorney General</p>
<p>(7) Briefly explain the regulation in clear and nontechnical language. (100 words or less)</p> <p>The Act of November 2, 2016 (P.L. 973, No. 11, 9) (Act 119 of 2016) repealed section 13.3(h)(1) of the Medical Practice Act (act) (63 P.S. § 422.13c(h)(1)), which set forth the temporary perfusionist license expiration upon examination failure provision. The rulemaking provides the necessary consistency between the act and the State Board of Medicine (Board) regulation.</p>		
<p>(8) State the statutory authority for the regulation. Include <u>specific</u> statutory citation.</p> <p>Section 16 of the act (63 P.S. § 422.8) authorizes the Board to adopt regulations as are reasonably necessary to carry out the purposes of the act. The Board proposes this rulemaking to conform its existing regulation to the new statutory provision in Act 119 of 2016. The Board implemented the operative terms of Act 119 of 2016 on or about its effective date of January 2, 2017.</p>		
<p>(9) Is the regulation mandated by any federal or state law or court order, or federal regulation? Are there any relevant state or federal court decisions? If yes, cite the specific law, case or regulation as well as, any deadlines for action.</p> <p>Yes, the regulation is mandated by the Act of November 2, 2016 (P.L. 973, No. 119) (Act 119 of 2016).</p>		

(10) State why the regulation is needed. Explain the compelling public interest that justifies the regulation. Describe who will benefit from the regulation. Quantify the benefits as completely as possible and approximate the number of people who will benefit.

The regulation is needed to provide consistency between the amendment to the act and the Board's regulations. Graduates of perfusion programs apply for a temporary graduate perfusion license, which, after issuance, allows the graduates to work in hospitals and earn the clinical experience required to sit for the exam and obtain the certification necessary for licensure. The license is issued for a period of two years and is nonrenewable. 63 P.S. § 422.13c(h)(1)(iii).

Prior to Act 119 of 2016, the act required that "the [temporary graduate] license shall expire immediately upon notice that the individual has failed the required examination under this act." *Id.* at § 422.13c(h)(2). The practical effect of this provision was that a graduate perfusionist license holder only had one opportunity to take and pass the perfusion examination. Examination failure was near-catastrophic to the career of a perfusionist candidate in the Commonwealth. The graduate license holder would typically lose their job at a hospital because the graduate license expired "immediately upon notice that the individual has failed the required examination under this act." *Id.*

Although the failure rate among first time test takers is low (for example, the failure rate for October 2020 nation-wide clinical examination was 4% or 7 examinees), with the amendment and this rulemaking, a holder of a temporary graduate perfusionist license is now permitted to take the examination more than once in the two-year period, if necessary, and may practice with the temporary license until they successfully complete the examination, or for two years, whichever occurs first.

The pool of licensed and/or certified perfusionists across the country is small. The Commonwealth exceeds surrounding states with 342 licensed perfusionists and one (1) temporary perfusionist. Perfusionists play a critical role in healthcare as operators of life support machines and life-sustaining equipment used during certain procedures. Thus, the Commonwealth's retention and attraction of licensed perfusionists is crucial to the care of its citizens.

(11) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulations.

There are no relevant federal standards.

(12) How does this regulation compare with those of the other states? How will this affect Pennsylvania's ability to compete with other states?

Less than half of states across the country require licensure of perfusionists; consequently, there are few states with temporary (or similar) perfusionist requirements. The deletion of the immediate expiration of temporary licenses will encourage perfusionists who have trained in the Commonwealth to remain, re-test and ideally obtain a standard license. According to the 2020 annual report of the certifying body, the American Board of Cardiovascular Perfusion, Pennsylvania has significantly more certified perfusionists residing in the state than many surrounding states.

Connecticut – The Connecticut General Statutes, Conn. Gen. Stat. § 20-162aa - 20-162cc, require a license for the practice of perfusion, specifically excludes from the licensure requirement the activities and

services by an intern or trainee and does not require any license for the intern or trainee. As of 2020, 63 certified perfusionists were residing in Connecticut.

Delaware – Delaware does not require licensure of perfusionists under its professional licensure act. The Delaware Code, Del. Code Ann. tit. 24, Ch. 17 (relating to licensure of physicians and allied professions). Delaware currently has 11 certified perfusionists residing in the state.

Maine – Maine’s professional and occupational licensure statutes are found in Title 32 of Main Revised Statutes (ME ST T. 32). Perfusionists are not required to be licensed by any of the allied health boards or the Board of Licensure in Medicine. There were 19 certified perfusionists residing in Maine at the time of the ABCP 2020 annual report.

Maryland – The Maryland Code, at Md. Code, Health Occ. § 14-5E-10, requires individuals training for the clinical examination to be licensed in a manner similar to Pennsylvania. In Maryland, the analogous license is referred to as a “perfusionist-basic” license. The license is valid for two years and allows the licensee to obtain the required training prior to the examination. The license is not subject to renewal or extension. Maryland has 65 licensed perfusionists residing in the state.

Massachusetts – Massachusetts regulations provide for a provisional perfusion license at 267 Mass. Reg. § 3.06. This scope of this license is similar to Pennsylvania’s temporary perfusion license. The provisional perfusion license automatically expires upon failure of the examination unless the holder applies for a one-year extension within thirty (30) days of the examination failure. Massachusetts currently has 84 certified perfusionists residing in the state.

New Hampshire – The New Hampshire Statutory scheme relating to professional and licensure and certification, N.H. Rev. Stat. § 310-A:1 of the Revised Statutes of New Hampshire does not require a license to practice perfusion. See also N.H. Rev. Stat. § 328-F:3 (relating to allied health professions).

New Jersey – New Jersey Statutes provide for a temporary perfusionist license in NJ. Stat. § 45:9-37.106. The license is valid for one year and can be renewed for one additional year. There are 135 certified perfusionists residing in New Jersey.

New York – Under the New York Education Law, a perfusionist training for the clinical examination is licensed through a limited permit. This permit is valid for one year and may be renewed for an additional year. See NY Educ. L § 6635. There are 223 certified perfusionists residing in New York.

Ohio – The statutes relating to occupational and professional licensure in Ohio are found in Title 47 of the Ohio Revised Code (OH ST T. XLVII). Title 47 does not contain any provisions relating to licensure of perfusionists. There are 227 certified perfusionists residing in Ohio.

Rhode Island – The professional licensing provisions applicable to health-related professions are found in the General Laws of Rhode Island. The General Laws of Rhode Island, R.I. Gen. Laws § 23-1, et. seq., do not contain a licensure requirement for perfusionists. There are four certified perfusionists in Rhode Island.

Virginia – The Virginia Department of Health Professions is governed by Title 54.1, Chapter 25. This chapter contains laws governing all health professions. Perfusionists are not a health profession subject to this, or any other statutory scheme, in the Commonwealth of Virginia. There are 92 certified perfusionists in Virginia.

West Virginia – The licensing of professions and occupations in West Virginia derives authority from Chapter 30 of the West Virginia Code. Chapter 30 does not require licensure of perfusionists. There are currently 25 certified perfusionists in West Virginia.

The Board believes removal of the immediate expiration of temporary licenses upon examination failure will make the Commonwealth more competitive. The temporary license provisions of surrounding states do not contain immediate expiration provisions. Therefore, with the removal of this provision, the Commonwealth is similarly situated to other states in attracting and retaining perfusionists.

(13) Will the regulation affect any other regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

No, this regulation will not affect any other regulations of the Bureau or any other state agency.

(14) Describe the communications with and solicitation of input from the public, any advisory council/group, small businesses and groups representing small businesses in the development and drafting of the regulation. List the specific persons and/or groups who were involved. (“Small business” is defined in Section 3 of the Regulatory Review Act, Act 76 of 2012.)

The Pennsylvania State Perfusion Society, which was instrumental in promoting the statutory amendment, is aware of and in support of the Board’s amendment to its regulation. Because this regulation is implementing a specific statutory amendment in the act, and the Board merely updated the regulations to reflect the statutory change, the Board did not engage in extensive public outreach and did not distribute an exposure draft prior to adopting this final-omitted regulation.

(15) Identify the types and number of persons, businesses, small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012) and organizations which will be affected by the regulation. How are they affected?

This regulation will affect graduates of perfusion programs and, by extension, hospitals and health systems. The number of persons affected is wholly dependent upon the number of applicants for the license type. Historically, the board receives less than ten applications annually for a temporary perfusionist license. Currently, the Board has one active temporary perfusionist license. Perfusionist trainees will benefit from the ability to re-take the certification examination should exam failure occur.

According to the Pennsylvania Department of Labor and Industry in 2020 (the most recent year for which data is available), perfusionists are not singularly categorized, but rather, are included in the category of “cardiovascular technologists and technicians.” Cardiovascular technologists and technicians held about 58,200 jobs in 2020. Cardiovascular technologists and technicians are employed in the following private sector positions: hospitals; state, local, and private (78%); offices of physicians (10%); outpatient care centers (3%); and medical laboratories (1%).

Small businesses are defined in Section 3 of the Regulatory Review Act, (71 P.S. § 745.3) which provides that a small business is defined by the SBA’s Small Business Size Regulations under 13 CFR Ch. 1 Part 121. These size standards have been established for types of businesses under the North American Industry Classification System (NAICS). In applying the NAICS standards to the types of businesses where licensees may work, the following businesses would be categorized as a small business as follows: general or surgical hospitals that have \$41.5 million or less in average annual receipts; offices of physicians that

have \$12.0 million or less in average annual receipts; outpatient care centers that have \$22.0 million or less in average annual receipts; and medical laboratories that have \$35.0 million or less in average annual receipts. Based upon this information, the Board believes that for the most part, the businesses that employ perfusionists would not be classified as small businesses. Even so, businesses such as hospitals and health systems, who employ cardiovascular technologists and technicians, will reap the benefits of the potential increase in the number of licensed perfusionists in their systems. To the extent that licensees are employed by small businesses, those businesses will also reap the benefits of the change in the law and regulations.

(16) List the persons, groups or entities, including small businesses, that will be required to comply with the regulation. Approximate the number that will be required to comply.

Annually, less than ten perfusionists training for the certification examination will be required to comply with the rulemaking.

(17) Identify the financial, economic and social impact of the regulation on individuals, small businesses, businesses and labor communities and other public and private organizations. Evaluate the benefits expected as a result of the regulation.

There are no adverse impacts associated with this regulation on individuals, small businesses, or any other entity. Perfusionists training for the certification examination will benefit by being afforded additional opportunities to take and pass the certification examination and continue to earn an income while doing so. Hospitals and health systems will benefit by the potential increase in perfusionists in training and the consequential fully licensed perfusionists.

(18) Explain how the benefits of the regulation outweigh any cost and adverse effects.

There are no costs or adverse effects of this regulation.

(19) Provide a specific estimate of the costs and/or savings to the **regulated community** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

There are no costs to the regulated community associated with this rulemaking.

(20) Provide a specific estimate of the costs and/or savings to the **local governments** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

There are no costs to local governments associated with this rulemaking.

(21) Provide a specific estimate of the costs and/or savings to the **state government** associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required. Explain how the dollar estimates were derived.

There are no costs or savings associated with the implementation of the regulation. All necessary changes to the Board's administrative process for this license type were implemented upon the passage of Act 119.

(22) For each of the groups and entities identified in items (19)-(21) above, submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.

Because this regulation mirrors the amendment made by Act 119 of 2016, which act has already been implemented by the Board, there are no additional procedures, reporting, recordkeeping or other paperwork required for implementation.

(22a) Are forms required for implementation of the regulation?

No.

(22b) If forms are required for implementation of the regulation, **attach copies of the forms here**. If your agency uses electronic forms, provide links to each form or a detailed description of the information required to be reported. **Failure to attach forms, provide links, or provide a detailed description of the information to be reported will constitute a faulty delivery of the regulation.**

N/A

	Current FY 21-22	FY +1 22-23	FY +2 23-24	FY +3 24-25	FY +4 25-26	FY +5 26-27
SAVINGS:						
Regulated Community	\$0	\$0	\$0	\$0	\$0	\$0
Local Government	\$0	\$0	\$0	\$0	\$0	\$0
State Government	\$0	\$0	\$0	\$0	\$0	\$0
Total Savings	\$0	\$0	\$0	\$0	\$0	\$0
COSTS:						
Regulated Community	\$0	\$0	\$0	\$0	\$0	\$0
Local Government	\$0	\$0	\$0	\$0	\$0	\$0
State Government	\$0	\$0	\$0	\$0	\$0	\$0
Total Costs	\$0	\$0	\$0	\$0	\$0	\$0
REVENUE LOSSES:						
Regulated Community	\$0	\$0	\$0	\$0	\$0	\$0
Local Government	\$0	\$0	\$0	\$0	\$0	\$0
State Government	\$0	\$0	\$0	\$0	\$0	\$0
Total Revenue Losses	\$0	\$0	\$0	\$0	\$0	\$0

(23a) Provide the past three-year expenditure history for programs affected by the regulation.

Program	FY -3 FY 18-19	FY -2 FY 19-20	FY -1 FY 21-22	Current FY FY 22-23 (budgeted)
State Board of Medicine	\$6,583,495.52	\$7,791,240.60	\$6,575,141.64	\$7,145,000.00

(24) For any regulation that may have an adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), provide an economic impact statement that includes the following:

- (a) An identification and estimate of the number of small businesses subject to the regulation.
- (b) The projected reporting, recordkeeping and other administrative costs required for compliance with the proposed regulation, including the type of professional skills necessary for preparation of the report or record.
- (c) A statement of probable effect on impacted small businesses.
- (d) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation.

Because the regulation has no adverse impact on small business, no economic impact statement was developed.

(25) List any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, the elderly, small businesses, and farmers.

There are no provisions developed to meet the particular needs of affected person or groups; the regulation mirrors an amendment to the act.

(26) Include a description of any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome acceptable alternative has been selected.

No alternative regulatory provisions have been considered because the regulation is required by Act 119 of 2016.

(27) In conducting a regulatory flexibility analysis, explain whether regulatory methods were considered that will minimize any adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), including:

- a) The establishment of less stringent compliance or reporting requirements for small businesses;
- b) The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;
- c) The consolidation or simplification of compliance or reporting requirements for small businesses;

- d) The establishment of performance standards for small businesses to replace design or operational standards required in the regulation; and
- e) The exemption of small businesses from all or any part of the requirements contained in the regulation.

As this rulemaking has no adverse impact on small business, no regulatory flexibility analysis was conducted.

(28) If data is the basis for this regulation, please provide a description of the data, explain in detail how the data was obtained, and how it meets the acceptability standard for empirical, replicable and testable data that is supported by documentation, statistics, reports, studies or research. Please submit data or supporting materials with the regulatory package. If the material exceeds 50 pages, please provide it in a searchable electronic format or provide a list of citations and internet links that, where possible, can be accessed in a searchable format in lieu of the actual material. If other data was considered but not used, please explain why that data was determined not to be acceptable.

The regulation is not based upon any data.

(29) Include a schedule for review of the regulation including:

- | | |
|-----------------------------------------------------------------------------------------------|--------------------|
| A. The length of the public comment period: | <u>N/A</u> |
| B. The date or dates on which any public meetings or hearings will be held: | <u>N/A</u> |
| C. The expected date of delivery of the final-form regulation: | <u>Fall 2022</u> |
| D. The expected effective date of the final-form regulation: | <u>Winter 2023</u> |
| E. The expected date by which compliance with the final-form regulation will be required: | <u>N/A</u> |
| F. The expected date by which required permits, licenses or other approvals must be obtained: | <u>N/A</u> |

(30) Describe the plan developed for evaluating the continuing effectiveness of the regulations after its implementation.

This rulemaking is a direct result of the passage of Act 119 of 2016. Therefore, the effectiveness will be evaluated at such intervals that may be required to ensure consistency with the act. The Board meets six times per year, with the remaining meetings for 2022 scheduled for the following dates: August 10, 2022, October 12, 2022, and December 14, 2022.

CDL-1

**FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU**

(Pursuant to Commonwealth Documents Law)

RECEIVED

MAR 30 2023

**Independent Regulatory
Review Commission**

DO NOT WRITE IN THIS SPACE

<p>Copy below is hereby approved as to form and legality. Attorney General</p> <p>BY: _____ (DEPUTY ATTORNEY GENERAL)</p> <p>_____ DATE OF APPROVAL</p> <p><input type="checkbox"/> Check if applicable Copy not approved. Objections attached.</p>	<p>Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by:</p> <p>Commissioner of Professional and Occupational Affairs _____ (AGENCY)</p> <p>DOCUMENT/FISCAL NOTE NO. <u>16A-4954</u></p> <p>DATE OF ADOPTION: _____</p> <p><i>Mark B. Woodland</i> BY: <u>Mark B. Woodland, M.D., M.S.</u></p> <p>TITLE <u>CHAIRMAN</u> (EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)</p>	<p>Copy below is hereby approved as to form and legality. Executive or Independent Agencies.</p> <p>BY: <i>[Signature]</i> _____ (Deputy General Counsel) (Chief Counsel, Independent Agency) (Strike inapplicable title)</p> <p><u>July 21, 2022</u> DATE OF APPROVAL</p> <p><input type="checkbox"/> Check if applicable. No Attorney General approval or objection within 30 days after submission.</p>
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FINAL RULEMAKING (WITH PROPOSED OMITTED)

**COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
STATE BOARD OF MEDICINE**

**49 PA. CODE CHAPTER 18
SUBCHAPTER J**

§ 18.604

APPLICATION FOR TEMPORARY GRADUATE PERFUSIONIST LICENSE

The State Board of Medicine (Board) proposes amends § 18.604 (relating to application for temporary graduate perfusionist license) to read as set forth in Annex A.

Effective date

The amendments will be effective upon notice or publication in the *Pennsylvania Bulletin*.

Statutory Authority

By the Act of November 2, 2016 (P.L. 973, No. 119) (Act 119 of 2016), section 13.3(h)(1) of the Medical Practice Act (act) (63 P.S. § 422.13c(h)(1)) was amended to delete the provision which provided that a temporary graduate perfusionist license expires immediately upon notice that the license holder has failed the examination required for licensure. Section 16 of the act (63 P.S. § 422.8) authorizes the Board to adopt regulations as are reasonably necessary to carry out the purposes of the act. The Board proposes this rulemaking to conform its existing regulation to the new statutory provision.

Background and Purpose

In order to qualify for licensure as a perfusionist in this Commonwealth, an applicant must hold current National certification from the American Board of Cardiovascular Perfusion (ABCP). To obtain National certification, an individual must have successfully completed the ABCP certification examination. The certification examination consists of two parts: the Perfusion Basic Science Examination (PBSE) and the Clinical Applications in Perfusion Examination (CAPE). The ABCP places no limits on the number of times an individual may take the PBSE or CAPE. Graduates of perfusion education programs are eligible to sit for the PBSE. Graduates of perfusion education programs who have completed at least 40 independent perfusions may sit for the CAPE.

The board may issue a temporary graduate license to practice perfusion to an individual who has graduated from an educational program, which allows the graduate to practice perfusion under direct supervision of a licensed perfusionist. 63 P.S. § 422.13c(h). The temporary permit allows individuals to complete the experiential requirement that is prerequisite to taking the CAPE.

Prior to Act 119 of 2016, the act required that “the [temporary graduate] license shall expire immediately upon notice that the individual has failed the required examination under this act.” *Id.* at 422.13c(h)(1)(iv). The practical effect of this provision was that a graduate perfusionist license holder only had one opportunity to take and pass the perfusion examination. Examination failure was near-catastrophic to the career of a perfusionist candidate in the Commonwealth. The graduate license holder would typically lose their job at a hospital because the graduate license expired “immediately upon notice that the individual has failed the required examination under this act.” *Id.*

To conform Pennsylvania’s requirements to national standards, the General Assembly enacted the Act 119 of 2016, which deleted the provision that made the temporary license expire if the license-holder failed the PBSE or CAPE.

The Board’s existing regulation, at 49 Pa. Code § 18.604(e), reflects the outdated and repealed provision requiring immediate expiration of the temporary graduate perfusionist license. Section 18.604(e) must be amended to reflect Act 119 of 2016. The Board has determined that this amendment is necessary to align the Board’s regulations with the self-executing provisions of Act 119 of 2016.

Omission of Proposed Rulemaking

Under section 204 of the Commonwealth Documents Law (CDL) (45 P.S. § 1204), the Board is authorized to omit the procedures for proposed rulemaking in sections 201 and 202 of the CDL (45 P.S. §§ 1201 and 1202) if the Board finds that the specified procedures are impracticable, unnecessary or contrary to the public interest. The Board has determined that publication of proposed rulemaking is unnecessary under the circumstances because Act 119 of 2016 requires the Board to amend its regulations to conform to the statutory amendment. The Board is thus promulgating this rulemaking a final-omitted regulation under the Regulatory Review Act, with notice of proposed rulemaking omitted under section 204 of the CDL.

Description of Amendments

Act 119 deleted the existing statutory provision which provided: “The license shall expire immediately upon notice that the individual has failed the required examination under this act.” The Board proposes to amend § 18.604 by rescinding subsection (e) to conform the regulation with the statutory amendment. Subsection (e) provides that “A temporary graduate perfusionist license expires upon notice to the Board that the holder has failed the Nationally-recognized certifying agency’s certification examination. The holder of a temporary graduate perfusionist license who fails the examination shall immediately cease practicing and return the license to the Board.”

Fiscal Impact and Paperwork Requirements

There is no fiscal impact, and no paperwork requirements are associated with this regulation, which conforms the Board’s regulations to current statutory provisions.

Regulatory Review

Under section 5.1(c) of the Regulatory Review Act (71 P.S. § 745.5a(c)), on March 30, 2023, the Board submitted copies of the regulation with final-form rulemaking, with proposed rulemaking omitted to the Independent Regulatory Review Commission (IRRC), chairpersons of the Senate Consumer Protection and Professional Licensure Committee (SPC/PLC) and the House Professional Licensure Committee (HPLC). On the same date, the Board submitted a copy of the regulation to the Office of Attorney General pursuant to section 204(b) of the Commonwealth Attorneys Act (71 P.S. §§ 732-204(b)).

Under sections 5.1(e) and (j.2) of the RRA (71 P.S. § 745.5a(e) and (j.2)), the regulations were deemed approved by the SPC/PLC and the HPLC on _____, 2022, and were approved by IRRC on _____, 2022, after IRRC’s public meeting on _____, 2022. OAG approved the final-omitted rulemaking on _____, 2022.

Additional Information

For additional information about the amendment, submit inquires to Shana M. Walter, Counsel, State Board of Medicine, P.O. Box 69523, Harrisburg, Pennsylvania 17106-9523, or by email to RA-STRegulatoryCounsel@pa.gov,

Findings

The Board finds that:

(1) Public notice of the Board’s intention to amend its regulations under the procedures in sections 201 and 202 of the Commonwealth Documents Law (CDL) (45 P.S. §§ 1201 and 1202) has been properly omitted for good cause under section 204 of the CDL (45 P.S. § 1204) because public comment is unnecessary given that the amendments adopted by this order are required to conform to the amendments to the Medical Practice Act of 1985.

(2) The amendment of the Board’s regulations in the manner provided in this order is necessary and appropriate for the administration of the Medical Practice Act.

Order

The Board, acting under its authorizing statute, orders that:

(a) The regulations of the Board hereby are amended at 49 Pa. Code § 18.604 to read as set forth in Annex A.

(b) The Board shall submit this order and Annex A to the Office of General Counsel and the Office of Attorney General for approval as to form and legality as required by law.

(c) The Board shall submit this order and Annex A to the Independent Regulatory Review Commission, SPC/PLC and the HPLC as required by law.

(d) The Board shall certify this order and Annex and deposit them with the Legislative Reference Bureau as required by law.

(e) This order shall take effect upon notice or publication in the *Pennsylvania Bulletin*.

Mark B. Woodland, M.S., M.D.,
Board Chair

ANNEX A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 18. STATE BOARD OF MEDICINE—PRACTITIONERS OTHER THAN

MEDICAL DOCTORS

* * * * *

Subchapter J. PERFUSIONISTS

* * * * *

§ 18.604. Application for temporary graduate perfusionist license.

(a) An applicant for a temporary graduate perfusionist license shall submit, on forms made available by the Board, a completed application, including the necessary supporting documents, and pay the fee in § 16.13(l) (relating to licensure, certification, examination and registration fees) for an application for a temporary graduate perfusionist license.

(b) The Board may grant a temporary graduate perfusionist license, which authorizes the license holder to practice only under the supervision and direction of a perfusionist licensed under the act, to an applicant who:

(1) Demonstrates that the applicant is eligible for and has applied to sit for the examination of a certifying agency approved by a Nationally-recognized accrediting agency approved by the Board.

(2) Demonstrates that the applicant has graduated from an accredited perfusion program approved by the Board.

(3) Demonstrates that the applicant is at least 18 years of age and of good moral character.

(4) Demonstrates that the applicant has obtained professional liability insurance as required under section 13.3(k) of the act (63 P. S. § 422.13c(k)).

(5) Otherwise complies with this subchapter.

(c) The Board may deny an application for a temporary graduate perfusionist license upon the grounds for disciplinary action in § 18.609 (relating to disciplinary action for licensed perfusionists).

(d) A temporary graduate perfusionist license expires 2 years after the date of the issuance and may not be renewed.

[(e) A temporary graduate perfusionist license expires upon notice to the Board that the holder has failed the Nationally-recognized certifying agency's certification examination. The holder of a temporary graduate perfusionist license who fails the examination shall immediately cease practicing and return the license to the Board.]



COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF MEDICINE
Post Office Box 2649
Harrisburg, Pennsylvania 17105-2649
(717) 783-7099

March 30, 2023

The Honorable George D. Bedwick, Chairman
INDEPENDENT REGULATORY REVIEW COMMISSION
14th Floor, Harristown 2, 333 Market Street
Harrisburg, Pennsylvania 17101

Re: Final Omitted Regulation
State Board of Medicine
16A-4954: Application for Temporary Graduate Perfusionist License

Dear Chairman Bedwick:

Enclosed is a copy of a final rulemaking package of the State Board of Medicine pertaining to 16A-4954: Application for Temporary Graduate Perfusionist License.

The Board will be pleased to provide whatever information the Commission may require during the course of its review of the rulemaking.

Sincerely,

A handwritten signature in cursive script, appearing to read "Mark B. Woodland".

Mark B. Woodland, M.S., M.D. Chairperson
State Board of Medicine

MBW/smw
Enclosure

cc: Arion Claggett, Acting Commissioner of Professional and Occupational Affairs
K. Kalonji Johnson, Deputy Secretary for Regulatory Programs
Andrew LaFratte, Executive Policy Specialist, Department of State
Cynthia Montgomery, Deputy Chief Counsel, Department of State
Jacqueline A. Wolfgang, Regulatory Unit Counsel, Department of State
Shana M. Walter, Counsel, State Board of Medicine
State Board of Medicine

From: [Smeltz, Jennifer](#)
To: [Christman, William](#)
Subject: RE: DELIVERY: Regulations 16A-4954 + 16A-5332 (Stefano)
Date: Thursday, March 30, 2023 10:14:48 AM

Received.

Jen Smeltz
Executive Director
Office of Senator Pat Stefano
Consumer Protection and Professional Licensure Committee
Phone: (717) 787-7175

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MAR 30 2023

Independent Regulatory
Review Commission

From: Christman, William <wchristman@pa.gov>
Sent: Thursday, March 30, 2023 8:38 AM
To: Smeltz, Jennifer <jmsmeltz@pasen.gov>
Subject: DELIVERY: Regulations 16A-4954 + 16A-5332 (Stefano)
Importance: High

Ⓞ CAUTION : External Email Ⓞ

Please provide written (email) confirmation of receipt of the delivery of the attached rulemakings.

Please be advised that the State Board of Medicine and the State Board of Osteopathic Medicine are delivering the following final omitted rulemakings:

- 16A-4954 Temporary Graduate Perfusionist-medical (final omitted)
 - This final-omitted rulemaking resolves an inconsistency between the Medical Practice Act, as amended by the Act of November 2, 2016 (P.L. 973, No. 119) (Act 119 of 2016) and the Board's regulations related to the temporary licensure of perfusionists. Act 119 of 2016 removed the provision from the practice act requiring immediate expiration of a temporary perfusionist license upon failure of the required examination. The rulemaking mirrors Act 119.
- 16A-5332 Temporary Graduate Perfusionist-osteo (final omitted)
 - This final-omitted rulemaking resolves an inconsistency between the Osteopathic Medical Practice Act, as amended by the Act of November 2, 2016 (P.L. 974, No. 120) (Act 120 of 2016) and the Board's regulations related to the temporary licensure of perfusionists. Act 120 of 2016 removed the provision from the practice act requiring immediate expiration of a temporary perfusionist license upon failure of the required examination. The rulemaking mirrors Act 120.

William Christman | Legal Assistant II
Office of Chief Counsel | Department of State
Governor's Office of General Counsel
P.O. Box 69523 | Harrisburg PA 17106 - 9523
Phone: 717.783.7200 | Fax: 717.787.0251
wchristman@pa.gov | www.dos.pa.gov

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MAR 30 2023

From: Francesca Summa
To: Christman, William; Nicole Sidle
Subject: RE: DELIVERY: Regulations 16A-4954 + 16A-5332 (Metzgar)
Date: Thursday, March 30, 2023 9:39:43 AM

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Received, thank you.

For the second rule, is it 16A-5332 or 16A-5334? I just need to clarify for filing purposes.

Thank you!
Francesca Summa

From: Christman, William <wchristman@pa.gov>
Sent: Thursday, March 30, 2023 8:39 AM
To: Nicole Sidle <nsidle@pahousegop.com>; Francesca Summa <fsumma@pahousegop.com>
Subject: DELIVERY: Regulations 16A-4954 + 16A-5332 (Metzgar)
Importance: High

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PRIVILEGED AND CONFIDENTIAL COMMUNICATION

From: Barton, Jamie
To: Christman, William; Orchard, Kari L.; Brett, Joseph D.
Subject: RE: DELIVERY: Regulations 16A-4954 + 16A-5332 (Burns)
Date: Thursday, March 30, 2023 9:08:18 AM

Received, thank you!

Ms. Jamie Barton
Senior Legislative Assistant
Office of State Rep. Frank Burns, Majority Chairman
House Professional Licensure Committee
332 Main Capitol
Harrisburg, PA 17120-2072
(717) 772-8056 - Phone
(717) 772-9965 - Fax

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From: Christman, William <wchristman@pa.gov>
Sent: Thursday, March 30, 2023 8:39 AM
To: Orchard, Kari L. <KOrchard@pahouse.net>; Barton, Jamie <JBarton@pahouse.net>; Brett, Joseph D. <JBrett@pahouse.net>
Subject: DELIVERY: Regulations 16A-4954 + 16A-5332 (Burns)
Importance: High

Please provide written (email) confirmation of receipt of the delivery of the attached rulemakings.

Please be advised that the State Board of Medicine and the State Board of Osteopathic Medicine are delivering the following final omitted rulemakings:

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From: Rolko, Seth
To: Christman, William; Vazquez, Enid
Subject: RE: DELIVERY: Regulations 16A-4954 + 16A-5332 (Boscola)
Date: Thursday, March 30, 2023 10:17:52 AM

Independent Regulatory
Review Commission

Received. Thanks.

From: Christman, William <wchristman@pa.gov>
Sent: Thursday, March 30, 2023 8:39 AM
To: Rolko, Seth <seth.rolko@pasenate.com>; Vazquez, Enid <Enid.Vazquez@pasenate.com>
Subject: DELIVERY: Regulations 16A-4954 + 16A-5332 (Boscola)
Importance: High

■ EXTERNAL EMAIL ■

Please provide written (email) confirmation of receipt of the delivery of the attached rulemakings.

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From: Elliott, Amy M.
To: Rizzi, Alicia (GC)
Cc: Trotter, Carolyn; Abelson, Addie
Subject: RE: [EXTERNAL] DOS Final-Omitted Regulation #16A-4954
Date: Thursday, March 30, 2023 1:14:56 PM

Receipt acknowledged

Amy M. Elliott
Chief Deputy Attorney General
Legal Review Section
717-783-6316 (w)
717-941-0523 (c)
aelliott@attorneygeneral.gov

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MAR 30 2023

Independent Regulatory
Review Commission

From: Rizzi, Alicia (GC) <arizzi@pa.gov>
Sent: Thursday, March 30, 2023 1:12 PM
To: Elliott, Amy M. <aelliott@attorneygeneral.gov>
Cc: Trotter, Carolyn <ctrotter@attorneygeneral.gov>; Abelson, Addie <adabelson@pa.gov>
Subject: [EXTERNAL] DOS Final-Omitted Regulation #16A-4954
Importance: High

CAUTION: This email originated from outside the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Good afternoon,

Attached please find the Department of State's final-omitted regulation #16A-4954.

Please provide an acknowledgement of receipt by replying to this email at your earliest convenience.

Thank you,

Alicia C. Rizzi | Legal Office Administrator
Governor's Office of General Counsel
Commonwealth of Pennsylvania
333 Market Street Tower, 17th Floor | Harrisburg, PA 17101
Phone: 717.810.7290 | Fax: 717.787-1788
arizzi@pa.gov | www.ogc.pa.gov

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