

# Comments of the Independent Regulatory Review Commission



## State Board of Medicine Regulation #16A-4953 (IRRC #3324)

### Registration of Naturopathic Doctors

February 17, 2022

We submit for your consideration the following comments on the proposed rulemaking published in the December 18, 2021 *Pennsylvania Bulletin*. Our comments are based on criteria in Section 5.2 of the Regulatory Review Act (71 P.S. § 745.5b). Section 5.1(a) of the Regulatory Review Act (71 P.S. § 745.5a(a)) directs the State Board of Medicine (Board) to respond to all comments received from us or any other source.

**1. Compliance with the provisions of the RRA or the regulations of the Commission in promulgating the regulation; Determining whether the regulation is in the public interest; and Clarity and lack of ambiguity.**

This proposed rulemaking implements the Naturopathic Doctor Registration Act (NDRA) (63 P.S. §§ 272.101-272.301) by amending the Board's existing Chapter 16 and 18 (relating to State Board of Medicine—general provisions; and State Board of Medicine—practitioners other than medical doctors) by adding a new Subchapter M (relating to the registration of naturopathic doctors) to Chapter 18, including setting the fees for the initial and biennial renewal of registration.

Section 5.2 of the RRA (71 P.S. § 745.5b) directs this Commission to determine whether a regulation is in the public interest. When making this determination, the Commission considers criteria such as economic or fiscal impacts, reasonableness, and need. To make that determination, the Commission must analyze the text of the proposed rulemaking and the reasons for the new or amended language. The Commission also considers the information a promulgating agency is required to provide under Section 745.5(a) in the Regulatory Analysis Form (RAF).

The Board explains in its response to RAF #26 that it elected to not enact any regulations which address the authorized scope of practice because the legislature did not provide a basic statutory framework to determine what does, and what does not constitute the practice of the profession. Furthermore, a review of the legislative history indicates the intent of the legislature was to enact a “title protection act, and not a true practice act.” Given the Board's explanation, we would

note that there are provisions of the proposal that conflict with its approach regarding the scope of practice. For instance:

- Section 18.15a(d) (relating to scope of practice of acupuncturists and practitioners of Oriental medicine) is being added to clarify that “[t]his section does not limit the **scope of practice of a naturopathic doctor** when recommending herbs, minerals and other supplements, or combinations, according to traditions other than Oriental medicine traditions.” [Emphasis added.]
- Section 18.911(c)(8) (relating to Code of ethics), a naturopathic doctor shall “[a]ccurately inform the patient, other health care professionals and the public of the **limitations of the practice of naturopathic medicine.**” [Emphasis added.]
- Section 18.911(d)(3) (relating to Code of ethics) states that a naturopathic doctor may not “engage in a commercial activity which conflicts with the **duties of a naturopathic doctor.**” [Emphasis added.]
- Section 18.911(e) (relating to Code of ethics) reads, “[a] naturopathic doctor may not perform a service or provide a service that the naturopathic doctor is not qualified to perform, or which is **beyond the scope of the naturopathic doctor’s education, training, capabilities or experience.**” [Emphasis added.]

The Board should either eliminate any references to the scope of practice, limitations of naturopathic medicine, or duties of a naturopathic doctor in the final version of this rulemaking or explain how these provisions are consistent with the legislature’s intent. Should the Board retain these provisions in the final-form regulation, it should describe how it will determine alleged violations of these particular sections. See 63 P.S. § 272.204(6)

## **2. Clarity and lack of ambiguity.**

“Naturopathic medicine” appears in several sections of the statute and regulatory proposal. The Board notes that the NDRA omits any definition for “naturopathic medicine,” but it does not explain why it did not include an interpretation of the term in the proposed regulation. Notwithstanding the Board’s discussion and position regarding the scope of practice, we question how the act will be administered and enforced and whether compliance by the regulated community can be attained if there is not a common understanding of what naturopathic medicine is.

Additionally, there are several other “key terms” used throughout the rulemaking for which there are no definitions. They include: “commercial activity,” “naturopathic evaluation,” “naturopathic service,” “naturopath or traditional naturopath,” “naturopathy” “natural substances,” “naturopathic plan of service,” “service regimen,” and “purveyors of merchandise or services.” In order for this Commission to determine whether the regulation is in the public interest, it must have a complete understanding of key terms used in the rulemaking. The Board

should define these essential terms in the final version of this regulation, or explain why it is unnecessary to do so and how it is in the public interest.

### **3. Non-regulatory language. – Clarity and lack of ambiguity; Implementation procedures.**

A regulation has the full force and effect of law. We have concerns related to the use of non-regulatory language, which does not establish standards that could be predicted by the regulated community, found throughout the proposed regulation. For example:

- Section 18.911(c)(3) reads, “**Adequately safeguard** confidential patient information, including storage and disposal of records.” [Emphasis added.]
- Section 18.911(c)(8) reads, “**Accurately inform** the patient, other health care professionals and the public of the **limitations of the practice of naturopathic medicine.**” [Emphasis added.]
- Section 18.911(c)(9) reads, “**Adequately assess** the patient to determine if contraindications against naturopathic service exist and refer the patient to an appropriate health care practitioner.” [Emphasis added.]
- Section 18.911(c)(11)(iv) reads, “Cooperate with any lawful investigation conducted by the Board, including all of the following: . . . Providing **meaningful and timely** access to relevant patient records.” [Emphasis added.]
- Section 18.911(d)(1) states, “A naturopathic doctor may not: Misrepresent credentials, qualifications or affiliations, and **shall attempt to correct others** who misrepresent the naturopathic doctor’s credentials, qualifications or affiliations.” [Emphasis added.]

These emphasized phrases do not set binding norms and lack clarity. For that reason, consistent implementation of these provisions by the Board and compliance by the regulated community could be difficult. We ask the Board to review the final-form regulation to ensure the use of regulatory language, setting clear compliance standards for the regulated community to meet.

### **4. Implementation procedures and timetables for compliance by the public and private sectors.**

RAF #29 asks the promulgating agency to include a schedule for review of the regulation including the expected date of delivery of the final-form regulation, the expected effective date of the final-form regulation, and the expected date by which compliance with the rulemaking will be required. In each of these instances, the Board identified “Winter 2021-2022.” The Board should amend its response to RAF #29 to reflect an updated estimate of the timeline for the final-form regulation.

**Chapter 16. State Board of Medicine—General Provisions**  
**Subchapter B. General License, Certification and Registration Provisions**

**5. Section 16.13. Licensure, certification, examination and registration fees. –Clarity and Economic or fiscal impacts.**

The Board proposes to add the Application for initial registration fee of \$100 and a biennial registration renewal fee of \$50 to the fee schedule. In RAF #17, the Board states that registrants that allow their registration to lapse would be required to pay a **\$100 reactivation fee.** [ Emphasis added.] The Board should submit a revised final-form regulation that includes the reactivation fee or explain why it is not needed.

The Board submitted a Fee Report Form for Naturopathic Doctor Initial Registration Application but did not submit Fee Report Forms for the processing of biennial renewal applications or applications for reactivation of naturopathic doctor registration. Fee Report Forms for every fee listed in this section should be included in the final rulemaking package.

**Chapter 18. State Board of Medicine –Practitioners Other than Medical Doctors**  
**(New) Subchapter M. Registration of Naturopathic Doctors**

**6. Section 18.903. Application for naturopathic doctor registration. – Clarity and Implementation procedures.**

Section 18.904(b)(2) and (3) and Section 18.905(b)(3) and (4) require a registrant, as a condition of biennial renewal and reactivation of inactive or expired registration, to disclose on the application any authorization to practice as a naturopathic doctor in another, district, territory, possession or country and whether or not there is disciplinary action pending before or taken by the appropriate licensing, registration or certification authority in another jurisdiction since the most recent application for biennial registration, whether or not authorized to practice or advertise in that other jurisdiction. We believe these disclosures are equally relevant to the initial application for naturopathic doctor registration and should be included in Section 18.903 or explain why it is unnecessary to do so.

**7. Section 18.905. Inactive status; reactivation of inactive or expired registration. – Clarity and Implementation procedures; and Economic or fiscal impacts.**

*Subsection (a)*

This subsection provides that a naturopathic doctor may request in writing that the Board place the registration on inactive status. It states that confirmation of inactive status will be forwarded to the registrant. We ask the Board to specify when the inactive status request becomes effective.

Under this subsection, a naturopathic doctor may not use the title of “naturopathic doctor” or “doctor of naturopathic medicine” or any other term implying that the individual is currently registered as a naturopathic doctor while on inactive status. The Board should revise this provision to include “or has an expired registration.”

*Subsection (b)*

Section 18.905(b)(1) requires a registrant, in order to reactivate an inactive or expired registration, in addition to completing an application for reactivation, to pay the **current biennial registration fee** in Section 16.13 (relating to licensure, certification, examination and registration fees) and any applicable late fees required under section 225 of the Bureau of Professional and Occupational Affairs Fee Act (63 P.S. § 1401-225). [Emphasis added.]

As previously noted, the Board writes in RAF #17 that only practitioners that allow their registration to lapse would be required to pay the \$100 reactivation fee. This section, however, does not address the “reactivation fee.” The Board should clarify its intent regarding the fees that are to be charged to a registrant under this section and make any necessary revisions to the RAF, Preamble, and Annex to the final-form regulation for consistency with the Board’s intent.

**8. Section 18.907. Acceptable titles and professional designation by registrants and non-registrants; prohibited titles. – Clarity and lack of ambiguity.**

*Subsection (b)*

Section 201 of the NDRA states: “It shall be unlawful for an individual to use the title of “naturopathic doctor” or “doctor of naturopathic medicine” unless that person is registered as a naturopathic doctor with the Board.” 63 P.S. § 272.201

Several commentators, including the statewide organization representing a group of traditional naturopaths, contend that the General Assembly did not intend to “preclude the use of “N.D.” by unregistered traditional naturopaths. If the General Assembly intended for the Board to regulate the use of the abbreviation “N.D.,” it would have retained the language that expressly prohibits unlicensed individuals from using it. They believe the Board’s proposal not only creates uncertainty among traditional naturopaths regarding the continued use of their degree but also causes public confusion. Additionally, they are concerned that it may impose a significant financial burden upon traditional naturopaths who may be required to revise signage and advertisements.

Senator Doug Mastriano requests that consideration be given for naturopathic doctors who have obtained their degrees and certifications in naturopathy from other schools not included in this proposed rulemaking. He believes that the proposal, if unamended, could be detrimental financially and professionally to the “thousands of naturopathic doctors and traditional naturopathic doctors” who have practiced for many generations. Given there is even a question

concerning the intentions of the legislature in passing the NDRA and this section, he asserts, is reason enough to “pause and revisit the issue.” Furthermore, he writes, “[i]t is unconscionable to restrict current naturopathic doctors of their titles and use of the term “Doctor of Naturopathy” which is their livelihood in such a manner and without cause on their part.”

Senator Mastriano and a number of commentators request that the Board amend Section 18.907(b) to provide that “[a]n individual who has not registered with the Board may claim to be, and hold oneself out as, a naturopath, a traditional naturopath, **DOCTOR OF NATUROPATHY, OR N.D.** and use any similar title implying that the individual practices naturopathy so long as the title does not also imply that the individual is a naturopathic doctor registered with the Board.” Emphasis added. The Commission, in its determination of whether this rulemaking is in the public interest, will review the Board’s response to commentators’ concerns.

**9. Section 18.908. Informed consent and disclosure of financial interests. – Clarity and lack of ambiguity.**

Subsection (b) reads that “[a] naturopathic doctor shall disclose to patients and prospective patients if the naturopathic doctor receives any commission, rebate, referral fee or similar financial incentive in connection with the referral of a patient to purveyors of merchandise or services, or for recommending any merchandise to a patient.” § 18.908(b)

Under Section 18.911 (relating to code of ethics) a naturopathic doctor may not “engage in commercial activity which conflicts with the duties of a naturopathic doctor” or “receive remuneration from, or provide remuneration to, or split a fee, for either making or accepting a referral of the patient to or from another health care provider.” §§ 18.911(d)(3) and (8)

We have three concerns. First, Section 18.908(b) requires disclosure to patients and prospective patients for behavior that is clearly prohibited under Section 18.911. Second, as mentioned previously in the discussion related to the Definitions section, the proposal is deficient in defining key terms such as “*purveyors of merchandise or services*,” and “*commercial activity*.” Third, the proposal is void of any specificity regarding the “duties of a naturopathic doctor.” Without the benefit of clearly defined terms and professional benchmarks, how will the regulated community comply with these financial disclosure requirements and code of ethics standards? The Board should submit a final rulemaking that makes clear its intent regarding financial disclosure and that is consistent with the code of ethics standards.

**10. Section 18.911. Code of Ethics. – Clarity and lack of ambiguity; and Reasonableness of requirement.**

*Subsection (f)*

Under this subsection, “[a] naturopathic doctor may not construe any failure to specify a particular ethical, legal or professional duty in this subchapter as a denial of the existence of other ethical, legal or professional duties or responsibilities that are equally as important and generally recognized in the naturopathic medicine profession.” The Board should delete this provision from the final-form regulation or explain the reasonableness of holding to account practitioners for duties and responsibilities that have not been specified. The Board should also explain how it will be enforced if it is carried over to the final version of this rulemaking.

#### **11. Section 18.913. Grounds for discipline. – Clarity.**

##### *Subsection (a)*

Section 18.913 (a)(8) authorizes the Board to impose disciplinary or corrective measures on a naturopathic doctor or applicant for registration as a naturopathic doctor for “[o]ffering, undertaking or agreeing to cure or treat a disease by a **secret** method, treatment, product or medicine.” [Emphasis added.] The Board should clarify its intent and explain the need for this provision in a revised Preamble to the final-form regulation.

##### *Subsection (b)*

The NDRA provides that “. . . [a] naturopathic doctor affected under this paragraph shall at **reasonable intervals** be afforded an opportunity to demonstrate that he can resume a competent practice of his profession with reasonable skill and safety to patients. 63 P.S. § 272.204(5)(iv). [Emphasis added.] The Board should provide a detailed description of how it will administer this provision in the final-form regulation.

#### **12. Miscellaneous. – Clarity.**

For consistency with the act, should §18.903(b)(3) read “An applicant who graduated prior to 1986 shall demonstrate a passing score on a state naturopathic **licensure** examination?” [Emphasis added.]

The final-form regulation should be amended to consistently use the terms “initial registration” and “naturopathic service.”