

RULES AND REGULATIONS

Title 49—PROFESSIONAL AND VOCATIONAL STANDARDS

STATE BOARD OF MEDICINE

[49 PA. CODE CHS. 16 AND 18]

Naturopathic Doctors; Advance Notice of Final Rulemaking

The State Board of Medicine (Board) is publishing an advance notice of final rulemaking (ANFR) seeking additional comment regarding key terms and definitions and corresponding amendments incorporating the key terms, as well as amendments to address clarity and lack of ambiguity. The proposed rulemaking was published at 51 Pa.B. 7877 (December 18, 2021).

Statutory Authority

The Naturopathic Doctor Registration Act (NDRA) (63 P.S. §§ 272.101—272.301), specifically, section 207 of the NDRA (63 P.S. § 272.207), provides that “[t]he board shall enforce and administer the provisions of this act and shall promulgate regulations that are consistent with the intent of this act.”

Background and Summary

The Board published this proposed rulemaking on December 18, 2021, seeking to provide the regulatory provisions necessary to implement the NDRA. The Board entertained public comment for 30 days and received comments from multiple perspectives, including naturopathic doctors, patients and State and local naturopathic doctor associations. Following the close of the public comment period, the Board received comments from the Independent Regulatory Review Commission (IRRC), as well as a legislative comment from the Honorable Senator Doug Mastriano.

The comments submitted by IRRC offer several suggestions as to the manner in which the proposed regulation could be amended to provide clarity and cure ambiguity, as well as eliminate non-regulatory language. Additionally, the comments submitted by IRRC suggest several key terms, if left undefined, would fail to provide an administrable and enforceable regulatory scheme. IRRC further commented that this lack of clarity would inhibit compliance by the regulated community. Specifically, IRRC seeks a definition of “naturopathic medicine,” “commercial activity,” “naturopathic evaluation,” “naturopathic service,” “naturopath or traditional naturopath,” “naturopathy,” “natural substances,” “naturopathic substances,” “naturopathic plan of service,” “service regimen” and “purveyors of merchandise or services.”

The Board reviewed these comments, among others, and concluded that the NDRA, by authorizing the Board to impose discipline when a naturopathic doctor provides a medical service below the standard of care, and further authorizing the Board to define the accepted standard of care, contains the requisite statutory authority for the Board to define several of the key terms for purposes of establishing the standard of care. Consequently, the Board is adding additional terms and definitions to the definition section, as well as corresponding ancillary amendments. The key terms being defined are: “naturopathic medicine” (relating to use of naturopathic physical medicine, natural therapies or counseling), “naturopathic physical medicine” (relating to use of physi-

cal agents and modalities), “naturopathic service” (relating to providing or performing naturopathic physical medicine, natural therapies or counseling) and “natural therapies” (relating to treatment utilizing plant, mineral or fungal derived active ingredients). In addition, the Board determined the terms “commercial activity” and “purveyor of merchandise or services” could be replaced with the term “marketing activity” (relating to a communication about a service or merchandise), thereby providing clarity that may have been lacking.

The Board is also amending the draft final-form rulemaking to address several other concerns of IRRC, including amending non-regulatory language and providing language evidencing the intent of the Board as it relates to financial disclosures. An additional amendment is being made to clarify a naturopathic doctor’s duties beyond the specific list contained in the section relating to ethics.

Contact Person, Availability of Final Regulations and Submission of Comments

The Board will accept comments by mail as well as comments transmitted by means of e-mail on the draft final-form rulemaking. Comments will not be accepted by facsimile, telephone or voicemail. Comments sent by e-mail must include the following in the subject field of the transmission: “Comments on 16A-4953—Naturopathic Doctors ANFR.” Comments submitted by mail as well as written comments must include the commenter’s name and address. Written comments must be received by the Board within 30 days of the publication of this notice in the *Pennsylvania Bulletin*. To request a copy of the draft final-form rulemaking or to provide a comment, contact Shana M. Walter, Board Counsel, State Board of Medicine, P.O. Box 69523, Harrisburg, PA 17106-5923 or RA-STRegulatoryCounsel@pa.gov.

MARK B. WOODLAND, MS, MD,

Chairperson

[Pa.B. Doc. No. 23-726. Filed for public inspection June 2, 2023, 9:00 a.m.]

Title 49—PROFESSIONAL AND VOCATIONAL STANDARDS

STATE BOARD OF MEDICINE

[49 PA. CODE CH. 18]

Application for Temporary Graduate Perfusionist License

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

Effective Date

This final-omitted rulemaking will be effective upon 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 of 1985 (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 8 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 adopts this final-omitted rulemaking to conform its existing regulation to the new statutory provision.

Background and Purpose

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 63 P.S. § 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 this 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 the Commonwealth’s requirements to National standards, the General Assembly enacted Act 119 of 2016 to delete 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 a 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 a 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 regulation as a final-

omitted rulemaking under the Regulatory Review Act (RRA) (71 P.S. §§ 745.1—745.14), with notice of proposed rulemaking omitted under section 204 of the CDL.

Description of Amendments

Act 119 of 2016 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 amends § 18.604 by deleting 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 associated with this final-omitted rulemaking, which conforms the Board’s regulations to current statutory provisions.

Regulatory Review

Under section 5.1(c) of the RRA (71 P.S. § 745.5a(c)), on March 30, 2023, the Board submitted copies of the final-omitted rulemaking, with a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC), the 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 final-omitted rulemaking to the Office of Attorney General under section 204(b) of the Commonwealth Attorneys Act (71 P.S. § 732-204(b)).

Under section 5.1(e) and (j.2) of the RRA (71 P.S. § 745.5a(e) and (j.2)), on May 17, 2023, the final-omitted rulemaking was deemed approved by the SPC/PLC and the HPLC. Under section 5.1(e) of the RRA, IRRC met on May 18, 2023, and approved the final-omitted rulemaking. OAG approved the final-omitted rulemaking on April 24, 2023.

Additional Information

For additional information about the amendment, submit inquiries to Shana M. Walter, Counsel, State Board of Medicine, P.O. Box 69523, Harrisburg, PA 17106-9523, or by e-mail 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 CDL has been properly omitted for good cause under section 204 of the CDL 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 (63 P.S. §§ 422.1—422.53).

(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 of 1985.

Order

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

(a) The regulations of the Board, 49 Pa. Code Chapter 18, are amended by amending § 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 IRRC, 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, MS, MD,
Chairperson

(Editor's Note: See 53 Pa.B. 3055 (June 3, 2023), for IRRC's approval order.)

Fiscal Note: 16A-4954. No fiscal impact; recommends adoption.

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) [Reserved].

[Pa.B. Doc. No. 23-727. Filed for public inspection June 2, 2023, 9:00 a.m.]

Title 49—PROFESSIONAL AND VOCATIONAL STANDARDS

STATE BOARD OF OSTEOPATHIC MEDICINE

[49 PA. CODE CH. 25]

Application for Temporary Graduate Perfusionist License

The State Board of Osteopathic Medicine (Board) amends § 25.804 (relating to application for temporary graduate perfusionist license) to read as set forth in Annex A.

Effective Date

This final-omitted rulemaking will be effective upon publication in the *Pennsylvania Bulletin*.

Statutory Authority

By Act 120 of November 2, 2016 (P.L. 974, No. 120) (Act 120 of 2016), section 13.3(h) of the Osteopathic Medical Practice Act (act) (63 P.S. § 271.13c(h)), 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. § 271.16) authorizes the Board to adopt regulations as are reasonably necessary to carry out the purposes of the act. The Board adopts this final-omitted rulemaking to conform its existing regulation to the new statutory provision.

Background and Purpose

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. 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. § 271.13c(h)(2). The temporary permit allows individuals to complete the experiential requirement that is prerequisite to taking the CAPE.

Prior to Act 120 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 63 P.S. § 271.13c(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 this 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 the Commonwealth’s requirements to National standards, the General Assembly enacted Act 120 of 2016 to delete the provision which provided that the temporary license would expire if the license-holder failed the PBSE or CAPE. The Board must now conform its regulations to the statute.

The Board’s existing regulation at 49 Pa. Code § 25.804(e) reflects the outdated and repealed provision requiring immediate expiration of the temporary graduate perfusionist license. Section 25.804(e) must be amended to reflect Act 120 of 2016. The Board has determined that this amendment is necessary to align the Board’s regulations with the self-executing provisions of Act 120 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 a 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 a proposed rulemaking is unnecessary under the circumstances because Act 120 of 2016 requires the Board to amend its regulations to conform to the statutory amendment. The Board is thus promulgating this regulation as a final-omitted rulemaking under the Regulatory Review Act (RRA) (71 P.S. §§ 745.1—745.14), with notice of proposed rulemaking omitted under section 204 of the CDL.

Description of Amendment

Act 120 of 2016 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 amends § 25.804 by deleting subsection (e) to conform the regulation with the statutory amendment. Subsection (e) currently 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 associated with this final-omitted rulemaking which conforms the Board’s regulations to current statutory provisions.

Regulatory Review

Under section 5.1(c) of the RRA (71 P.S. § 745.5a(c)), on March 30, 2023, the Board submitted copies of the final-omitted rulemaking, with a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC), 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 final-omitted rulemaking to the Office of Attorney General under section 204(b) of the Commonwealth Attorneys Act (71 P.S. § 732-204(b)).

Under section 5.1(e) and (j.2) of the RRA (71 P.S. § 745.5a(e) and (j.2)), on May 17, 2023, the final-omitted rulemaking was deemed approved by the SPC/PLC and the HPLC. Under section 5.1(e) of the RRA, IRRC met on May 18, 2023, and approved the final-omitted rulemaking. OAG approved the final-omitted rulemaking on April 24, 2023.

Additional Information

For additional information about the amendment, submit inquires to Shana M. Walter, Counsel, State Board of Osteopathic Medicine, P.O. Box 69523, Harrisburg, PA 17106-9523 or by e-mail 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 CDL has been properly omitted under section 204 of the CDL because public comment is unnecessary given that the amendments adopted by this order are required to conform to the amendments to the Osteopathic Medical Practice Act (63 P.S. §§ 271.1—271.18).

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

Order

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

(a) The regulations of the Board, 49 Pa. Code Chapter 25, are amended by amending § 25.804 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 IRRC, the 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*.

WILLIAM B. SWALLOW, DO,
Chairperson

(*Editor’s Note:* See 53 Pa.B. 3055 (June 3, 2023), for IRRC’s approval order.)

Fiscal Note: 16A-5332. No fiscal impact; recommends adoption.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 25. STATE BOARD OF OSTEOPATHIC MEDICINE

Subchapter N. PERFUSIONISTS

§ 25.804. 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 § 25.231 (relating to schedule of 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. § 271.13c(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 § 25.809 (relating to disciplinary action for licensed perfusionists).

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

(e) [Reserved].

[Pa.B. Doc. No. 23-728. Filed for public inspection June 2, 2023, 9:00 a.m.]