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## **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

[53 Pa.B. 2961] [Saturday, June 3, 2023]

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 physical 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

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