Regulatory Analysis Form

(Completed by Promulgating Agency)

(All Comments submitted on this regulation will appear on IRRC's website)

(1) Agency

Department of State, Bureau of Professional and Occupational Affairs, State Board of Medicine

(2) Agency Number: 16A

Identification Number: 4953

REVIEW COMMISSION RECEIVED

INDEPENDENT REGULATORY

Independent Regulatory Review Commission January 18, 2024

IRRC Number: 3324

(3) PA Code Cite:

49 Pa. Code §§ 16.1, 16.11—16.13, 18.13a, 18.15, 18.15a and 18.901—18.913

(4) Short Title: **Registration of Naturopathic Doctors**

(5) Agency Contacts (List Telephone Number and Email Address):

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(6) Type of Rulemaking (check applicable box):	
Droposed Pegulation	Emergency Certification

☐ Proposed Regulation ☐ Final Regulation ☐ Final Omitted Regulation nergency Certification Regulation; Certification by the Governor Certification by the Attorney General

(7) Briefly explain the regulation in clear and nontechnical language. (100 words or less)

The final-form rulemaking will promulgate regulations to implement the Naturopathic Doctor Registration Act (NDRA) (63 P.S. §§ 272.101—272.301). The rulemaking sets forth necessary definitions utilized in the rulemaking; application, renewal and reinstatement requirements; requires the display of registration; sets forth acceptable professional titles and prohibited titles; requires informed consent and disclosure of financial interests in products and services; and requires the maintenance and production of naturopathic medical records. The rulemaking also sets forth standards for advertising; ethical conduct; prohibits sexual misconduct and sets forth potential grounds for discipline as well as the sanctions which may be imposed by the Board. Additionally, it establishes fees for initial registration and biennial renewal of registration. The Board is also taking this opportunity to remove outdated references relating to "drugless therapists."

(8) State the statutory authority for the regulation. Include <u>specific</u> statutory citation.

The primary statutory authority to regulate the registration of naturopathic doctors is the Naturopathic Doctor Registration Act (NDRA) (63 P.S. 272.101—272.301). Specifically, section 207 of the NDRA 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." (63 P.S. § 272.207) Further, section 203(b) of the NDRA (63 P.S. § 272.203(b)) provides the authority of the Board to require naturopathic doctor registrations to be renewed "in a manner and at such intervals as the board shall determine by regulation." Sections 202(6) and 203(c) of the NDRA (63 P.S. § 272.202(6) and 272.203(c)) set forth the authority of the Board to set fees for initial registration and biennial renewal of registration. The Board sets all fees by regulation.

The Board is also taking this opportunity to update its regulations and to remove outdated provisions in the Board's existing regulations relating to "drugless therapists" under the authority of Section 8 of the Medical Practice Act of 1985 (act) (63 P.S. § 422.8), which provides, in part, that, "[t]he board, in the exercise of its duties under this act, shall have the power to adopt such regulations as are reasonably necessary to carry out the purposes of this act." This authority necessarily includes the power to repeal provisions of the regulations that are no longer necessary.

(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.

No. The rulemaking is not mandated by any federal or state law or court order, or federal regulation.

The Board's decision to eliminate references to drugless therapists was guided, but not required, by *Reisinger v. Com., State Bd. of Med. Ed. & Licensure*, 399 A.2d 1160 (Pa. Cmwlth. 1979).

Reisinger involved an individual trained as a chiropractor and naturopathic doctor who petitioned for licensure as a "drugless therapist," but was denied because the Board determined that the Board no longer had the authority to license drugless therapists. On appeal, the Commonwealth Court agreed, holding that although the Board could continue to register and regulate persons engaged in the practice of drugless therapy, "the Board lacks the authority now to license Drugless Therapists." Since 1951 (1 month after the State Board of Chiropractic began operations), the Board has continued to biennially register/renew existing drugless therapist licenses and has continued to regulate their practice, but has not issued new licenses. No individual currently holds an active license as a drugless therapist from the Board. The last remaining individual who held an active license as a drugless therapist did not renew his license in 2016 and it is the Board's understanding that he died in December of 2014, shortly after submitting his renewal application for the 2015-2016 renewal period. The prior two most recent licensees of the Board last renewed their licenses in 2008. Therefore, it appears that all individuals who held a license as a drugless therapist have either retired from practice or are deceased and it is no longer necessary to keep any references to drugless therapists in the Board's regulations. This is especially true now that the Board will be registering individuals as naturopathic doctors under this rulemaking.

(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 final-form rulemaking is necessary to implement the NDRA – legislation which has not been the subject of previous regulation. Those entitled to registration will benefit from the regulations in that it will set forth the requirements for registration and renewal and provide guidance and standardization to common issues such as advertising, ethical guidelines, informed consent and financial disclosures.

For purposes of this rulemaking, the Board assumes that between 100 and 250 individuals will initially meet the requirements for registration as a naturopathic doctor set forth in the NDRA and the final-form rulemaking. The two closest accredited naturopathic medicine schools are located in Connecticut and Illinois, respectively. It is impossible to determine how many individuals may elect to locate/relocate to the Commonwealth now that there will be state-authorized registration. The Board assumes that after it completes the initial round of registering individuals currently satisfying the requirement for registration, it will receive approximately 10 new naturopathic doctor applications each year.

Consumers of the services of naturopathic doctors will benefit by the regulations because they would be assured that a registered naturopathic doctor meets the qualifications contained in the NDRA and the regulations and will be bound by the Code of Ethics and other standards set forth in the regulations. The general public would also benefit from the ability to file complaints related to unethical or unprofessional conduct by registered naturopathic doctors.

(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 Federal standards for the licensing or registration of naturopathic doctors.

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

A review of the laws and regulations of the various states in the Northeast region indicates that only Connecticut, Maine, Maryland, New Hampshire, Rhode Island and Vermont currently regulate naturopathic doctors. In Massachusetts, a law providing for the licensure of naturopathic doctors was passed in 2017, but no licenses have been issued yet. It is our understanding that they are in the process of promulgating regulations at this time. Delaware, New York, New Jersey, Ohio and West Virginia do not regulate naturopathic doctors. The following is a review of the requirements for naturopathic doctors in those states in the Northeast region that regulate their practice.

Connecticut:

The Connecticut State Board of Naturopathic Examiners regulates the practice of naturopathy in that state. To practice naturopathy, one must be licensed as a naturopathic physician. In order to be eligible for licensure, an applicant must have: Completed two (2) years of pre-professional college education; graduated from a school of naturopathy approved by the Connecticut State Board of Naturopathic Examiners and Department of Public Health, with award of the Doctor of Naturopathy degree. Approved schools include only those schools accredited or in candidate status with the Council

on Naturopathic Medical Education (CNME); and successfully completed both the Basic Sciences (Part I) and Clinical Sciences Examination (Part II) of the Naturopathic Physician Licensing Examination (NPLEX). The initial application fee is \$565. The license is renewable annually at a fee of \$570. "Reinstatement" of a lapsed license requires a fee of \$565. Unlike Pennsylvania, Connecticut has a true "practice act" and defines the practice of naturopathy as "the science, art and practice of healing by natural methods as recognized by the Council of Naturopathic Medical Education and that comprises diagnosis, prevention and treatment of disease and health optimization by stimulation and support of the body's natural healing processes, as approved by the State Board of Naturopathic Examiners, with the consent of the Commissioner of Public Health, and shall include (1) counseling; (2) the practice of the mechanical and material sciences of healing as follows: The mechanical sciences such as mechanotherapy, articular manipulation, corrective and orthopedic gymnastics, physiotherapy, hydrotherapy, electrotherapy and phototherapy; and the material sciences such as nutrition, dietetics, phytotherapy, treatment by natural substances and external applications; (3) ordering diagnostic tests and other diagnostic procedures as such tests and procedures relate to the practice of mechanical and material sciences of healing as described in subdivision (2) of this subsection; (4) ordering medical devices and durable medical equipment; and (5) removing ear wax, spirometry, tuberculosis testing and venipuncture for blood testing. For purposes of this section, "natural substances" means substances that are not narcotic substances, as defined in subdivision (30) of section 21a-240, do not require the written or oral prescription of a licensed practitioner to be dispensed and are only administered orally." CT ST Chapter 373, § 20-34. There do not appear to be any restrictions on the use of titles.

Maine:

The Maine Board of Complementary Health Care Providers licenses naturopathic doctors in that state. The initial licensure fee is \$180, with an annual renewal fee of \$180. To be eligible for a license to practice naturopathic medicine, the applicant must be a graduate of an approved naturopathic medical college and pass or have passed a competency-based examination approved by the board, covering the appropriate naturopathic subjects, including basic and clinical sciences.

Maine also has a true practice act in that a person may not practice naturopathic medicine or profess to be a naturopathic doctor without holding a license. The scope of practice of a naturopathic doctor in Maine is set forth by statute as follows: A naturopathic doctor may use and order for preventative and therapeutic purposes the following natural medicines and therapies: food, food extracts, vitamins, minerals, enzymes, digestive aids, whole gland thyroid and other natural hormones, plant substances, all homeopathic preparations, immunizations, counseling, hypnotherapy, biofeedback, dietary therapy, naturopathic manipulative therapy, naturopathic physical medicine, therapeutic devices, barrier devices for contraception and office procedures. Naturopathic doctors may also prescribe medications, including natural antibiotics and topical medicines; may use physical examinations for diagnostic purposes including phlebotomy, clinical laboratory tests, speculum examinations and physiological function tests, excluding all endoscopies and physiological function tests requiring infusion, injection, inhalation or ingestion of medications to perform tests; may order ultrasound, x-ray and electrocardiogram tests but must refer to an appropriate licensed health care professional for conducting and interpreting the tests; may prescribe therapeutic devices or use noninvasive diagnostic procedures commonly used by allopathic or osteopathic physicians in general practice; and have a limited scope of prescriptive authority (nonprescription and noncontrolled drugs). ME ST T. 32 § 12522. In Maine, a licensee must use the title "naturopathic doctor." Naturopathic doctors have the exclusive right to the use of the terms "naturopathic doctor," "naturopathic," "naturopath," "doctor of naturopathic medicine," "doctor of naturopathy," "naturopathic medicine," "naturopathic health care," "naturopathy" and the recognized abbreviation "N.D." Use of the title "physician" by the licensee is prohibited.

<u>Maryland</u>:

The Maryland State Board of Medicine licenses naturopathic doctors in that state. The qualifications for a license as a naturopathic doctor includes possession of a doctorate in naturopathic medicine from an approved naturopathic medical program; successful completion of the licensing examination, Part I and Part II, administered by NABNE or its successor agency and demonstration of oral and written competency in English. In addition, a naturopathic doctor must have a "consultation and collaboration" agreement" with a licensed physician. The initial application fee is \$790, and the biennial renewal fee is \$512. In Maryland, a naturopathic doctor may order and perform physical and laboratory examinations for diagnostic purposes, including phlebotomy, clinical laboratory tests, orificial examinations, electrocardiograms with over read by a cardiologist, and physiological function tests; order diagnostic imaging studies and interpret the reports of diagnostic imaging studies; dispense or order natural medicines (foods, vitamins, enzymes, botanicals, homeopathics, etc.); administer natural medicines (foods, vitamins, enzymes, botanicals, homeopathics, etc.); administer auto-injectable epinephrine; administer or perform hot or cold hydrotherapy, naturopathic physical medicine, electromagnetic energy, and therapeutic exercise for the purpose of providing basic therapeutic care services, except that if a referral to another licensed provider is appropriate for ongoing rehabilitation or habilitation services, the naturopathic doctor shall make the referral; provide health education and health counseling; and perform naturopathic musculoskeletal mobilization. COMAR 10.32.21.08. An individual licensed to practice naturopathic medicine in Maryland may not use the title "physician". Titles include: "doctor of naturopathic medicine", "doctor of naturopathy", "naturopathic doctor", "naturopath" or "N.D.".

Massachusetts:

Although Massachusetts has not issued any licenses yet, the Massachusetts General Assembly passed the law requiring the licensure of naturopathic doctors in 2017. It is our understanding that the Board of Registration in Naturopathy is in the process of promulgating regulations and establishing fees. The law in Massachusetts requires an applicant for initial licensure as a naturopathic doctor to have graduated from and hold a doctor of naturopathic medicine or doctor of naturopathy degree from an approved naturopathic medical college; provided, however, that an applicant shall have satisfactorily completed a minimum of 1,200 hours of board-approved clinical training before graduation from that college. In addition, an applicant for a license shall have successfully passed a competency-based national naturopathic licensing examination approved by the board. The practice of naturopathic health care in Massachusetts includes: the prevention and treatment of human illness, injury or disease through education, dietary or nutritional advice and the promotion of healthy ways of living; the use of non-invasive physical examinations and the ordering of clinical and laboratory procedures from licensed clinics or laboratories to evaluate injuries, illnesses and conditions in the human body; dispensing, administering, ordering and prescribing natural medicines of mineral, animal or botanical origin, including food products or extracts, vitamins, minerals, enzymes, digestive aids, natural hormones, plant substances, homeopathic preparations, natural antibiotics, topical medicines and nonprescription drugs, therapeutic devices and barrier contraceptives to prevent or treat illnesses, injuries and conditions of the human body; the use of manual mechanical manipulation of body structures or tissues, in accordance with naturopathic principles; the use of naturopathic physical medicine to maintain or restore normal physiological functioning of the human body; and mandatory tracking and documentation of the immunization status of a patient under 18 years of age and the required referral of that patient to a primary care or collaborative care physician where evidence exists that the individual has not been immunized. It does not include: performing surgery or invasive procedures or examinations, abortions or the use of radiation, radioactive substances or local, general or spinal anesthesia; prescribing, dispensing or administering a drug classified as a controlled substance or prescription drug; the practice of acupuncture and traditional Chinese medicine; or the practice of emergency medicine, except as a person rendering gratuitous services in an emergency or for the care of minor injuries.

<u>New Hampshire</u>:

In New Hampshire, the Naturopathic Board of Examiners licenses individuals to practice naturopathic medicine. To qualify for a license as a "doctor of naturopathic medicine" one must be a graduate of a naturopathic medical college which is accredited by the Council on Naturopathic Medical Education or another such accrediting agency recognized by the federal government; and pass a competency based examination prescribed by the board covering the appropriate naturopathic subjects; or be a graduate of a naturopathic medical college which has been approved by the board as having appropriate education standards for naturopathic medical programs which granted degrees prior to 1981. In addition, the individual shall take and pass a New Hampshire jurisprudence examination to ensure that licensed naturopathic doctors understand the laws, rules, and scope of practice. The initial application fee is \$300. The license is renewed biennially at a fee of \$300. In New Hampshire, doctors of naturopathic medicine are authorized to use for preventive and therapeutic purposes the following natural medicines and therapies: food, food extracts, vitamins, minerals, enzymes, digestive aids, whole gland thyroid, plant substances, all homeopathic preparations, topical medicines, counseling, hypnotherapy, biofeedback, dietary therapy, naturopathic physical medicine, therapeutic devices, and barrier devices for contraception; may use for diagnostic purposes physical and orifical examinations, X-rays, electrocardiograms, ultrasound, phlebotomy, clinical laboratory tests and examinations, and physiological function tests; and may prescribe nonprescription medications and therapeutic devices or use noninvasive diagnostic procedures practice. commonly used by medical practitioners in general Doctors of naturopathic medicine shall not prescribe, dispense, or administer any legend or controlled substances, except those natural medicines as authorized by this chapter; perform surgical procedures; practice emergency medicine, except as a good samaritan rendering gratuitous services in the case of emergency and except for the care of minor injuries; practice or claim to practice medicine and surgery, osteopathy, dentistry, podiatry, optometry, chiropractic, physical therapy, or any other system or method of treatment not authorized in this chapter. Doctors of naturopathic medicine with specialty certification in naturopathic childbirth pursuant to RSA 328-E:12 shall be authorized to use oxytocin and pitocin. Licensees shall use the title "doctor of naturopathic medicine" and the recognized abbreviation "N.D." Doctors of naturopathic medicine shall have the exclusive right to use of the terms: "doctor of naturopathic medicine," "naturopathic doctor," "naturopath," "doctor of naturopathy," "naturopathic medicine," "naturopathic health care," "naturopathy," and "N.D." See NH Rev ST Chapter 328-E (relating to naturopathic health care practice).

Rhode Island:

In Rhode Island, the Department of Health houses the Board of Licensure of Naturopathy. To qualify for a license to practice naturopathy, an applicant shall have been granted a degree of doctor of naturopathy from an approved naturopathy college; pass an examination approved by the board including but not limited to Part I (biomedical science examination) and Part II (clinical science examination) of the Naturopathic Physicians Licensing Examinations or successor; and have in place a written collaboration and consultation agreement with a licensed physician. The initial application fee is \$310. The license is renewed biennially at a fee of \$310. A license authorizes a licensee, consistent with naturopathic education and training and competence demonstrated by passing the doctor of naturopathy licensing examination, to: order and perform physical and laboratory examinations for diagnostic purposes;

dispense or order natural substances of mineral, animal, or botanical origin, including food, extracts of food, nutraceuticals, vitamins, amino acids, minerals, enzymes, botanicals and their extracts, botanical substances, homeopathic substances, and all dietary supplements and nonprescription drugs as defined by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., that use various routes of administration, including oral, nasal, auricular, ocular, rectal, vaginal, and transdermal; administer natural substances of mineral, animal, or botanical origin, including food, extracts of food, nutraceuticals, vitamins, amino acids, minerals, enzymes, botanicals and their extracts, botanical substances, homeopathic substances, and all dietary supplements and nonprescription drugs as defined by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., using transdermal routes of administration; administer or perform hot or cold hydrotherapy, electromagnetic energy, and therapeutic exercise for the purpose of providing basic therapeutic care services, except that if a referral to another licensed provider is appropriate for ongoing rehabilitation or habilitation services, the doctor of naturopathy shall make the referral; provide health education and health counseling; and perform naturopathic musculoskeletal mobilization. A person licensed as a doctor of naturopathy in Rhode Island may use the designation "DN."

Vermont:

In Vermont, a naturopathic physician must be licensed by the Vermont Office of Professional Regulation. To qualify for a license as a naturopathic physician, the individual must hold a degree of doctor of naturopathic medicine, or a degree determined to be essentially equivalent to such degree, from an approved naturopathic medical college and pass a two-part Naturopathic Physicians Licensing Exam (NPLEX), unless the applicant is exempt from examination. The fee for initial licensure is \$100, while the biennial renewal fee is \$240. The act in Vermont is a true practice act, in that one may not practice naturopathic medicine without holding a license as a naturopathic physician. The act defines the "practice of naturopathic medicine" to mean "a system of health care that utilizes education, natural medicines, and natural therapies to support and stimulate a patient's intrinsic self-healing processes, and to prevent, diagnose and treat human health conditions, injuries and pain. In connection with such system of health care, an individual licensed [as a naturopathic physician] may: A) Administer or provide for preventative and therapeutic purposes nonprescription medicines, topical medicines, botanical medicines, homeopathic medicines, counseling, hypnotherapy, nutritional and dietary therapy, naturopathic physical medicine, naturopathic childbirth, therapeutic devices, barrier devices for contraception and prescription medicines authorized by law; and B) use diagnostic procedures commonly used by physicians in general practice, including physical and orificial examinations, electrocardiograms, diagnostic imaging techniques, phlebotomy, clinical laboratory tests and examinations, and physiological function tests. A licensed naturopathic physician in Vermont is authorized to work independently and does not require supervision by any other health care professional. In Vermont, a person licensed as a naturopathic physician may use the designations "N.D.," "doctor of naturopathic medicine," "naturopathic doctor," "doctor of naturopathy," or "naturopathic physician."

Based on a review of these requirements, the Board does not believe that the final-form rulemaking will place Pennsylvania at a competitive disadvantage in that the qualifications for licensure in each of these states (a degree in naturopathic medicine and passage of the national examination) are essentially the same as the NDRA requires for the registration of naturopathic doctors in the Commonwealth. In addition, the fees associated with registration proposed in this rulemaking are considerably lower than those in effect in the states listed above.

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

No.

(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.)

All of the Board's rulemaking proposals are discussed in public committee meetings which are routinely attended by representatives of the public and the regulated community. The Board circulated four (4) exposure draft revisions to over 200 individuals/organizations and held seven (7) committee meetings over approximately 18 months in an effort to solicit and reach consensus within the public and regulated community on as many points as possible. The list of participants in the discussions relating to the proposed rulemaking are set forth in attached Appendix "A."

Thereafter, the proposed rulemaking was published at 51 Pa.B. 7877 (December 18, 2021) for 30 days of public comment during which time the Board received comments from members of the public, as set forth in Appendix "B." Following the close of the public comment period, the Board received comments from Senator Jay Costa and Senator Mastriano as well as the Independent Regulatory Review Commission (IRRC). All of these comments were discussed at public Board meetings.

After reviewing these comments, the Board elected to publish an "advance notice of final rulemaking" ("ANFR") to solicit additional comment about changes it intended to make to the final-form rulemaking. The ANFR was published in the *Pennsylvania Bulletin* on June 3, 2023, and was shared with entities and individuals having an interest in the rulemaking. After publication of the ANFR, the Board received additional comments from Senator Costa and Senator Mastriano as well as members of the public. A list of commentors to the ANFR is attached hereto as Appendix "C." The Board discussed those comments on July 18, 2023, and on September 12, 2023, voted to promulgate the final-form rulemaking.

(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?

The Board does not currently license or register naturopathic doctors. According to the Pennsylvania Department of Labor & Industry's Center for Workforce Information and Analysis, naturopathic physicians are self-employed or work primarily in general medical/surgical hospitals, in offices of physicians, for home health care services, or work in government (Federal and state).

For the business entities listed above, small businesses are defined in Section 3 of the Regulatory Review Act, Act 76 of 2012, which provides that a small business is defined by the U.S. Small Business Administration's (SBA) 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). Per the SBA's <u>Table of Small Business Size Standards</u>, the small business threshold for offices of physicians (621111) is \$16 million or less in average annual receipts. For a general medical/surgical hospital (622110) to be considered a small business, the threshold would be \$47 million or less in average annual receipts. For home health care services (621610), the small business threshold would be \$19 million in average annual receipts.

According to the SBA's 2022 <u>Small Business Profile</u>, there are 1,099,158 small businesses in Pennsylvania, making up 99.6% of all Pennsylvania Businesses. Of the 1,099,158 small businesses, 872,647 small businesses are non-employers, 196,444 employ less than 20 employees, and additional 29,307 employ between 20 and 499 employees. Thus, the overwhelming majority of businesses in Pennsylvania are considered small businesses by the SBA.

It is anticipated that the effects of the regulation will be primarily on individuals who are self-employed or employed in small businesses. All persons who seek registration as a naturopathic doctor will be required to comply with the regulations and therefore will be required to file applications and pay fees and adhere to the standards set forth in the regulations. Those individuals who do not seek registration will be prohibited from holding themselves out as a "naturopathic doctor," "registered naturopathic doctor" or "doctor of naturopathic medicine." For purposes of this rulemaking, the Board estimates that between 100 and 250 individuals may initially apply for registration as a naturopathic doctor, followed by 10 additional applicants annually. It is unknown how many individuals that currently hold themselves out as naturopathic doctors or doctors of naturopathic medicine will be unable to meet the qualifications for registration set forth in the NDRA and the regulations and therefore will need to stop using those titles.

(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.

All persons who seek registration will be required to comply with the regulations and those who do not seek registration will be prohibited from holding out as a "naturopathic doctor," "registered naturopathic doctor" or "doctor of naturopathic medicine." It is anticipated that approximately 100 - 250 persons will seek registration and will be required to comply with the regulations. It is unknown how many will not be eligible for registration or will voluntarily elect to not register and therefore will be prohibited from holding themselves out as a "naturopathic doctor" or "doctor of naturopathic doctor" or "doctor of naturopathic medicine."

(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.

The primary financial impact of the regulation falls on individuals who seek registration, as they will be required to pay a \$100 fee for initial registration and a \$50 biennial renewal fee. As these fees are imposed on individuals, the only impact on businesses, including small businesses would be incurred if employers of naturopathic doctors assume the licensure related costs for their employees, or if a naturopathic doctor is self-employed.

Individuals who are currently holding themselves out as a "naturopathic doctor" or "doctor of naturopathic medicine" who either do not qualify for registration under the NDRA and these regulations or who choose not to register with the Board would be impacted by the prohibition on continuing to use those titles. To do so would risk enforcement action and the possibility of the imposition of a civil penalty of up to \$10,000.

According to the prime sponsor of the NDRA bill, the registration of naturopathic doctors will help to fill the medical void in many communities lacking general practice doctors. In addition, these individuals are

highly trained specialists in the areas of nutrition, herbal medicine, homeopathy, and are the only group of medical providers trained in herb-drug and herb-nutraceutical interactions. In many states, naturopathic doctors work side by side with medical doctors to provide integrative care and routinely consult with medical doctors and osteopathic physicians on drug-herb interactions and natural alternatives to conventional care. In Pennsylvania, hospitals have already begun to integrate the services of naturopathic doctors. The Cancer Treatment Centers of America in Philadelphia has several naturopathic doctors on staff to provide integrative care for its patients. U.P.M.C. Shadyside Hospital has a center for integrative medicine with a naturopathic doctor on staff and Hershey Medical Center has some of its students do rotations with naturopathic doctors.

The registration of naturopathic doctors will help patients who are seeking naturopathic medical care select qualified practitioners. Registration of naturopathic doctors would give Pennsylvania residents a choice in their health care and provide for an integrative model of healthcare. The patients of Pennsylvania registered naturopathic doctors will be able to access this type of care and be assured that their treatment providers meet the minimum qualifications provided for by the NDRA. In addition, the Commonwealth of Pennsylvania needs to attract additional quality care providers who will help to reduce the burden of chronic disease.

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

The benefits set forth in (17) above clearly outweigh the minimal costs associated with registration of naturopathic doctors and biennial renewal of those registrations as set forth in (19) below.

(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.

The regulated community of naturopathic doctors will incur costs associated with initial registration and with biennial renewal of registration. For purposes of this rulemaking, the Board estimates that between 100 and 250 individuals may initially apply for registration as a naturopathic doctor, followed by 10 additional applicants annually. Thus, the estimated costs to the regulated community were calculated by the Board as follows:

FY 23-24 – 100 to 250 initial applicants at \$100 = \$10,000 to \$25,000

FY 24-25 – Biennial renewal of 100 to 250 registered naturopathic doctors at \$50 = \$5,000 to \$12,500 Plus, an additional 10 applicants at \$100 = \$1,000

FY 26-27 – Biennial renewal of 120 to 270 registered naturopathic doctors at \$50 = \$6,000 to \$13,500 Plus, an additional 10 applicants at \$100 = \$1,000

FY 25-26 – An additional 10 applicants at \$100 = \$1,000

FY 27-28 – An additional 10 applicants at \$100 = \$1,000

FY 28-29 – Biennial renewal of 140 to 290 registered naturopathic doctors at \$50 = \$7,000 to \$14,500 Plus, an additional 10 applicants at \$100 = \$1,000

The Board does not anticipate any additional legal, accounting or consulting procedures would be required.

(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 expected costs or savings for local governments.

(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.

The State Board of Medicine will incur IT development costs associated with developing the PALS initial application for registration of naturopathic doctors; biennial renewal/reactivation applications; and NABNE integration (for uploading of exam scores), currently estimated at \$29,680 - \$35,616. It is anticipated that this cost will be incurred in the current fiscal year in anticipation of implementation upon publication of the final-form rulemaking. Ongoing costs associated with administering the new registration will be incurred, but will be covered by the fees imposed on the regulated community through the regulation.

(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.

The only paperwork required to be submitted related to the implementation of the regulation would be the initial, renewal and reactivation applications.

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

Yes.

(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.**

It is anticipated that the initial registration and biennial renewal processes will be implemented through the PA Licensing System (PALS) at <u>www.pals.pa.gov</u>. Attached are "checklist" items indicating the

information that will be required for initial registration; the verification of education form; and the checklist items for biennial renewal/reactivation of a naturopathic doctor registration.

(23) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

	Current FY 23-24	FY +1 24-25-	FY +2 25-26	FY +3 26-27	FY +4 27-28	FY +5 28-29
SAVINGS:	\$0	\$0	\$0	\$0	\$0	\$0
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:	\$0	\$0	\$0	\$0	\$0	\$0
Regulated Community	\$10,000 - \$25,000	\$6,000 - \$13,500	\$1,000	\$7,000- \$14,500	\$1,000	\$8,000 - \$15,500
Local Government	\$0	\$0	\$0	\$0	\$0	\$0
State Government	\$29,680- 35,616	\$0	\$0	\$0	\$0	\$0
Total Costs	\$39,680 - \$60,616	\$6,000 - \$13,500	\$1,000	\$7,000- \$14,500	\$1,000	\$8,000 - \$15,500
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 1 20-21 (actual)	FY 2 21-22 (actual)	FY 3 22-23 (estimated)	Current FY 23-24 (budgeted)
State Board of Medicine	\$7,669,29.91	\$6,789,149.62	\$6,978,000.00	\$6,993,000.00

(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.

Assuming that all potential applicants for registration as a naturopathic doctor either are small businesses or are employed by small businesses, approximately 100 - 250 small businesses could be subject to the regulation. The direct costs required for compliance with the proposed regulation involves the initial licensure fee of \$100 and the biennial renewal fee of \$50 for any naturopathic doctor seeking registration under the NDRA. These costs may be passed on to consumers of naturopathic medical services, but this impact would be minimal. The paperwork requirements entail the completion of the initial online application and the biennial renewal application. Completing these online forms do not require any specific type of professional skills. Thus, the probable effect on small businesses is the need to register and pay associated fees for naturopathic doctors that are small businesses or work for small businesses. The Board could perceive of no less intrusive or less costly alternative method for implementing the statutory mandates of the NDRA that would be consistent with the legislative intent.

(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 special provisions developed to meet the particular needs of any of the identified groups.

(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.

Scope of Practice:

There are two provisions in the NDRA that would seem to indicate that a registration is required to practice naturopathic medicine. Section 203(a) of the NDRA provides for the issuance of a registration "entitling the applicant to practice naturopathic medicine in this Commonwealth." Additionally, section 204(a)(10) of the NDRA makes it a violation for a registrant to "[act] outside the scope of a registration." However, the NDRA omits any definition for "naturopathic medicine" or other indication of the scope of practice of a registered naturopathic doctor. Investigation by the Board regarding the scope of practice for naturopathic doctors in other jurisdictions indicated a general lack of consistency among jurisdictions but for the fact that a scope of practice is actually defined.

The delegation of legislative power "requires that the basic policy choices involved in 'legislative power' actually be made by the Legislature as constitutionally mandated." <u>Tosto v. Pennsylvania Nursing Home</u> <u>Loan Agency</u>, 460 Pa. 1, 331 A.2d 198, 202 (1975), quoting <u>Chartiers Valley Joint Schools v. Allegheny</u> <u>County Board of School Directors</u>, 418 Pa. 520, 529, 211 A.2d 487, 492 (1965). One of the reasons for

the doctrine is that it ensures that "basic policy choices' be made by duly authorized and politically responsible officials." In defining key terms in the final-form rulemaking, the Board is not executing the basic policy function of the General Assembly. Instead, the Board is offering definitional guideposts to ensure notice to the regulated community of acts that may lead to discipline and uniformity in application of the provisions of the NRDA by the Board.

Additionally, the Board notes that, overall, the NDRA seeks to regulate which individuals may hold themselves out as a naturopathic doctor. As indicated by Democratic Leader Costa in the comment to the ANFR, the purpose of the NDRA was to "expand[] safe and regulated access to naturopathic medicine for Pennsylvanians by providing for the registration of naturopathic doctors who graduated from accredited colleges, completed federally recognized postgraduate education and competency-based licenser examinations, and met advanced clinical training requirements. While the NRDA is regarded primarily as a title protection act and not a true practice act, sections 203(a) and 204(a)(10) remained even after several iterations of HB 516 and SB 621 were brought before the respective chambers of the General Assembly. The Board gleaned a sufficient amount of intent from the final version of the NDRA to find proper and uniform application and exaction of the NDRA required definitional guideposts. Thus, the Board formulated definitions of key terms and included those terms in the ANFR and in the final-form rulemaking.

Removal of outdated regulations related to drugless therapists:

Finally, the final-form rulemaking will also remove all regulatory references to "drugless therapists." The Board last issued a new license to practice as a drugless therapist in 1951 (1 month after the State Board of Chiropractic began operations) and has no authority to issue new drugless therapist licenses. *See, Reisinger v. Com., State Bd. of Med. Ed. & Licensure*, 41 Pa. Cmwlth. 553, 399 A.2d 1160 (1979). No individual currently holds an active license as a drugless therapist from the Board. The last remaining individual who held an active license as a drugless therapist did not renew his license in 2016 and it is the Board's understanding that he died in December of 2014, shortly after submitting his renewal application for the 2015-2016 renewal period. The prior two most recent licensees of the Board last renewed their licenses in 2008.

The Board considered maintaining reference to Drugless Therapists in its regulations; however, one of the commonly accepted activities of rulemaking is to review the need and effectiveness of regulations and to either plan for the elimination of unneeded regulations via sunset provisions, or to delete unnecessary and outdated regulations when conducting regular regulatory review. As it appears that no new drugless therapist licenses may be issued, and all individuals who held a license as a drugless therapist have either voluntarily retired from practice or are deceased, the Board has determined that it is no longer necessary to keep any references to drugless therapists in the Board's regulations and has elected to delete the appropriate provisions.

The Board believes the proposed rulemaking reflects the least burdensome acceptable alternative consistent with the statutory mandates of the NDRA for the registration of naturopathic doctors.

(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.

The Board could perceive of no less stringent compliance or reporting requirements, or deadlines for compliance or reporting for individuals based on the size of business for which they work. Excluding a naturopathic doctor from all or any part of the registration requirements would be contrary to the statutory intent of the NDRA and the public interest.

(28) If data is the basis for this regulation, please provide a description of the data, explain <u>in detail</u> 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.

No data serves as the basis for this proposed rulemaking.

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

- B. The date or dates on which any public meetings or hearings will be held: The Board meets in public session 9 times each year. All regulatory proposals are discussed at regularly scheduled board meetings. See item (30) below for 2024 meeting dates.
- C. The expected date of delivery of the final-form regulation:Winter 2023-2024
- D. The expected effective date of the final-form regulation:Winter 2023-2024, upon publication of the final-form rulemaking in the *Pennsylvania Bulletin*.
- E. The expected date by which compliance with the final-form regulation will be required:Winter 2023-2024, upon publication of the final-form rulemaking in the *Pennsylvania Bulletin*.
- F. The expected date by which required permits, licenses or other approvals must be obtained:N/A

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

The Board continuously evaluates the effectiveness of the Board's regulations and implementation of regulations. The Board discusses all regulatory proposals in conjunction with its regularly scheduled public meetings, typically on the afternoon of the board meeting. The Board meets nine times a year. The Board is scheduled to meet on the following dates in 2024: January 30, March 5, April 16, May 21, June 25, August 6, September 17, November 5 and December 17.

PENNSYLVANIA STATE BOARD OF MEDICINE										
VERIFICATION OF DOCTORAL DEGREE FROM A NATUROPATHIC SCHOOL										
Complete Section 1 of	this pag	e and forv	vard to	the colleg	ge or unive	ersity where	you complete	d your naturo	pathic do	ctoral program.
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City:					State:				Zip:	
DATE OF BIRTH: Month Day Year SOCIAL SECURITY NUMBER:										
NAME OF SCHOOL:			I					•	<u> </u>	
DATES OF ATTENDANCE: FROM: Month Day Year Month Day Year							Year			
Submit the verification of naturopathic doctoral degree form to your school and request the school return the completed form and an official transcript directly to the Board. THIS FORM MAY NOT BE COMPLETED/SUBMITTED TO THE BOARD PRIOR TO GRADUATION SECTION 2 – TO BE COMPLETED BY DIRECTOR OF NATUROPATHIC DOCTORAL PROGRAM						PROGRAM				
NAME OF PROGRAM	:									
ADDRESS:	Stre	et:								
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I CERTIFY THAT THE AB PROGRAM, WHICH INCLU AND MODALITIES AND IN	DED AT L	EAST 4,10	00 TOT	AL CREDIT	T HOURS IN	BASIC AND	CLINICAL SCI			
DEGREE AWARDED:						GRADU	ATION DATE	E: Month	Day	Year
SIGNATURE OF PRO	GRAM I	DIRECTO	DR:							
DATE: Month	Day	Year								
Upon completio	n, schoo	ol must re	eturn tl	his comp	leted forn	n directly to	the Pennsyl	vania State	Board of	Medicine.
			F RE	TURN 1		RM TO	THE APPL	ICANT		
STATE I	Regular Mailing AddressCourier Delivery AddressSTATE BOARD OF MEDICINESTATE BOARD OF MEDICINEP.O. BOX 26492601 NORTH THIRD STREETHARRISBURG, PA 17105-2649HARRISBURG, PA 17110									

NATUROPATHIC DOCTOR INITIAL APPLICATION

PALS CHECKLIST ITEMS

CHECKLIST	INSTRUCTIONS
NAME	
Application	All applications are processed in order of submission. If this application is not completed within six months, updates of certain sections and/or supporting documents will be required. If the application has not been completed within one year from the date it was received, applicants will be required to submit a new application (another application processing fee) and supporting documents, as necessary.
Application Fee	NON REFUNDABLE FEE in the amount of \$100, made payable by credit/debit card. I the application has not been completed within one year from the date it was received, applicants will be required to submit a new application (another application processing fee) and supporting documents, as necessary.
CHILD ABUSE CE	All health-related licensees/certificate/registrants and funeral directors are considered "mandatory reporters" under section 6311 of the Child Protective Services Law (23 P.S. § 6311). Therefore, all persons applying for issuance of an initial license, certificate or registration from any of the health-related boards (except the State Board of Veterinary Medicine) or from the State Board of Funeral Directors are required to complete, as a condition of licensure, certification or registration, 3 hours of approved training by the Department of Human Services (DHS) on top pf the child abuse recognition and reporting. After you have completed the required course, the approved provider will electronically submit your name, date of attendance, etc. to the Bureau. For that reason, it is imperative that you register for the course using the information provided on your application for licensure/certification/registration. A list of DHS-approved child abuse education providers can be found on the Department of State website.
CRIMINAL HISTORY CHECK	Provide a recent Criminal History Records Check (CHRC) from the state police or other state agency that is the official repository for criminal history record information for every state in which you have lived, worked or completed professional training/studies for the past five (5) years. The report(s) must be dated within 90 days of the date the application is submitted. For applicants living, working or completing training/studies in Pennsylvania, your CHRC request will be automatically submitted to the Pennsylvania State Police upon submission of this application. The PATCH fee will be included at checkout. Your PA CHRC will be sent directly to the Board/Commission. You will be notified if additional action is required. For individuals living, working or completing training/studies of Pennsylvania during the past five (5) years, in lieu of obtaining individual state background checks, you may elect to provide BOTH a state CHRC from the state in which you currently reside, AND your FBI identity History Summary Check available at https://www.fbi.gov/services/cjis/identity-history-summary-checks

	Please note: For applicants currently living, working or completing training/studies in California, Arizona or Ohio: Due to the laws of these states, the Board is not an eligible recipient of CHRC's or your CHRC will not be issued to you for upload to the Board. Please obtain your Federal Bureau of Investigation (FBI) Identity History Summary Check available at the link noted above.
CURRENT CPR CERTIFICATION	Please upload a copy of the front and back of your current CPR certification obtained through the American Red Cross, the American Heart Association or a similar health authority or professional body approved by the Board.
DATABANK REPORT	Provide an official notification of information (Self-Query) from the National Practitioner Data Bank. Please refer to the NPDB website for additional information. When you receive the "Response to your Self- Query, you will need to upload it to your online application. The reported will need to be uploaded, where prompted, in order to submit your application.
EDUCATION VERIFICATION	Forward the Verification of Education form to your school/university to complete. You are only required to verify the level of education completed which qualifies you for this license. The school must return the completed verification form directly to the Board. The form will be available for download and printing when the application is submitted.
EDUCATIONAL TRANSCRIPTS	Request that your school provide an official transcript <u>directly</u> to the Board. If the official transcript does not provide detailed information regarding the courses attended from which the applicant's eligibility is determined, the Board retains the right to request a copy of the school curriculum.
EXAM RESULTS	Request the NABNE to submit the certifying examination scores for Parts I and II directly to the Board. If you graduated prior to 1986, arrange for the State Board office to submit proof of a passing score on a state naturopathic examination.
LETTER OF GOOD STANDING	Contact the licensing authorities of the states, territories or countries where you hold or eve held a license, certificate, permit, registration or other authorization to practice a health-related profession (whether active, inactive, expired or current) and request letters of goo standing/verification of licensure in that state or jurisdiction. The letter must include the following: license issue and expiration date, license status (current or expired) and disciplinary standing. The letter(s) of good standing must be sent directly to the Board.
RESUME/ CURRICULUM VITAE	You will need to upload, where prompted, a current Curriculum Vitae listing all periods of employment or unemployment (i.e. child rearing, research, etc.) from graduation from naturopathic school to present. The list must be in chronological order, include the month and year, and indicate the state/territory in which the employment occurred. The resume/ curriculum vitae will need to be uploaded in order to submit your application.
BACHELOR'S DEGREE TRANCRIPTS	Request that your school provide an official transcript <u>directly</u> to the Board verifying that you obtained a bachelor's degree from a regionally accredited or pre-accredited college or university or the equivalent.

Legal Questions

1 Do you hold or have you ever held a license, certificate, permit, registration or other authorization to practice in any health-related profession in any state or jurisdiction?

2 Please provide the profession and state or jurisdiction.

3 Have you withdrawn an application for a professional or occupational license, certificate, permit or registration, had an application denied or refused, or for disciplinary reasons agreed not to apply or reapply for a professional or occupational license, certificate, permit or registration in any state or jurisdiction?

4 Have you had disciplinary action taken against a professional or occupational license, certificate, permit, registration or other authorization to practice a profession or occupation issued to you in any state or jurisdiction or have you agreed to voluntary surrender in lieu of discipline?

5 Do you currently have any disciplinary charges pending against your professional or occupational license, certificate, permit or registration in any state or jurisdiction?

6 Do you currently have any criminal charges pending and unresolved in any state or jurisdiction?

7 Have you ever had practice privileges denied, revoked, suspended or restricted by a hospital or any health care facility?

8 Have you ever had your DEA registration denied, revoked or restricted?

9 Have you ever had provider privileges denied, revoked, suspended or restricted by a Medical Assistance agency, Medicare, third party payor or another authority?

10 Have you ever been charged by a hospital, university, or research facility with violating research protocols, falsifying research, or engaging in other research misconduct?

11 Have you engaged in, the intemperate or habitual use or abuse of alcohol or narcotics, hallucinogenics or other drugs or substances that may impair judgment or coordination?

12 Since May 19, 2002, have you been the subject of a civil malpractice lawsuit If yes, please submit a copy of the entire Civil Complaint, which must include the filing date and the date you were served. Submit a statement which includes complete details of the complaints that have been filed against you.

13 Docket Number

14 Filing Date:

15 Date you were served:

Standard Questions

1 Name of Naturopathic School

2 Address of Naturopathic School

3 Will any of your supporting documents be submitted under another name or names?

4 Please list the other name(s)

You must submit a copy of a legal document verifying the name(s). The following are acceptable name change verification documents:

(1) Marriage Certificate:

- (2) Divorce decree which indicates the retaking of your maiden name:
- (3) Other "legal" document indicating the retaking of a maiden name:
- (4) For a "legal" name change, a copy of the court document must be provided.

5 List all of the states you have lived or worked in during the last 5 years.

Provide a recent Criminal History Records Check (CHRC) from the state police or other state agency for every state in which you have lived, worked, or completed professional training/studies for the past five (5 years. The report(s) must be dated within 90 days of the date the application is submitted. For applicants living, working, or completing training/studies in Pennsylvania, your CHRC request will be automatically submitted to the Pennsylvania State Police upon submission of this application. The PATCH fee will be included at checkout. Your PA CHRC will be sent directly to the Board/Commission. You will be notified if additional action is required. For individuals living, working, or completing training/studies outside of Pennsylvania during the past five (5) years, in lieu of obtaining individual state background checks, you may elect to provide BOTH a state CHRC from the state in which you currently reside, AND your FBI Identity History Summary Check, available at https://www.fbi.gov/services/cjis/identity-history-summary-checks.

Please note: For applicants currently living, working, or completing training/studies in California, Arizona, or Ohio: Due to the laws of these states, the Board is not an eligible recipient of CHRC's or your CHRC will not be issued to you for upload to the Board. Please obtain your Federal Bureau of Investigation (FBI) Identity History Summary Check, available at the link noted above.

Questions

1 Have you served in the U.S. Armed Forces?

2 Thank you for your service. Would you like to register with the PA Veterans Registry? The PA Veterans Registry provides veterans with information about federal, state and local benefits, programs and services that are available to Pennsylvania veterans and links veterans with resources that can provide assistance. Registration is quick and easy, and provides the Department of Military and Veterans Affairs (DMVA) with a way to contact you regarding the benefits and services you may be eligible for. If you check "Yes," you will receive an email with instructions to assist you in registering.

NATUROPATHIC DOCTOR RENEWAL/REACTIVATION

CheckList Name	Instructions
Application	Practicing on an expired license may result in disciplinary actions and additional monetary fees.
Application Fee	A fee of \$50.00 is required. Please note that all fees are non-refundable.
Child Abuse CE	All health-related licensees/certificate holders and funeral directors are considered "mandatory reporters" under section 6311 of the Child Protective Services Law (23 P.S. § 6311). Therefore, all persons applying for renewal of a license or certificate from any of the health-related boards (except the State Board of Veterinary Medicine) or from the State Board of Funeral Directors are required to complete, as a condition of biennial renewal, 2 hours of approved training on the topic of child abuse recognition and reporting. After you have completed the required course, the approved provider will electronically submit your name, date of attendance, etc. to the Bureau. For that reason, it is imperative that you register for the course using the information provided on your application for licensure/certification. A list of approved child abuse education providers can be found on the Department of State Website.

Renewal Questions:

Legal Questions:

1. Since your initial application or last renewal, whichever is later, have you had disciplinary action taken against a professional or occupational license, certificate, permit, registration or other authorization to practice a profession or occupation issued to you in any state or jurisdiction or have you agreed to voluntary surrender in lieu of discipline?

2. Do you currently have any disciplinary charges pending against your professional or occupational license, certificate, permit or registration in any state or jurisdiction?

3. Since your initial application or last renewal, whichever is later, have you withdrawn an application for a professional or occupational license, certificate, permit or registration, had an application denied or refused, or for disciplinary reasons agreed not to apply or reapply for a professional or occupational license, certificate, permit or registration?

4. Since your initial application or your last renewal, whichever is later, have you had your DEA registration denied, revoked or restricted?

5. Since your initial application or your last renewal, whichever is later, have you had provider privileges denied, revoked, suspended or restricted by a Medical Assistance agency, Medicare, third party payor or another authority?

6. Since your initial application or your last renewal, whichever is later, have you had practice privileges denied, revoked, suspended, or restricted by a hospital or any health care facility?

7. Since your initial application or your last renewal, whichever is later, have you been charged by a hospital, university, or research facility with violating research protocols, falsifying research, or engaging in other research misconduct?

8. Since your initial application or last renewal, whichever is later, have you engaged in the intemperate or habitual use or abuse of alcohol or narcotics, hallucinogenics or other drugs or substances that may impair judgment or coordination?

9. Since your initial application or your last renewal, whichever is later, have you been the subject of a civil malpractice lawsuit?

9. a - Have you previously reported the complaint to the Board?

If yes, provide the state, county, and docket number.

9.b - If no, upload a copy of the entire Civil Complaint, which must include the filing date and the date you were served.

Standard Questions:

1. Are you submitting a name change with this renewal?

You must submit a copy of a legal document verifying the name(s). The following are acceptable name change verification documents:

(1) Marriage Certificate:

(2) Divorce decree which indicates the retaking of your maiden name:

(3) Other "legal" document indicating the retaking of a maiden name:

(4) For a "legal" name change, a copy of the court document must be provided.

2. With the exception of the one you are currently renewing, do you hold, or have you ever held, a license, certificate, permit, registration or other authorization to practice a profession or occupation in any state or jurisdiction?

Please provide the profession and state or jurisdiction.

3. Do you hold current valid CPR certification in Adult CPR? Courses for CPR certification must be obtained through the American Red Cross, the American Heart Association or an agency substantially similar approved by the Board. Note: Online CPR courses are not acceptable to fulfill this requirement.

Questions:

1. Have you served in the U.S. Armed Forces?

FEE REPORT FORM

Agency:	State - BPOA	Date : July 17, 2019
Contact:	K. Kalonji Johnson, Commissioner Bureau of Professional & Occupational Aff	airs
Phone No.	783-7194	

Fee Title, Rate and Estimated Collections:

Naturopathic Doctor Initial Reg	gistration Application:	\$100.00
Estimated yearly revenue:	\$1,000	(10 applications x \$100.00)

Fee Description:

The fee will be charged to every applicant for registration as a Naturopathic Doctor.

Fee Objective:

The fee should (1) offset the identifiable costs incurred by the State Board of Medicine to process an application and (2) defray a portion of the Board's administrative overhead.

Fee-Related Activities and Costs:

Staff time-process application	(.25hr)	\$12.30
Board Administrator review	(.25hr)	\$16.96
Board Attorney review	(.25hr)	\$26.88
Board Member review	(.25hr)	\$26.00
Transaction fee		\$2.40
Administrative Overhead:		\$14.00
	Total Estimated Cost:	\$98.54
	Proposed Fee:	\$100.00

Analysis, Comment, and Recommendation:

It is recommended that a fee of \$100.00 be established for processing an application for registration as a Naturopathic Doctor.

Board Staff –Staff receives and reviews the application by ensuring all documents are received, complete and correct. Staff downloads supporting documents (exam scores, letters of good standing, etc). Staff matches supporting documents with the respective application, or creates a miscellaneous mail number in the licensing system and files the supporting documents. Staff makes appropriate notations in the applicant's file through the licensing system. If any documents are not received and/or are incorrect, staff creates and mails/emails a discrepancy letter. In addition to evaluating the materials received, applications may require staff to complete additional research or clearance reports online. Applications with disciplinary/legal issues will require staff to review lengthy legal documents. When complete, staff forwards applications with disciplinary/legal action to the Board's Legal Counsel for review. Counsel may request the application be reviewed by the Board or possibly the Professional Health Monitoring Program. For applications that require Board review, staff prepares and scans the application to be placed on the Board's meeting agenda. When an application is ready to be issued, staff issues the license through the licensing system.

Attachment A

- Henriette Alban, ND
- Leia Anderson
- Angie Armbrust
- Alex Bonner
- Rachel Bright, ND
- The Honorable Jay Costa, Jr.
- Susan DeSantis, PA-C
- Marty Edwards, ND
- Lynn Feinman
- Andrew Harvan, Esq.
- Dwayne Haus
- Bob Henry
- John L. Herr
- Gay Hilton, ND
- Traci Hobson, Esq.
- Jeremy Irvine
- Julie Lachman, ND
- Kerry Lange
- Betty A. Magill
- Mary Marshall
- Ted Mowatt, CAE
- Barbara Myers, ND
- Edward L. Nielsen, M.H.S
- PA Academy of Nutrition and Dietetics
- Heather DeLuca
- PA Assoc of Naturopathic Physicians
- Michael Reece, ND
- Cynthia Rish
- Wesley J. Rish, Esq.
- Milena Safran
- Timothy Salotto, ND
- Heather Shultz
- Michael Siget, Esq.
- Randy Stevens
- Lisa C. Stevenson, Esq.
- Heidi Weinhold, ND
- Marie Winters, ND

Attachment B

16A-4953 Commenters List following Proposed Publication

RAF Question #14

Attachment B

Last Name	First Name	E-mail	Mailing Address	City, St Zip
Abram	Penni		466 Route 74	Port Royal, PA 17082
Alper	Naomi	nalperpalm@icloud.com	3006 Tarnbrook Dr	Mt. Laurel, NJ 0804_
Amplo	Margherita		1008 Wiggins Way	West Chester, PA 19380
Anders	Timothy	timbojenkins23@gmail.com	2529 Hersham Rd H-19	,
Ast	, Dr. Hayleigh	asth@hs.uci.edu		
Ast	Patricia	asth@hs.uci.edu		
Ast	Jeffrey		34 Castle Dr	Gilbertsville, PA 19525
Ast	Bob	robert.ast@trob32.com		·
Barnes	Elizabeth		247 Cumberland Rd	Camp Hill, PA 17011
Barth	Stephen	sbarth@barthconsultinggroup.com	96 Harvey Ave	Doylestown, PA 18901
Baum	Aaron		145 Pennsylvania Ave	Douglasville, PA 19518
Beatty	Elizabeth		453 Almond Ave Apt 8	Long Beach, CA 90802
Belmont	Ana		27930 Cabot Rd.	Laguna Niguel, CA 92677-120
Berger	Susan		1660 Murray Ave	Pittsburgh, PA 15217
Berk	Amy		428 Maregan Dr	Sellersville, PA 18960
Borneman	John		1315 Wrenfield Way	Villanova, PA 19085
Boyce	Roy		243 Loyalsock Dr.	Douglassville, PA 19518
Bricker	June		54 Nickle Dr	Mifflintown, PA 17059
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AF Question	¥14
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Attachment C

16A-4953 Commenters List following ANFR

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FACE SHEET FOR FILING DOCUMENTS WITH THE LEGISLATIVE REFERENCE BUREAU			RECEIVED Independent Regulatory Review Commission January 18, 2024
(Pursuant to Commonwealth Documents Law)			
			WRITE IN THIS SPACE
Copy below is hereby approved as to form and legality. Attorney General	Copy below is here by certified to be a t of a document issued, prescribed or	rue and correct copy	Copy below is hereby approved as to form and legality. Executive or Independent Agencies.
BY:(DEPUTY ATTORNEY GENERAL)	<u>State Board of Medicine</u> (AGENCY) DOCUMENT/FISCAL NOTE NO. <u>16A-4953</u>		BY:
	DOCUMENT/FISCAL NOTE NO. TOR-	+900	
DATE OF APPROVAL	DATE OF ADOPTION:		1/9/2024 DATE OF APPROVAL
Check if applicable Copy not approved. Objections attached.	BY: Mark B. Woodland, M.S., I TITLE Board Chair (EXECUTIVE OFFICER, CHAIRM		Check if applicable. No Attorney General approval or objection within 30 days after submission.

FINAL RULEMAKING

COMMONWEALTH OF PENNSYLVANIA DEPARTMENT OF STATE BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS STATE BOARD OF MEDICINE

TITLE 49 PA CODE CHAPTERS 16 AND 18 §§ 16.1, 16.11—16.13, 18.13a, 18.15, 18.15a and 18.901—18.913

REGISTRATION OF NATUROPATHIC DOCTORS

The State Board of Medicine (Board) hereby amends Chapters 16 and 18 (relating to State Board of Medicine – general provisions; and State Board of Medicine – practitioners other than medical doctors) to read as set forth in Annex A. Specifically, the Board amends §§ 16.1, 16.11—16.13, 18.13a, 18.15, 18.15a, and adds Subchapter M (relating to registration of naturopathic doctors) to Chapter 18 at §§ 18.901—18.913.

Effective Date

The final-form rulemaking will be effective upon publication in the Pennsylvania Bulletin.

Statutory Authority

The primary statutory authority to regulate the registration of naturopathic doctors is 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." Further, section 203(b) of the NDRA (63 P.S. § 272.203(b)), provides the authority of the Board to require naturopathic doctor registrations to be renewed "...in a manner and at such intervals as the board shall determine by regulation...." Sections 202(6) and 203(c) of the NDRA (63 P.S. § 272.202(6)) set forth the authority of the Board to set fees for initial registration and biennial renewal of registration. The Board sets all fees by regulation.

The Board is taking this opportunity to update its regulations and to remove outdated provisions in the Board's existing regulations relating to "drugless therapists" under the authority of Section 8 of the Medical Practice Act of 1985 (act) (63 P.S. § 422.8), which provides, in part, that, "[t]he board, in the exercise of its duties under this act, shall have the power to adopt such regulations as are reasonably necessary to carry out the purposes of this act." This authority necessarily includes the power to repeal provisions of the regulations that are no longer necessary.

Background, Need for and Description of Amendments

The Board amends § 16.1 (relating to definitions) to update the definitions of "act" and "Board-regulated practitioner." The definition of "act" is being amended to update the citation to the Medical Practice Act of 1985 (63 P.S. §§ 422.1—422.53). The definition of "Board-regulated practitioner" is being amended to delete references to "drugless therapists" and to add several license classifications which are currently missing from the definition. Specifically, the licensure classifications of respiratory therapist, genetic counselor, prosthetist, orthotist, pedorthist, orthotic fitter and naturopathic doctor have been added to the definition of "Board-regulated practitioner" in § 16.1. Persons applying for a registration issued by the Board are also included in the definition of "Board-regulated practitioner."

Additionally, the final-form regulation deletes all regulatory references to "drugless therapists." The Board last issued a new license to practice as a drugless therapist in 1951 (1 month after the State Board of Chiropractic began operations) and no longer has the authority to issue new drugless therapist licenses. *See Reisinger v. Com., State Bd. of Med. Ed. & Licensure*, 399 A.2d 1160 (Pa. Cmwlth. 1979). *Reisinger* involved an individual trained as a chiropractor and naturopathic doctor who petitioned for licensure as a "drugless therapist," but was denied because the Board determined that it no longer had the authority to license drugless therapists. On appeal, the Commonwealth Court agreed, holding that although the Board could continue to register and regulate persons engaged in the practice of drugless therapy, "the Board lacks the authority now to license Drugless Therapists." See id, 399 A.2d at 1163. Since 1951, the Board has continued to biennially register/renew existing drugless therapist licenses and has continued to regulate their practice but has not issued new licenses. No individual currently holds an active license as a drugless therapist in the Board's regulations. This is especially true now that the Board will be registering individuals as naturopathic doctors under this final-form rulemaking.

As such, the Board also amends § 16.11 (relating to licenses, certificates and registrations) to delete the reference to biennial registration of a drugless therapist license and add the initial registration as a naturopathic doctor and the biennial registration of a naturopathic doctor. Section 16.12 (relating to general qualifications for licenses and certificates) is amended to update its title and to extend its provisions to initial registrations issued by the Board. In addition, the fees associated with biennial renewal of the drugless therapist license are deleted from § 16.13 (relating to licensure, certification, examination and registration fees), and the fees associated with naturopathic doctor registration, including the initial registration fee of \$100 and biennial registration renewal fee of \$50, are being added.

Next, the Board amends Chapter 18, Subchapter B (relating to the registration and practice of acupuncturists and practitioners of Oriental medicine) to address the perceived overlap between the practice of a registered naturopathic doctor and a licensed acupuncturist or practitioner of Oriental medicine. Specifically, §§ 18.13a and 18.15a (relating to requirements for licensure as a practitioner of Oriental medicine; and scope of practice of acupuncturists and practitioners of Oriental medicine) are being amended to point out that these regulations do not limit a registered naturopathic doctor when recommending herbs, minerals and other supplements according to traditions other than Oriental medicine traditions. Section 18.15 (relating to practice responsibilities of acupuncturist and practitioner of Oriental medicine who is not a physician) was significantly amended and reorganized on September 16, 2023, at 53 Pa.B. 5759, necessitating amendments to subsections (a)(10) and (b.1)(3) with regard to identification tags/badges for licensed acupuncturists and practitioners of Oriental medicine who are also registered as naturopathic doctors.

The Board adds Subchapter M to Chapter 18 to implement the provisions of the NDRA. Section 18.901 (relating to purpose) notes that this subchapter implements the registration of naturopathic doctors as required under the NDRA. Section 18.902 (relating to definitions) defines necessary terms used in Subchapter M, including "authorization to practice," "CNME—Council on Naturopathic Medical Education," "marketing activity," "merchandise," "NABNE—North American Board of Naturopathic Examiners," "naturopathic doctor," "naturopathic medicine," "naturopathic physical medicine," "naturopathic service," "natural therapies," "NDRA," "NPLEX—Naturopathic Physicians Licensing Examinations," and "regionally accredited or preaccredited college or university."

Next, the Board includes the process and requirements to apply for a registration as a naturopathic doctor in § 18.903 (relating to application for naturopathic doctor registration), including the qualifications for registration as a naturopathic doctor as set forth in section 202 of the NDRA. The Board is also including the requirement that an applicant for registration as a naturopathic doctor shall have completed at least 3 hours of approved education/training in child abuse recognition and reporting requirements, as required for all board-regulated practitioners under 23 Pa.C.S. § 6383(b)(3)(i) (relating to education and training) and in the Board's regulations at § 16.108(a) (relating to child abuse recognition and reporting—mandatory training requirement).

The Board includes the requirements for the biennial renewal of the naturopathic doctor registration in § 18.904 (relating to biennial registration of naturopathic doctor) as required by section 203(b) of the NDRA. Section 203(b) of the NDRA provides for renewal "...in a manner and at such intervals as the board shall determine by regulation...." As such, the final-form regulation requires that all registrations of naturopathic doctors will expire on December 31st of each even-numbered year, to correspond with the expiration of all existing licenses issued by the Board. The manner of renewing a registration is found in subsection (b), which sets forth the requirements for renewal as informed by the existing practice of the Board. As a condition of biennial renewal, the Board requires the completion of at least 2 hours of approved continuing education in child abuse recognition and reporting, as required under 23 Pa.C.S. § 6383(b)(3)(ii) and the Board's regulations at § 16.108(b).

Similarly, the Board provides for reactivation of inactive and expired registrations in § 18.905 (relating to inactive status; reactivation of inactive and expired registration). Again, the manner in which expired and inactive registrations are reactivated is informed by the Board's existing practices and includes payment of applicable fees and the completion of the required continuing education in child abuse recognition and reporting. Section 18.906 (relating to display of registration) simply requires registered naturopathic doctors to prominently display their certificate of registration at the registrant's regular place of business and have evidence of current registration available for inspection when providing services at other locations.

In § 18.907 (relating to acceptable titles and professional designations by registrants; prohibited titles) the Board clarifies the acceptable titles that may be used by registered naturopathic doctors. Section 201 of the NDRA (63 P.S. § 272.201) provides that "[i]t 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." Further, § 18.907 makes it clear that a naturopathic doctor who uses the designation "Dr." shall further identify himself or herself as a "naturopathic doctor," "registered naturopathic doctor" or "doctor of naturopathic medicine" and may not use any term or designation that implies that the naturopathic doctor is authorized to practice medicine or any other health care profession, unless the naturopathic doctor also holds a current and active authorization to practice the other profession issued by the appropriate licensing authority of this Commonwealth. The Board has chosen not to regulate the terms that may be used by individuals who are not registered naturopathic doctors as beyond the Board's statutory authority.

Next, the Board addresses informed consent and required disclosures in § 18.908 (relating to informed consent and disclosure of financial interests). In this section, the Board requires that the informed consent include notice that the naturopathic doctor is not a physician. Further, in subsection (b), the Board includes a requirement that a naturopathic doctor inform the patient if the naturopathic doctor will receive any financial incentive for marketing activities, as that term in now defined in the final-form rulemaking.

In § 18.909 (relating to naturopathic records) the Board provides standards for the creation and retention of patient records and authorizes a naturopathic doctor to charge patients no more than the applicable costs for production of health records as annually adjusted by the Secretary of Health and published in the *Pennsylvania Bulletin*. It further prohibits a naturopathic doctor from requiring payment for naturopathic services rendered as a condition of releasing records to a patient or the patient's designee.

Section 18.910 (relating to advertising) sets forth information that must be included in all advertisements for naturopathic services by registered naturopathic doctors, as well as standards for what may not be included in advertisements. Items that must be included in all advertisements include the name of the naturopathic doctor as registered with the Board and the words "naturopathic doctor" or "doctor of naturopathic medicine." Prohibitions include misrepresentations and other statements that are likely to mislead or deceive, those that create false or unjustified expectations as to results and those that imply that a manifestly incurable condition can be cured or that guarantee a cure of any condition. The Board is prohibiting statements recommending any modality or service that is inconsistent with the health, safety and welfare of the public. In addition, a registered naturopathic doctor may not include the term "physician" unless also licensed as a physician or physician assistant by the Board or the State Board of Osteopathic Medicine.

Section 18.911 (relating to Code of Ethics) establishes the ethical principles for registered naturopathic doctors in this Commonwealth. These principles were informed by the ethical standards of other health care professions regulated by the Board and the ethical standards for licensed naturopathic doctors in other states and by National organizations such as the American Association of Naturopathic Physicians. These standards include items relating to competence, confidentiality and privacy, informed consent and maintenance of professional boundaries. Specific unethical conduct is prohibited such as making misrepresentations relating to credentials,

qualifications or affiliations; engaging in fraudulent, dishonest or deceitful conduct; exploiting the professional relationship including a personal, sexual, romantic or financial relationship; and engaging in sexual misconduct.

Section 18.912 (relating to sexual misconduct) makes clear that sexual misconduct, to include sexual exploitation of a current or former patient or of an immediate family member of a patient, and sexual behavior with a current patient, constitute unprofessional conduct and subjects the registered naturopathic doctor to disciplinary action.

Finally, § 18.913 (relating to grounds for discipline) sets forth the grounds for discipline of a registered naturopathic doctor, including those reasons set forth in section 204 of the NDRA (63 P.S. § 272.204), and additional reasons such as engaging in fraud in obtaining a registration as a naturopathic doctor; false or deceptive advertising; aiding, assisting, employing or advising an unregistered individual to hold themselves out in a manner which states or implies that the individual is a naturopathic doctor; paying or receiving a commission, bonus, kickback or rebate or engaging in a fee splitting arrangement based on patient referrals; promoting the sale of services, drugs, devices, appliances or goods to a patient so as to exploit the patient for financial gain; failing to disclose the contents of substances or merchandise or the nature and description of naturopathic services recommended, provided or offered to a patient; failing to maintain records; and failing to cooperate with a lawful investigation of the Board. Subsection (b) summarizes the panoply of potential disciplinary and corrective actions that the Board may impose for violations as authorized by the NDRA, the act and 63 Pa.C.S. § 3108(b) (relating to civil penalties), including denying an application for registration, administering a public reprimand, imposing probation or other restrictions on a registration, requiring other corrective actions or assessing monetary civil penalties and costs of investigation.

Proposed Rulemaking

Notice of the proposed rulemaking was published at 51 Pa.B. 7877 (December 18, 2021). The Board did not receive any comments from the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC) or from the House Professional Licensure Committee (HPLC). The Independent Regulatory Review Committee (IRRC) reviewed the proposed regulation and provided comments and recommendations. The Board received a comment from Senator Doug Mastriano as well as comments from multiple stakeholders and members of the public.

Advance Notice of Final Rulemaking

After reviewing the comments to the proposed rulemaking, the Board determined the amendments contemplated as a result of these comments were sufficiently significant to warrant the solicitation of additional comments. Thus, the Board published an "Advance Notice of Final Rulemaking" (ANFR). See 53 Pa. B. 2961 (June 3, 2023). In the ANFR, the Board proposed adding key terms and definitions to the definition section, rectifying ambiguity, providing clarity and replacing non-regulatory language with regulatory language, among other things. As a result

of the publication of the ANFR, the Board received comments from Senator Jay Costa and Senator Doug Mastriano, stakeholders and members of the public.

Summary of Comments to the Proposed Rulemaking and Advance Notice of Final Rulemaking and the Board's Response

General letters of support received in response to proposed rulemaking

The Board received approximately 60 comments from members of the public expressing support for this regulation. These comments were received in a form letter generally indicating an anticipated positive impact on public assurance of competency of naturopathic doctors, an increase in the number of practitioners in the Commonwealth and the potential for mainstream recognition of these services, including by insurance companies in the form of plan coverage. In addition, the Board received comments from three patients of naturopathic doctors expressing the importance of their naturopathic doctor's role to their health.

The Board received several individual comments expressing support for the regulations as a whole and indicating the belief that registration of naturopathic doctors will assist with access to business and practice resources and increase opportunities for integrative care and collaboration across the health care community. The Pennsylvania Association of Naturopathic Doctors submitted a comment that included general support for the registration of naturopathic doctors to increase the health care workforce.

The CNME offered that the registration of naturopathic doctors in the Commonwealth will benefit individuals seeking "integrative/natural healthcare approaches," naturopathic doctors currently practicing in the Commonwealth or those who may wish to relocate from other states, and the overall health and well-being of the citizens of this Commonwealth. The comment further described the function of the CNME in establishing standards for naturopathic doctor training programs and the acceptance of these standards by multiple states. The CNME offers that its standards provide public assurance of the safety and effectiveness of graduates of naturopathic doctor programs.

§ 16.1. Definitions

The American Association of Naturopathic Medical Colleges submitted a comment inquiring into the nature of the practice of a drugless therapist. The Board directs the commentor to the lengthy discussion set forth above relating to drugless therapists, a licensure category which was eliminated decades ago. As such, the Board determined that another lengthy discussion about an outdated classification of licensee was unnecessary except to note that the "drugless therapist" was eliminated when the State Board of Chiropractic began issuing licenses to practice chiropractic.

§ 18.13a. Requirements for licensure as a practitioner of Oriental medicine.

In response to the ANFR, the Board received 46 comments relating to § 18.13a(e) asserting that § 18.13a(e) stands for the proposition that a registration is required for "recommending herbs, minerals and other supplements, or combinations, according to traditions other than Oriental medicine traditions." With this interpretation, the commentors suggest that no individual other than a Board licensee/registrant would be able to recommend herbs, minerals or supplements to another individual in any context. The commentors' misinterpretation appears to be a result of the lack of context for the amendment. A reading § 18.13a in its entirety makes clear that § 18.13a(e) relates solely to registered naturopathic doctors who are also licensed acupuncturists. There is no explicit or implied restriction on "GNC clerks" or "mothers," as suggested by the commentors, when recommending herbs, minerals and other supplements according to traditions than Oriental medicine traditions. Thus, the Board did not amend the final-form rulemaking as a result of these comments.

The Board also received a comment to the ANFR from the Association of Accredited Naturopathic Medical Colleges (AANMC) in response to all subsections using the term "Oriental medicine." AANMC asserts the term "Oriental" is inappropriate. The appropriateness of the term "Oriental medicine" was discussed at length in the proposed rulemaking relating to acupuncturists and practitioners of Oriental medicine at 52 Pa.B. 985 (February 12, 2022). For the reasons set forth in that proposed rulemaking, the Board has not replaced the term used here.

§ 18.15. Practice responsibilities of acupuncturist and practitioner of Oriental medicine who is not a physician.

The Board did not receive any comments on the proposed rulemaking relating to this section. The Board did receive 46 form comments to this section in response to the ANFR. The group of commentors assert concerns about § 18.15(b) relating to the title(s) that may be used by an individual licensed as an acupuncturist. In addition, the Board received a comment from a self-identified naturopathic doctor and licensed acupuncturist, which comment further addresses the usage of the terms "doctor of naturopathy" or "N.D." by acupuncturists, as set forth in § 18.15. The Board received a comment which generally takes issue with the required name tag or badge indicating the title of the licensee.

The Board notes that § 18.15(b) was deleted by final rulemaking published at 53 Pa.B. 5759 (September 16, 2023), and § 18.15 was significantly restructured, necessitating amendments to move the identification/badge requirements to § 18.15(a)(10), pertaining to acupuncturists, and to § 18.15(b.1)(3), pertaining to practitioners of Oriental medicine. The Board notes that section 201 of the NDRA, 63 P.S. § 272.201, makes it unlawful for an individual to use the title of "naturopathic doctor" or "doctor of naturopathic medicine" unless registered by the Board. Therefore, the Board has determined that its statutory authority only extends to the use of those

titles. The amendments to § 18.15 merely permit licensed acupuncturists and practitioners of Oriental medicine to incorporate either of these terms on their required identification if they are also registered with the board as a naturopathic doctor under the NDRA.

§ 18.15a. Scope of practice of acupuncturists and practitioners of Oriental medicine.

As indicated by IRRC in its comment to the proposed rulemaking, proposed § 18.15a(d) contained language appearing to reference a scope of practice. In this section, and throughout the rulemaking, the Board has eliminated references to the "scope of practice" of a naturopathic doctor where necessary based on the legislative intent of the NDRA to create a registration for individuals that meet the qualifications set forth in the NDRA. The Board notes that the provision in § 18.15a(d) simply provides an exception for individuals registered as naturopathic doctors when recommending herbs, minerals and other supplements.

§ 18.902. Definitions.

In a comment to the proposed rulemaking received from IRRC, a list of terms classified as essential to administer and enforce the act and provide the regulated community with a common understanding of key terms was provided. In response to this comment, the Board added and defined the following key terms in the ANFR: "naturopathic medicine," "naturopathic physical medicine," "naturopathic service," and "natural therapies." The NDRA authorizes the Board to impose discipline when a naturopathic doctor provides a naturopathic service below the standard of care. Thus, the Board concludes that the NDRA contains the requisite statutory authority for the Board to define several key terms. Thus, as set forth in the ANFR, "naturopathic medicine," "naturopathic physical medicine," "naturopathic service," and "natural therapies" are defined in the final-form rulemaking. In addition, the Board determined the terms "commercial activity" and "purveyor of merchandise or services" could be replaced with the term "marketing activity" and defined, thereby providing clarity that may have been lacking. The Board finds that the remaining terms identified by IRRC ("naturopathic evaluation," "naturopathy," "natural substances," "naturopathic plan of service" and "service regimen") have either been removed from the finalform rulemaking or have been clarified by the added definitions, and therefore do not need to be defined in the final-form rulemaking.

The Board received 46 form comments relating to the terms and definitions added in response to the comments from IRRC and as set forth in the ANFR. Specifically, the commentors opine that, by negative implication, "only board-registered doctors of naturopathic medicine" may perform naturopathic medicine, naturopathic services and naturopathic therapies. This group of commentors suggest that by defining these terms, the Board has devised a scope of practice unauthorized by the NDRA. To the contrary, the Board defines the terms in the final-form rulemaking to provide a regulatory scheme that is administrable and enforceable as to naturopathic doctors registered by the Board. By way of specific example, under section 204(8) of the NDRA, the Board is permitted to discipline a registrant for immoral or unprofessional conduct, which

conduct includes "acting outside the scope of a registration." Without the additional definitions provided in the final-form rulemaking, this provision of the NDRA may be unenforceable because it would fail to place registrants on notice of their obligations and the consequences for failing to meet those obligations. Therefore, the Board declines to delete these additional terms as suggested by the commenters. However, the Board notes that there is no provision in the NDRA that makes it unlawful to provide these types of services without being registered. Indeed, the only prohibition provided for by the NDRA is found in section 201 of the NDRA, 63 P.S. § 272.201, which makes it unlawful for an individual to use the title of "naturopathic doctor" or "doctor of naturopathic medicine" unless registered by the Board. It was not the Board's intention to regulate the activities of unregistered individuals who provide these types of services by negative implication as suggested by the commenters.

The Board received comments from CNME as well as a practicing naturopathic doctor suggesting the definition of CNME in § 18.902 should include language that would include CNME's existing role of program accreditor. Specifically, the CNME accredits naturopathic doctor programs, which are offered by institutions of higher education which have been accredited by an accrediting body recognized by the U.S. Department of Education. To clarify the role of CNME as a program accreditor, the Board amended the definition of CNME in the final-form rulemaking.

The Board received a comment from a practicing naturopath suggesting the addition of a definition for the key term identified by IRRC, "traditional naturopath." Given that the term "traditional naturopath" does not appear in the final-form rulemaking as a result of the removal of § 18.907(b) (relating to acceptable titles and professional designations by registrants; prohibited titles), this is no longer a key term and does not require a definition.

The Board received an additional comment suggesting that the Board specifically permit naturopathic physicians to perform multiple tasks, including medical and nutritional testing and granting prescriptive authority. The comment also suggests, and provides, definitions for natural substances and naturopath, and suggests amendments to the definition of natural therapies. The Board declines to amend or add definitions as suggested, particularly because many of the tasks listed by the commentor fall squarely within the scope of practice of other health care practitioners required to be licensed by other boards within the Bureau of Professional and Occupational Affairs, and would require an act of the General Assembly to provide such authority.

§ 18.903. Application for naturopathic doctor registration.

IRRC asked whether, for consistency with the NDRA, should § 18.903(b)(3) read "An applicant who graduated prior to 1986 shall demonstrate a passing score on a state naturopathic **licensure** examination." The Board declines to use the term "licensure" examination because not all states that regulate naturopathic doctors use the term "license;" at least one state uses the term "registration." Therefore, to be inclusive of all state regulatory schemes relating to naturopathic

doctors regardless of whether the categorization term is a license, registration or something else, the Board elected to simply refer to a state naturopathic examination.

The Board received a comment on the proposed rulemaking relating to the education requirements for registration as a naturopathic doctor as set forth in § 18.903(b). The Board identified these education requirements to ensure competency of naturopathic doctors and protect the public, which requirements are consistent with the NDRA. The Board is not authorized to modify the statutorily imposed education requirements and declines to do so.

Following publication of the ANFR, Senator Costa, the prime sponsor of the NDRA, provided valuable comments relating to the legislative intent of the NDRA. Senator Costa stated the requirements for registration as a naturopathic doctor are to provide "safe and regulated access to naturopathic medicine for Pennsylvanians." To that end, Senator Costa succinctly reiterated many of the qualifications for registration as set forth in section 202 of the NDRA: graduate of an accredited college, completion of a federally recognized postgraduate education, competency-based licensure examinations and completion of advanced clinical training. The regulations mimic these requirements for registration.

A comment was received suggesting the North American Board of Naturopathic Examiners (NABNE) is not the singular examination provider capable of measuring the competency of a prospective naturopathic doctor. Instead, it is asserted by the commentor that the National Board of Naturopathic Examiners (NBNE) is likewise qualified to be an examiner provider. Notably the commentor does acknowledge the NDRA provides only for the NPLEX examination to meet the registration requirements. In opposition, the comment received from NABNE sets forth its perception of the differences between traditional naturopathic doctors are regulated and the associated identification of either or both the NABNE and NPLEX. As set forth by Senator Costa, the requirements for registration as a naturopathic doctor are to provide safe and regulated access to naturopathic medicine. Therefore, the Board declines to add an additional examination provider not contemplated or authorized by the NDRA.

IRRC commented that inconsistency exists between the disciplinary history disclosures on initial applications in § 18.903 and those for registration and renewal and reactivation registration applications in § 18.904(b)(3) (relating to biennial registration of naturopathic doctor). Section 18.903 relates to the criteria for registration as a naturopathic doctor and is consistent with other regulatory provisions relating to criteria for a license, certificate, permit or registration. The disclosures required by all applicants for a license, certification or registration are set forth in the Board's regulations in § 16.16 (relating to reporting of disciplinary actions, criminal dispositions and other licenses, certificates or authorizations to practice). These disclosures include "[d]isciplinary action instituted against the applicant by a licensing authority of another state, territory or possession of the United States, another country or a branch of the Federal government." Because § 16.16 applies to applications for registrations as a naturopathic doctor, it

would be duplicative and inconsistent to insert this same requirement in § 18.903. However, the Board has added a cross-reference to § 16.16 for the sake of clarity.

The CNME provided a comment which defines the role of CNME in the accreditation process as did two other commentors. The CNME accredits naturopathic doctor programs, which are offered by institutions of higher education which have been accredited by an accrediting body recognized by the U.S. Department of Education. To clarify the role of CNME as a program accreditor, the Board amended § 18.903(b)(2) in the final-form rulemaking. The Board notes CNME provided information relating to the difference between the training obtained through a CNME-accredited program and other programs teaching some level of naturopathy.

The Board received 18 form comments, a comment from The American Association of Naturopathic Physicians (AANP) and a comment from a practicing naturopathic doctor requesting consistency between the number of continuing education hours in child abuse recognition and reporting required for initial registration and renewal. The commentors suggest 23 Pa. C.S. 6383(b)(3)(i) (relating to education and training), the statute from which the Board derives its authority to require this continuing education, requires only 2 hours of training at the time of initial application and as such, the language in § 18.903(b)(5) (requiring at least 3 hours of training in child abuse recognition and reporting for initial licensure) should be modified accordingly. The regulation, as written, reflects the differing requirements for the training hours in child abuse recognition and reporting for individuals seeking initial registration (at least 3 hours) set forth at 23 Pa.C.S. § 6383(b)(3)(i) and registrants seeking renewal or reactivation of a registration (at least 2 hours) set forth at 23 Pa.C.S. § 6383(b)(3)(ii). This language is also consistent with the training requirement and continuing education hours required by the Board for all other Board-regulated practitioners in Chapter 16 at § 16.108 (relating to child abuse recognition and reporting mandatory training requirement). To aid clarity, the Board has added a cross-reference to § 16.108.

Finally, AANMC suggests the deleting the word "licensure" in the parenthetical found at the end of § 18.903(a). The parenthetical represents the verbatim title of § 16.13. Therefore, the Board declines to make the requested amendment.

§ 18.904. Biennial registration of naturopathic doctor.

The Board received 18 form comments, a comment from AANP as well as a comment from a naturopathic doctor requesting consistency between the number of continuing education hours in child abuse recognition and reporting required for initial registration and renewal. As set forth above, the required hours are consistent with 23 Pa. C.S. § 6383 and the requirements for other board-regulated practitioners. To aid clarity, the Board has added a cross-reference to the mandatory training requirements in § 16.108.

§ 18.905. Inactive status; reactivation of inactive or expired registration.

The comments to the proposed rulemaking received from IRRC contain several suggestions for amendments to § 18.905. First, IRRC suggests revising § 18.905(a) to provide specificity of the effective date of inactive status. Section 18.905(a), as written, is consistent with the language in §§ 18.310 (relating to inactive status of respiratory therapist license); 18.526 (relating to inactive status of behavior specialist license); 18.608 (relating to inactive status of perfusionist license); 18.707 (relating to inactive status of genetic counselor license); and 18.863 (relating to inactive status of prostethist, orthostist, pedorthist and orthotic fitter licenses). It should be noted that the Board currently receives requests for inactive status through the online licensing system. Therefore, requests are processed and become effective within 24 hours, with notice thereof sent to the requestor within the same timeframe. Because an amendment would cause inconsistency with the regulations of other allied professions regulated by the Board and because inactive status is an automatic function of the online licensing system, the Board does not find inclusion of a specific date to be necessary.

Also relating to § 18.905(a), IRRC suggests including the title usage prohibition upon registrants with an expired registration. Because § 18.905(a) relates only to inactive status, the Board concludes that introducing expired status would cause confusion to the regulated community. The Board notes that the title usage prohibition for expired licenses is already set forth in § 18.904(a). In addition, § 18.907(a) and (c) require an individual to have a current, active and unsuspended registration to use the title of or hold oneself out as, a naturopathic doctor, registered naturopathic doctor, doctor of naturopathic medicine, or any similar title implying that the individual holds a current registration. Thus, the Board did not make a change to § 18.905(a).

IRRC commented that a reactivation fee was not included in the proposed rulemaking, despite inclusion in RAF #17. The Board will not charge a separate reactivation fee. The only fee that will be charged is the usual renewal fee. Therefore, reference to this fee does not need to be included in § 18.905(b). The RAF has been corrected.

After publication of the ANFR, the Board received 18 form comments, and comments from NABNE, AANP, AANMC and a practicing naturopathic physician relating to the clinical competency requirement. The commentors request that the clinical competency requirement set forth in § 18.905(b) be limited to NPLEX Part II—Core Clinical Science Examination. In response to these comments, and upon the determination of the Board that passage of the NPLEX Part II would provide the assurance of clinical competency sought by the Board for reactivation, the suggested amendment has been made in the final-form rulemaking.

In response to the ANFR, the Board received two comments relating to prohibitions and disclosures while a naturopathic doctor's registration is expired or inactive. Sections 18.904(a) and 18.905(a) prohibit the use of several titles by a naturopathic doctor while expired or on inactive status and § 18.905(b)(2) requires disclosure if one of these titles is used during a period of time registration is inactive or expired. One commentor suggests medical doctors and other healthcare professionals are permitted to use their titles while inactive or in expired status and as such,

naturopathic doctors should be no different.

The Board notes that section 201 of the NDRA, 63 P.S. § 272.201, clearly states that "[i]t 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." In addition, section 206(a)(3) of the NDRA, pertaining to violation of the act, provides the Board the authority to impose a civil penalty on "[a]n individual who holds himself out as a registrant without being properly registered as provided in this act." Thus, a naturopathic doctor may not use any of the three titles set forth in § 18.905 if their registration is expired or inactive.

The Board directs the commentors to the Medical Practice Act of 1985 (act) (63 P.S. §§ 272.101—272.301), which prohibits medical doctors, as well as other Board-regulated practitioners, from utilizing certain titles without a valid, current license. See, for example, section 13.3(a) of the act (63 P.S. § 422.13c(a)) which makes it "unlawful for any person to hold himself out the public as a perfusionist...unless the person holds a valid, current license issued by the board..." Further, a medical doctor is defined in Section 2 of the act as "an individual who has acquired one of the following licenses to practice medicine and surgery issued by the board: (1) license without restriction; (2) interim limited license; (3) graduate license..." Section 10 of the act states "no person other than a medical doctor shall engage in any of the following conduct except as authorized or exempted in this act: ...(3) hold forth as authorized to practice medicine and surgery through use of a title, including, but not necessarily limited to, medical doctor, doctor of medicine, doctor of medicine and surgery, doctor of a designated disease, physician, physician of a designated disease, or any abbreviation of the foregoing."

However, the Board acknowledges that the language in § 18.905 is somewhat different than the corresponding regulations for other Board-regulated practitioners. This is because the NDRA is not a true "practice" act. For all other professions, the act and regulations prohibit "practicing" or "holding oneself out as authorized to practice" when a license, certificate, permit or registration is expired or inactive. Further, Board-regulated practitioners are required to disclose whether they practiced while their license was expired or inactive. Because the NDRA contains no such prohibition, but rather prohibits the use of certain protected titles as noted above. Therefore, the final-from rulemaking prohibits the use of these protected titles when a registration is expired or inactive to be consistent. For these reasons, the Board has made no changes to these provisions.

The additional comment received relating to § 18.905 takes issue with the prohibition on usage of terms implying current registration with the Board unless the individual is so registered. Similar to other commentors, it is asserted that this subsection should not be used to prohibit the use of the post-nominal "N.D." by any person, whether registered or not, who has earned such a degree. As with other professions containing similar prohibitions, the goal of the Board is the promotion of public safety through discernable methods for the public at large to easily distinguish between individuals who are licensed or registered with the Board, and those who are not. Because

the Board finds § 18.905(a) and (d) of this final-form rulemaking to be consistent with the intent of the NDRA, the Board declines to amend the subsections as requested.

§ 18.907. Acceptable titles and professional designations by registrants and non-registrants; prohibited titles.

IRRC provided comment to § 18.907 indicating it would await the Board response to comments on this section. In response to all comments received on the proposed rulemaking, the Board initially determined maintaining § 18.907 as written was appropriate and as such, declined to make suggested amendments in the ANFR. Upon review of the comments to the proposed rulemaking as well as comments to the ANFR, the Board determined removal of § 18.907(b) is consistent with the legislative intent of the NDRA.

Response to Comments to § 18.907(b) as proposed

The Board received a comment from Senator Mastriano wherein concern was raised relating to the restriction of the use of the title Doctor of Naturopathy to those who are registered with the Board. Senator Mastriano suggests that the restriction will cause financial and professional hardship to established naturopathic doctors and traditional naturopathic doctors, some of whom may have been practicing for decades. The proposed amendment to this section offered by Senator Mastriano would allow an individual to use the title "doctor of naturopathy" or "N.D." so long as the title does not imply that the individual is a naturopathic doctor registered with the Board.

The Board received six additional comments in substantially similar form relating to § 18.907. Through this letter, these individuals set forth opposition to § 18.907(b) and assert that the NDRA does not specifically preclude individuals who identified themselves as a "Naturopathic Doctor" and/or used the abbreviation "N.D." prior to the enactment of the NDRA ("traditional naturopaths") from maintaining use of those designations. The commenters posit they should be able to retain the use of both the designation "Naturopathic Doctor" and "N.D." abbreviation without the necessity of registration as required by the NDRA and this regulation.

In support thereof, Senator Mastriano and the other commenters refer to the legislative history of the NDRA and the final enactment as standing for the proposition that the General Assembly did not intend for the Board to regulate the use of the abbreviation "N.D." or "naturopathic doctor". Additionally, the commenters opine traditional naturopaths will incur expenses to change signage and other forms to comply with § 18.907(b). Further concern was expressed that § 18.907(b) creates uncertainty among traditional naturopaths' continued use of the degree they earned, "doctor of naturopathy" or "N.D." Finally, it is asserted that members of the public are confused as to whether they can continue seeing traditional naturopaths. The commenters' proposed solution to the above is an amendment to § 18.907(b) that would allow a non-registered person to use "doctor of naturopathy or N.D." as long use thereof does not imply

that the individual is a naturopathic doctor registered with the Board.

In response to the foregoing, the Board reiterates several provisions from the NRDA. First, section 102 of the NDRA (63 P.S. § 272.102) defines the term "naturopathic doctor" as "[a]n individual who holds an active registration under this act." Second, section 201 (63 Pa. C.S. § 272.201) makes unlawful the use of the "title 'naturopathic doctor' or 'doctor of naturopathic medicine' unless that person is registered as a naturopathic doctor with the board." However, in response to the commenters' concerns, the Board determined that the removal of subsection (b) which seeks to regulate individuals who are not registered with the Board is sufficient to address their concerns and is consistent with the NDRA.

The Pennsylvania Association of Naturopathic Doctors suggests the addition of the postnominal "N.D." to § 18.907(a) to ensure that use of this designation is limited to individuals who have completed accredited naturopathic doctor programs. The Board received several additional comments from naturopathic doctors who possess the education requirements set forth in the regulations and their desire to restrict usage of the terms "naturopathic doctor" and use of "N.D." to those who have obtained that same education. The Board finds the language of § 18.907 is sufficient and does not necessitate a listing of post-nominals or more specific usage exclusions that are not contained in the NDRA.

Response to Comments to § 18.907(b) received after ANFR publication

In the comment submitted from Senator Jay Costa, as it pertains to section § 18.907(b), Senator Costa indicates this subsection as written is contrary to the language and legislative intent of the NDRA. In support of the request to delete § 18.907(b), Senator Costa states it was not the intent of the General Assembly to "address unregistered lay or traditional providers under the NDRA or, as a consequence, its governing regulations." In keeping with the legislative intent as set forth by Senator Costa, § 18.907(b) has been deleted in the final-form rulemaking.

The Board also received a comment from Senator Mastriano, with Representatives Keefer, Zimmerman, Fink, Kauffman, Gleim and Borowicz additional signatories to this letter. The Board thanks Senator Mastriano as well as the Representatives for the in-depth and careful consideration given to the text of the ANFR. Senator Mastriano provided a comment relating to use limitation of the terms "Doctor of Naturopathy" and "N.D." As set forth above, reference to the post-nominal "N.D." has been deleted in the final-form rulemaking. The Board likewise deleted § 18.907(b). The Board does not find additional amendments are necessary to address the concerns relating to this comment.

The Board received 46 form comments suggesting that § 18.907 is insufficiently specific. As set forth fully above in response to the comment received from Senator Costa, § 18.907(b) has been deleted in the final-form rulemaking. By way of further response, the Board asserts the list of titles in § 18.907(a) and the phrase "any similar title implying that the individual holds a current

registration as a naturopathic doctor in this Commonwealth" are sufficiently specific to place individuals on notice that they may be subjected to disciplinary action for title utilization without having first secured registration from the Board.

Additional comments were received regarding the deletion of 18.907(b). The Board received 18comm ents in substantially similar form, a comment from a practicing naturopathic doctor, the CNME, the AANP and a comment from a practicing naturopathic doctor requesting the removal of section 18.907(b). As set forth fully above in response to the comment received from Senator Costa, § 18.907(b) has been deleted in the final-form rulemaking.

The Board received a comment from a self-identified traditional naturopath, who opposes any restriction on the use of "N.D." As set forth in the NDRA, it is "unlawful for an individual to use the title 'naturopathic doctor' or 'doctor of naturopathic medicine' unless that person is registered as a naturopathic doctor with the board." As set forth above in response to Senator Costa and many other commentors, § 18.907(b), which addressed traditional naturopaths such as this commentor, has been deleted from the final-form rulemaking.

In addition to the foregoing, a self-identified naturopathic doctor comments that public confusion will surface should the regulations specifically provide for indiscriminate title usage by registrants and non-registrants or fail to address title usage at all. The Board finds the NDRA and § 18.907 (as it reads with the removal of subsection (b) as provided herein) are sufficient to address concerns that members of the public will not be able distinguish between a registered naturopathic doctor and any other non-registered individual practicing naturopathy. The commentor further suggests providing a post-nominal that could be used by an individual who holds a degree as a naturopathic doctor but is not registered with the Board. There are many practitioners regulated by the Board to practice a particular profession. The Board declines to make any changes to the final-form rulemaking specific to naturopathic doctors that would result in inconsistency with other Board-regulated practitioners.

An additional comment was received highlighting the differences between an individual who would qualify for registration as naturopathic doctor and traditional naturopaths. The comment also relays a concern that usage of the post-nominal "N.D." by anyone, registered with the Board or not, will blur the distinction between those who have obtained a naturopathic doctor degree after completing a robust postgraduate naturopathic doctor program and those who have engaged in other types of naturopathic education or training. The Board removed § 18.907(b) in this final-form rulemaking for the multiple reasons set forth herein. The Board believes this will allay, to the extent possible, commentors' concerns that the public will be unable to distinguish a registered naturopathic doctor, who has met the corresponding education and training requirements, from all others practicing as traditional naturopaths.

The Board received a comment from the Association of Accredited Naturopathic Medical

Colleges (AANMC) relating to this section and post-nominal usage. The AANMC opines that the patients are often unable to distinguish between a naturopathic doctor who meets the education and training requirements in the regulation and a naturopath who does not meet those requirements. For public safety purposes, and to promote the public understanding of the distinction between the two, AANMC suggests title protection within the regulation of the following terms: naturopath, traditional naturopath, naturopathic doctor and naturopathic physician, and the post-nominals N.D., N.M.D. and D.N.M. The Board has removed § 18.907(b) for the reasons set forth herein. The Board declines to include the requested titles and post-nominals in the regulation.

The AANMC requests the regulation authorize the use of N.D. or N.D. (ret.) by individuals who have earned a naturopathic doctor degree but may not be registered with the Board for various reasons, including retirement and engagement in academia. This appears to contradict the request of AANMC to limit the usage of N.D. to those who are registered with the Board. Nevertheless, the Board similarly finds that § 18.907 provides sufficient notice to the public of when certain title usage is appropriate.

AANP offered an additional comment relating to § 18.907(c). In its comment, the AANP suggests an amendment that would include the post-nominals for the designations contained in the subsection as published. The Board declines to include the post-nominals as requested.

§ 18.908. Informed consent and disclosure of financial interest.

The comments received from IRRC address several facets of § 18.908. The first of the three concerns raised relate to what appears to be a conflict between § 18.908(b), which requires disclosures relating to certain financial incentives, and § 18.911(d)(3) and (d)(8) (relating to Code of Ethics), which appears to categorize the same activity as unethical. The second concern of IRRC related to the lack of a definition for "purveyors of merchandise or services" and "commercial activity." To cure any inconsistencies, the Board replaced the terms "purveyors of merchandise or services" and "commercial activity" with the term "marketing activity" and provided a definition in § 18.902. The definition of the term "marketing activity" excludes health care providers as service providers. The Board published these amendments in the ANFR along with other added definitions and finds these changes to be sufficient to address the third concern of IRRC (relating to duties of a naturopathic doctor).

In response to the ANFR, the Board received a comment regarding §§ 18.908(b) and 18.913(a)(6) (relating to grounds for discipline); the commentor asserts the former is too broad and the latter too restrictive resulting in a provision that is difficult for the regulated public to follow and the Board to enforce. The commenter further suggests removal of § 18.913(a)(6), pertaining to the authority to discipline for promoting the sale of services, drugs, devices, appliances or goods to a patient so as to exploit the patient for financial gain, as it is duplicative given the breadth of § 18.908(b). The Board notes that §§ 18.908(b), 18.911(d), 18.913(a)(5) and 18.913(a)(6) address the monetary aspects attendant to the practice of naturopathic medicine.

Upon review, the Board determined that § 18.908(b) can be more narrowly tailored to apply only to merchandise, as it appears that §§ 18.911(d), 18.913(a)(5) and 18.913(a)(6) address the other financial-related topics of concern to the Board. As a result of that amendment, the Board declines to delete § 18.913(a)(6) as requested.

An additional comment was received requesting removal of § 18.908 in its entirety. The Board declines to remove this section. The Board would like to note that informed consent is also a duty of physicians prior to conducting certain procedures, as set forth in section 504 of the MCARE Act, Act of June 30, 2021, (P.L. 330, No. 61), 40 P.S. §§ 1303.101—1303.910.

In addition, the disclosure of financial interests in § 18.908(b), with the amendments made in response to the ANFR comments received, address commissions, rebates, referral fees or other financial incentives received by the registrant for recommending any merchandise to the patient. This subsection is a means of public protection and is consistent with Federal and State laws governing other healthcare practitioners and healthcare related fields. For example: (1) pharmaceutical manufacturer gift bans of items exceeding a specific dollar amount and other restrictions; (2) Federal anti-kickback laws which make it illegal to knowingly and willfully offer, pay or provide anything of value to induce an individual or entity to recommend or prescribe a product or service reimbursed by the government; (3) the Prescription Drug Marketing Act of 1987 prohibits the sale, purchase, or trade of drug samples and for an individual to sell or seek reimbursement for samples; and (4) The Physician Payments Sunshine Act, which is designed to increase transparency around financial relationships between physicians, teaching hospitals, and manufacturers of drugs, medical devices and biologics. For all of the reasons set forth herein, the Board does not find it is in the public interest to delete § 18.908.

§ 18.911. Code of Ethics.

Five subsections were found by IRRC to contain non-regulatory language lacking clarity and failing to set a binding norm. In response thereto, the Board amended the annex and published in the ANFR clear compliance standards for the regulated community. Section 18.911(f) was amended consistent with these comments, as set forth in the ANFR, to prohibit a naturopathic doctor from using the absence of a specific ethical, legal or professional duty as a defense to a disciplinary action, when the duty is within the standard of care. In addition, the Board amended the language in § 18.911(c) as suggested. With regard to § 18.911(d)(3), the Board amended the subsection to replace the term "commercial activity" with the term "marketing activity" and replace reference to the "duties of a naturopathic doctor" with a cross-reference to § 18.911(c).

In response to the concern relating to the enforceability of these regulations as contemplated by the language of the NDRA, the Board added 18.911(d)(13) which specifically precludes providing or performing a naturopathic service at a level beneath the standard of care.

The Board received a comment to § 18.911 unrelated to the compliance standards as

modified pursuant to the IRRC comments to the proposed rulemaking. AANMC requested the Board confirm that § 18.911(b) does not contradict the Americans with Disabilities Act. The Board complies with Federal laws relating to the Americans with Disabilities Act while exercising its authority to protect the public. The Board's concern is not with all disabilities, but only those that impact an individual's ability to practice naturopathic medicine or provide naturopathic services with reasonable skill and safety to patients and has amended this provision accordingly.

§ 18.913. Grounds for discipline.

In response to a comment received from IRRC, the Board amended § 18.913(a)(8) to clarify that a naturopathic doctor is prohibited from failing to disclose the contents of medicines or merchandise or the nature and description of naturopathic services, replacing the language in the proposed relating to "secret method, treatment, product or medicine." The Board believes the amended language addresses the concerns of IRRC.

IRRC also submitted a comment to subsection (b) pertaining to the Board's authority in section 204(5)(iv) of the NDRA to impose disciplinary or corrective action when a naturopathic doctor is unable to practice naturopathic medicine with reasonable skill and safety to patients by reason of illness, addiction, or other enumerated conditions. Specifically, IRRC notes that ""a naturopathic doctor 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," and asks the Board to provide a detailed descript of how it will administer this provision in the final-form rulemaking. The Board notes that nearly identical language can be found in section 41(5) of the Medical Practice Act for all other Board-regulated practitioners and has been part of the Board's practice since at least 1985. Generally, a Board-regulated practitioner may petition for relief from a disciplinary order under this provision at any time and is given an opportunity to demonstrate that he or she can resume a competent practice of his or her profession with reasonable skill and safety. Thus, the Board does not dictate what a "reasonable interval" may be and leaves that to the affected individual to determine. The Board is required to follow the General Rules of Administrative Practice and Procedure (1 Pa.Code, Part II), the Medical Practice Act, the Board's regulations in Chapter 16 (relating to general provisions) and any other statutory or constitutional authority relating to due process and the property interest a naturopathic doctor may have in a registration when enforcing these provisions. The Board declines to reiterate those standards in this final-form rulemaking.

The Board received a comment in response to the ANFR pertaining to § 18.913(a)(6), in which the commentor asserts that the acts that would constitute patient deception and exploitation are vague. While the Board cannot foresee, and consequently list, every activity that could be considered deceitful or exploitive, the common legal definition of exploitation and understanding of exploitation are sufficient to overcome the purported vagueness. Therefore, the Board declines to make an amendment.

IRRC Comments to RAF

IRRC noted the incorrect dates set forth the RAF at #29. The Board amends its response to RAF #29 to reflect the correct timeline.

IRRC also notes the reactivation fee of \$100 set forth in RAF #17 and the absence of the same fee in the regulation. The Board will not require registrants to pay an additional \$100 reactivation fee. Therefore, reference to this fee has been removed from RAF #17.

Comments to proposed rulemaking applicable to multiple or unspecified subsections

IRRC mentions inconsistency with usage of the terms "initial registration" and "naturopathic service." The Board finds the amendments made in response to the prior comments made by IRRC to correct inconsistencies.

The Board received a comment to the proposed rulemaking suggesting the inclusion of the abbreviation "N.D." in all parts of the regulation where the titles "naturopathic doctor" and "doctor of naturopathic medicine" appear for the purpose of excluding any individual who does not have a current registration with the Board from using the abbreviation for the title "naturopathic doctor." In balancing the competing interests identified through the various comments, the Board finds the inclusion throughout the regulation of the phrase "any other term implying that the individual is currently registered as a naturopathic doctor" is sufficiently inclusive and consistent with legislative intent and the plain language of the NDRA.

The Board received a comment to the proposed rulemaking suggesting further clarification on whether naturopathic doctors are providing homeopathic care, medical care or nursing care, and the level of education required. The Board believes that the addition of the definitions requested by IRRC satisfies the request for clarity as to what type of care naturopathic doctors provide. In addition, the act and the Professional Nursing Law (63 P.S. §§ 211—226) limit the practice of these professions to those who are properly licensed by the applicable Board. The educational requirements for naturopathic doctors registered with the Board are set forth in the NDRA and § 18.903. In addition, the educational requirements and practice responsibilities of all other health-related professions are set forth in the respective Boards' practice acts and regulations.

The Board received a comment to the proposed rulemaking expressing concern relating to the implementation of oversight of naturopathic doctors registered with the Board. In response thereto, the Board refers the commenter to §§ 18.911—18.913 and to the Board's regulations in Chapter 16, subchapter E, pertaining to the Board's disciplinary process and procedures.

Comments to ANFR applicable to multiple or unspecified subsections

Senator Doug Mastriano

As indicated above relative to § 18.907(b), the Board received a comment from Senator Mastriano. Representatives Keefer, Zimmerman, Fink, Kauffman, Gleim and Borowicz were also signatories to this letter. The Board recognizes that the pool of naturopathic doctors who may qualify for registration as a naturopathic doctor does not encompass all current practitioners of naturopathy. The final-form regulation reflects a regulatory scheme the Board finds is consistent with the legislative intent of the NDRA.

The Board received a comment requesting the Board authorize prescriptive authority for naturopathic doctors. Authorization for prescriptive authority must be derived from a specific act of the General Assembly. Because this authority does not exist, the Board has not and will not consider prescriptive authority for registered naturopathic doctors.

The American Naturopathic Association (ANA) provided comments which highlight the difference between the class of professionals who meet the registration requirements of the NDRA and all others who identify as traditional naturopaths and suggests both should be permitted to register as naturopathic doctors. The ANA posits that these regulations would "severely limit the practice of many in the State of Pennsylvania." However, the ANA fails to provide specific details as to how these regulations limit that practice. Thus, the Board is unable to respond directly to this comment. The ANA concludes that a separate regulatory scheme is needed to encompass the practice of the traditional naturopathy. The Board appreciates the comments and brief, yet comprehensive, historical narrative of the "schism between naturopaths." However, the creation of a new type of license, registration, permit or certification for traditional naturopaths is a function of the General Assembly. Therefore, the Board is unable to act upon the suggestions of the ANA.

Description of Amendments to the Final-form Rulemaking

The Board amends § 18.13a(e) to remove implicit reference to the scope of practice of a naturopathic doctor by replacing the phrase "the practice of a naturopathic doctor" with "a registered naturopathic doctor."

The Board amends § 18.15 to delete the proposed amendment to subsection (b), which was deleted in a previous rulemaking of the Board. Because that rulemaking restructured § 18.15, it was necessary to amend subsections (a) and (b.1) to provide that an individual licensed as an acupuncturist or as a practitioner of Oriental medicine who also possesses a current and active registration as a naturopathic doctor may utilize the title "doctor of naturopathic medicine" or "naturopathic doctor" notwithstanding the general prohibition on the use of the word "doctor" on their identification tag or badge.

The Board amends § 18.15a(d) to remove implicit reference to the scope of practice of a naturopathic doctor by replacing the phrase "the practice of a naturopathic doctor" with "a registered naturopathic doctor."

The Board amends § 18.902 (relating to definitions) to revise the definition of "CNME" to correspond to the information provided by CNME as to programmatic accreditation. The Board added definitions for the following terms: "marketing activity," "naturopathic medicine," "naturopathic physical medicine," "naturopathic service" and "natural therapies." Finally, the Board has deleted "natural substances" from the definition of "merchandise" because it is overbroad, and the remaining list is sufficient.

The Board amends § 18.903(a) to include a cross reference to § 16.16 for clarity. Section 18.903(b) is amended to simply refer to a registration as a naturopathic doctor and (b)(2) to read "holds a doctoral degree from an institutionally accredited or pre-accredited college or university offering a naturopathic doctor program which has been granted programmatic candidacy or accreditation by the CNME..." instead of "holds a doctoral degree from a naturopathic school accredited by the CNME..." based on the comment submitted by CNME. Finally, § 18.903(b)(5) is amended to include a cross reference to the mandatory training requirement in child abuse recognition and reporting in § 16.108(a) as a condition of initial registration to aid clarity.

The Board amends § 18.904(a) to add "registered naturopathic doctor" to the list of titles prohibited from use when registration is expired to be consistent with § 18.907. Additionally, the Board amends § 18.904(b)(5) to add a cross reference to the mandatory continuing education in child abuse recognition and reporting in Chapter 16 at § 18.108(b) as a condition of biennial renewal to aid clarity.

The Board amends § 18.905(a) and (b)(2) to add "registered naturopathic doctor" to the list of titles prohibited from use when registration is on inactive status. § 18.905(b)(6) is also amended to add a cross reference to the mandatory continuing education in child abuse recognition and reporting in Chapter 16 at § 18.108(b) as a condition of reactivation of an expired or inactive registration. The Board amends § 18.905(c) to specify the examination required to demonstrate competency is the "NPLEX Part II—Core Clinical Science Examination."

The Board amends § 18.907 to change the title from "Acceptable titles and professional designations by registrants and non-registrants; prohibited titles" to "Acceptable titles and professional designations by registrants; prohibited titles." The Board further amends § 18.907 to delete proposed subsection (b) which sought to instruct non-registrants as to what titles they could utilize.

The Board amends § 18.908(b) to replace "referral of a patient to purveyors of merchandise or services or for recommending any merchandise to a patient" to "any marketing activity relating to merchandise."

The Board is amending § 18.910(b)(9) to replace the undefined term "natural substances" with the defined term "merchandise" and to utilize the defined term "naturopathic service."

The Board amends§ 18.911(a) to clarify that the Board is concerned about impairments that impact a naturopathic doctor's ability to practice naturopathic medicine or to provide naturopathic services. Section 18.911(c) is amended to remove "non-regulatory" language, to use the defined term "naturopathic services" throughout and to provided needed clarity.

The Board amends § 18.911(d) as follows: (d)(3) is amended to read "engage in a marketing activity which conflicts with subsection (c)" instead of "engage in a commercial activity which conflicts with the duties of a naturopathic doctor;" (d)(9) is amended to remove the phrase "a particular course of care" and add the phrase "particular naturopathic service;" (d)(13) is added which reads "provide or perform a naturopathic service at a level beneath the accepted standard of care for a naturopathic doctor which would be normally exercised by the average professional of the same kind in this Commonwealth under the circumstances, including locality and whether the naturopathic doctor is or purports to be a specialist in the area;" and to use the defined term "naturopathic service" throughout.

The Board amends § 18.911(e) to read "A naturopathic doctor may not perform or provide a naturopathic service that the naturopathic doctor is not qualified to perform, or which is beyond the naturopathic doctor's education and training.

The Board amends § 18.911(f) to replace the entire subsection with the following language: "A naturopathic doctor may not assert as a defense to a disciplinary action under 204 of the NDRA (63 P.S. § 272.204) or § 18.913 (relating to grounds for discipline), the absence of a specific ethical, legal or professional duty in this subsection when such duty is normally exercised by the average professional of the same kind in this Commonwealth under the circumstances, including locality and whether the naturopathic doctor is or purports to be a specialist in the area.

The Board amends § 18.913(a)(8) to replace "offering, undertaking or agreeing to cure or treat a disease by a secret method, treatment, product or medicine" with "failing to disclose the contents of merchandise or the nature and description of services recommended, provided or offered to a patient."

Fiscal Impact and Paperwork Requirements

The only fiscal impacts of this final-form rulemaking are the fees imposed upon naturopathic doctors for initial registration (\$100) or biennial renewal (\$50). Naturopathic doctors applying for initial registration, biennial renewal of registration or reactivation of an inactive or expired registration will be required to submit online applications and submit required documentation to the Board.

Sunset Date

The Board continuously monitors the effectiveness of its regulations. Therefore, no sunset date has been assigned.

Regulatory Review

Under Section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on February 5, 2022, the Board submitted a copy of the proposed rulemaking, published at 52 Pa.B. 835 (December 18, 2021) and a copy of a Regulatory Analysis form to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the SCP/PLC and the HPLC. A copy of this material is available to the public upon request.

Under section 5(c) of the Regulatory Review Act (71 P.S. § 745.5(c)), the Board provided IRRC, SCP/PLC, and HPLC with copies of comments received as well as other documents when requested. In preparing the final-form regulation, the Board considered comments received from IRRC, the legislative comment received from Senator Mastriano as well as all public comments received. The Board received no comments from the HPLC or SCP/PLC.

Under section 5.1(a) of the Regulatory Review Act (71 P.S. § 745.5a(a)), on January 17, 2024, the Board delivered this final-form rulemaking to IRRC, the HPLC and the SCP/PLC. Under section 5.1 (j.2) of the Regulation Review Act, the final-form rulemaking was deemed approved by the HPLC and the SCP/PLC on ______, 2024. Under section 5.1(e) of the Regulatory Review Act, IRRC met on ______, 2024, and approved the final-form rulemaking.

Additional Information

Additional information may be obtained by writing to Saiyad Ali, Acting Board Administrator, State Board of Medicine, P.O. Box 2649, Harrisburg, PA 17105-2649, ST-MEDICINE@PA.GOV.

Findings

The Board finds that:

(1) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§ 1201 and 1202), known as the Commonwealth Documents Law and the regulations promulgated thereunder, 1 Pa. Code §§ 7.1 and 7.2 (relating to notice of proposed rulemaking required; and adoption of regulations).

(2) A public comment period was provided as required by law, and all comments received were considered in drafting this final-form rulemaking.

(3) The amendments to this final-form rulemaking do not enlarge the original purpose of the proposed rulemaking published at 51 Pa.B. 7877 (December 18, 2021).

(4) This final-form rulemaking is necessary and appropriate for the administration of the Naturopathic Doctor Registration Act, 63 P.S. §§ 272.101–272.301.

Order

The Board, therefore, orders that:

(a) The regulations of the Board at 49 Pa. Code Chapters 16 and 18 are amended by amending §§ 16.1, 16.11—16.13, 18.13a, 18.15, 18.15a, and adding Subchapter M (relating to registration of naturopathic doctors) to Chapter 18 at §§ 18.901—18.913, as set forth in the Annex.

(b) The Board shall submit the final-form regulation to the Office of Attorney General and the Office of General Counsel for approval as required by law.

(c) The Board shall submit the final-form regulation to IRRC, the HPLC and the SCP/PLC as required by law.

(d) The Board shall certify the final-form regulation and deposit it with the Legislative Reference Bureau as required by law.

(e) This final-form regulation shall take effect upon notice or publication in the *Pennsylvania Bulletin.*

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

ANNEX A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS PART I. DEPARTMENT OF STATE Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS CHAPTER 16. STATE BOARD OF MEDICINE – GENERAL PROVISIONS Subchapter A. BASIC DEFINITIONS AND INFORMATION

§ 16.1. Definitions.

The following words and terms, when used in this chapter and Chapters 17 and 18 (relating to State Board of Medicine—medical doctors; and State Board of Medicine—practitioners other than medical doctors), have the following meanings, unless the context clearly indicates otherwise:

* * * * *

Act—The Medical Practice Act of 1985 (63 P. S. §§ 422.1—[422.45] 422.53).

Approved activity – A continuing medical education activity accepted for AMA PRA credit.

Board – The State Board of Medicine.

Board-regulated practitioner—A medical doctor, midwife, physician assistant, [drugless therapist,] respiratory therapist, athletic trainer, acupuncturist, practitioner of Oriental medicine, genetic counselor, behavior specialist, perfusionist, prosthetist, orthotist, pedorthist, orthotic fitter, <u>naturopathic doctor</u> or an applicant for a license, <u>registration</u> or certificate that the Board may issue.

* * * * *

Subchapter B. GENERAL LICENSE, CERTIFICATION AND REGISTRATION PROVISIONS

§ 16.11. Licenses, certificates and registrations.

* * * * *

- (c) The following registrations are issued by the Board:
 - (1) Registration as a supervising physician of a physician assistant.
 - (1.1) Initial registration as a naturopathic doctor.
 - (2) Biennial registration of a license without restriction.
 - (3) Biennial registration of an extraterritorial license.
 - (4) Biennial registration of a midwife license.
 - (5) Biennial registration of a physician assistant license.
 - (6) [Biennial registration of a drugless therapist license.] (Reserved).
 - (7) Biennial registration of a limited license-permanent.

* * * * *

- (18) Biennial registration of an orthotic fitter license.
- (19) Biennial registration of a naturopathic doctor registration.

§ 16.12. General qualifications for licenses, registrations and certificates.

To qualify for [a] <u>an initial license, registration</u> or certificate issued by the Board, an applicant shall establish that the following criteria are satisfied:

* * * * *

§ 16.13. Licensure, certification, examination and registration fees.

* * * * *

- (d) *Acupuncturist licenses:*
 - (1) Acupuncturist:

Application\$30		
Biennial renewal\$40		
(2)	Practitioner of Oriental medicine license:	
Application\$30		

	Biennial renewal\$40
(e)	[Drugless therapist license:
	Biennial renewal \$40] (Reserved).
	* * * *
(q)	Orthotic Fitters:
	Application for orthotic fitter license\$25
	Biennial renewal of orthotic fitter license\$75
	Application for reactivation of orthotic fitter license\$25
	Application for orthotic fitter temporary permit\$25
<u>(r)</u>	Naturopathic doctor registration:
	Application for initial registration\$100
	Biennial renewal \$ 50
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CHAPTER 18. STATE BOARD OF MEDICINE—PRACTITIONERS OTHER THAN MEDICAL DOCTORS

Subchapter B. REGISTRATION AND PRACTICE OF ACUPUNCTURISTS AND PRACTITIONERS OF ORIENTAL MEDICINE

§ 18.13a. Requirements for licensure as a practitioner of Oriental medicine.

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(d) This section does not apply to a medical doctor licensed as an acupuncturist nor does it restrict the practice of medicine by a medical doctor.

(e) This section does not limit the practice of a REGISTERED naturopathic doctor who is also licensed as an acupuncturist when recommending herbs, minerals and other supplements, or combinations, according to traditions other than Oriental medicine traditions.

§ 18.15. Practice responsibilities of acupuncturist and practitioner of Oriental medicine who is not a physician.

(a) *Responsibilities to patient and public—acupuncturist who is not a physician*. An acupuncturist who is not a physician:

* * * * *

(10) Shall wear a tag or badge with lettering clearly visible to the patient bearing the acupuncturist's name and the title "Acupuncturist." The use of the words, doctor, physician or any title or abbreviation implying licensure as a physician on this tag or badge is prohibited, PROVIDED, HOWEVER, THAT AN INDIVIDUAL LICENSED AS AN ACUPUNCTURIST WHO ALSO POSSESSES A CURRENT AND ACTIVE REGISTRATION AS A NATUROPATHIC DOCTOR MAY UTILIZE THE TITLE "DOCTOR OF NATUROPATHIC MEDICINE" OR "NATUROPATHIC DOCTOR" IN ADDITION TO THE TITLE "ACUPUNCTURIST."

(b) *Identification of acupuncturist or practitioner of Oriental medicine*. An acupuncturist who is not a medical doctor shall wear a tag or badge with lettering clearly visible to the patient bearing the acupuncturist's name and the title "acupuncturist" or "practitioner of Oriental medicine," as appropriate. The use of the [word doctor] <u>words "doctor," "physician" or any title or abbreviation implying licensure as a physician</u> on this tag or badge is prohibited<u>: provided, however, that an individual licensed as an acupuncturist who also possesses a current and active registration as a <u>naturopathic doctor may utilize the title "Doctor of Naturopathic Medicine," "Naturopathic Doctor," "N.D." in addition to the title "acupuncturist." (RESERVED).</u></u>

(b.1) Additional responsibilities to patient and public—practitioner of Oriental medicine who is not a physician. In addition to the responsibilities in subsection (a)((1)—(9), a licensed practitioner of Oriental medicine who provides, or contemplates providing, herbal therapy:

* * * * *

(3) Shall wear a tag or badge with lettering clearly visible to the patient bearing the licensee's name, as well as the title "Practitioner of Oriental Medicine." The use of the

words doctor, physician or any title or abbreviation implying licensure as a physician on this tag or badge is prohibited, PROVIDED, HOWEVER, THAT AN INDIVIDUAL LICENSED AS A PRACTITIONER OF ORIENTAL MEDICINE WHO ALSO POSSESSES A CURRENT AND ACTIVE REGISTRATION AS A NATUROPATHIC DOCTOR MAY UTILIZE THE TITLE "DOCTOR OF NATUROPATHIC MEDICINE" OR "NATUROPATHIC DOCTOR" IN ADDITION TO THE TITLE "PRACTITIONER OF ORIENTAL MEDICINE."

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§ 18.15a. Scope of practice of acupuncturists and practitioners of Oriental medicine.

* * * * *

(c) This subsection does not limit the scope of practice of a medical doctor who is registered as an acupuncturist.

(d) This section does not limit the scope of practice of a REGISTERED naturopathic doctor when recommending herbs, minerals and other supplements, or combinations, according to traditions other than Oriental medicine traditions.

(Editor's note: The following Subchapter is added and printed in regular type to enhance readability.)

Subchapter M. REGISTRATION OF NATUROPATHIC DOCTORS

18.901. Purpose.

18.902. Definitions.

18.903. Application for naturopathic doctor registration.

18.904. Biennial registration of naturopathic doctor.

18.905. Inactive status; reactivation of inactive or expired registration.

18.906. Display of registration.

18.907. Acceptable titles and professional designations by registrants and non-registrants;

prohibited titles.

18.908. Informed consent and disclosure of financial interests.

18.909. Naturopathic records.

18.910. Advertising.

18.911. Code of Ethics.

18.912. Sexual misconduct.

18.913. Grounds for discipline.

§ 18.901. Purpose.

This subchapter implements the Naturopathic Doctor Registration Act (63 P.S. §§ 272.101–272.301) pertaining to the registration of naturopathic doctors.

§ 18.902. Definitions.

The following words and terms, when used in this subchapter, have the following meanings, unless the context clearly indicates otherwise:

Authorization to practice—A license, registration, certificate, permit, authorization or approval issued by a state or Federal agency which authorizes the holder to advertise, engage in, or both advertise and engage in the practice of a profession or occupation.

CNME—Council on Naturopathic Medical Education—The accrediting body which GRANTS CANDIDACY AND ACCREDITATION TO accredits schools PROGRAMS of naturopathic medicine for the education of naturopathic doctors.

MARKETING ACTIVITY— A COMMUNICATION ABOUT A SERVICE OR MERCHANDISE THAT ENCOURAGES RECIPIENTS OF THE COMMUNICATION TO PURCHASE OR USE THE MERCHANDISE OR SERVICE. FOR PURPOSES OF THIS CHAPTER, THE TERM DOES NOT INCLUDE A SERVICE FROM OR REFERRAL TO ANOTHER HEALTH CARE PRACTITIONER.

Merchandise—Items that can be sold including vitamins, supplements, food, food extracts, homeopathic remedies, botanical medicines, AND herbs and natural substances.

NABNE—North American Board of Naturopathic Examiners—The organization which administers the Naturopathic Physicians Licensing Examinations (NPLEX).

Naturopathic doctor—An individual who holds an active registration issued by the Board under the NDRA.

NATUROPATHIC MEDICINE –NATUROPATHIC PHYSICAL MEDICINE, NATURAL THERAPIES, NATUROPATHIC COUNSELING OR A COMBINATION THEREOF, TO SUPPORT AND STIMULATE THE INDIVIDUAL'S SELF-HEALING PROCESSES.

NATUROPATHIC PHYSICAL MEDICINE – THE USE OF THE PHYSICAL AGENTS OF AIR, WATER, HEAT, COLD, SOUND AND LIGHT, AND THE PHYSICAL MODALITIES OF ELECTROTHERAPY, BIOFEEDBACK, DIATHERMY, ULTRAVIOLET LIGHT, ULTRASOUND, HYDROTHERAPY AND EXERCISE, INCLUDING NATUROPATHIC MANIPULATION AND MOBILIZATION THERAPY.

NATUROPATHIC SERVICE – PROVIDING OR PERFORMING NATUROPATHIC PHYSICAL MEDICINE, NATURAL THERAPIES, NATUROPATHIC COUNSELING OR A COMBINATION THEREOF, TO SUPPORT AND STIMULATE AN INDIVIDUAL'S SELF-HEALING PROCESSES.

NATURAL THERAPIES – TREATMENT OF AN INDIVIDUAL THROUGH THE USE OF SUBSTANCES IN WHICH THE ACTIVE INGREDIENT IS DERIVED FROM PLANT, MINERAL OR FUNGAL SOURCES, OR ANY SUBSTANCE FOUND IN NATURE, AND

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WHICH MAY ALSO CONTAIN COMMON PHARMACEUTICAL EXCIPIENTS, AND NONPRESCRIPTION DRUGS AS DEFINED BY THE FEDERAL FOOD, DRUG, AND COSMETIC ACT (52 STAT. 1040, 21 U.S.C. §§ 301—399g).

NDRA—The Naturopathic Doctor Registration Act (63 P. S. §§ 272.101—272.301).

NPLEX—Naturopathic Physicians Licensing Examinations - The licensing examination accepted by the Board as a prerequisite to registration, consisting of Part I – Biomedical Science Examination and Part II – Core Clinical Science Examination, or its successor recognized by the Board.

Regionally accredited or pre-accredited college or university—A college or university which is accredited or pre-accredited by one of the following:

- (1) Accrediting Commission of Career Schools and Colleges.
- (2) Accrediting Council for Continuing Education and Training.
- (3) Accrediting Council for Independent Colleges and Schools.
- (4) Council on Occupational Education.
- (5) Distance Education Accrediting Commission.
- (6) Higher Learning Commission.
- (7) Middle States Commission on Higher Education.
- (8) Middle States Commission on Secondary Schools.
- (9) New England Commission of Higher Education.
- (10) New York State Board of Regents and the Commissioner of Education.
- (11) Northwest Commission on Colleges and Universities.
- (12) Southern Association of Colleges and Schools, Commission on Colleges.

(13) Western Association of Schools and Colleges, Accrediting Commission for Community and Junior Colleges.

(14) Western Association of Schools and Colleges, Senior Colleges and University Commission.

(15) Any other regional or national accrediting agency which has been recognized by the United States Department of Education as being a reliable authority concerning the quality of education or training offered by the institutions of higher education or higher education programs they accredit.

§ 18.903. Application for naturopathic doctor registration.

(a) An applicant for a registration to practice naturopathic medicine shall submit, on an application made available by the Board, a completed application for a registration, including the necessary supporting documents, INCLUDING INFORMATION REQUIRED BY § 16.16 (RELATING TO REPORTING OF DISCIPLINARY ACTIONS, CRIMINAL DISPOSITIONS AND OTHER LICENSES, CERTIFICATES OR AUTHORIZATIONS TO PRACTICE) and pay the application fee in § 16.13 (relating to licensure, certification, examination and registration fees).

(b) Except as otherwise provided by law, the Board will issue a registration to practice naturopathic medicine AS A NATUROPATHIC DOCTOR to an applicant who meets all of the following requirements:

(1) Holds a bachelor's degree from a regionally accredited or pre-accredited college or university or the equivalent.

(2) Holds a doctoral degree from AN INSTITUTIONALLY ACCREDITED OR PRE-ACCREDITED naturopathic school COLLEGE OR UNIVERSITY OFFERING A

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NATUROPATHIC DOCTOR PROGRAM WHICH HAS BEEN GRANTED PROGRAMMATIC CANDIDACY OR ACCREDITATION accredited by the CNME which consists of at least 4,100 total credit hours in basic and clinical sciences and naturopathic philosophy and modalities, including at least 2,500 hours of academic instruction and at least 1,200 hours of supervised clinical training. Proof of the degree shall be sent directly from the applicant's education program and include an official transcript.

(3) Has passed Parts I and II of a competency-based national naturopathic licensing examination administered by the NABNE or a successor agency. An applicant who graduated prior to 1986 shall demonstrate a passing score on a state naturopathic examination.

(4) Holds a current basic cardio-pulmonary resuscitation (CPR) certificate issued by the American Heart Association, American Red Cross or a similar health authority or professional body approved by the Board.

(5) Has completed at least 3 hours of approved education/training in child abuse recognition and reporting requirements as set forth in 23 Pa.C.S. § 6383(b)(3)(i) (relating to education and training) AND IN CHAPTER 16 AT § 16.108(a) (RELATING TO CHILD ABUSE RECOGNITION AND REPORTING—MANDATORY TRAINING REQUIREMENT).

(6) Is of good moral character.

(c) The Board may deny an application for registration as a naturopathic doctor upon any of the grounds for disciplinary action in § 18.913 (relating to disciplinary action for applicants and naturopathic doctors).

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§ 18.904. Biennial registration of naturopathic doctor.

(a) The registration of a naturopathic doctor will expire biennially on December 31 of each even-numbered year in accordance with § 16.15 (relating to biennial registration; inactive status and unregistered status). A naturopathic doctor may not use the title of "naturopathic doctor," "doctor of naturopathic medicine," "REGISTERED NATUROPATHIC DOCTOR" or any other term implying that the individual is currently registered as a naturopathic doctor unless the individual holds a current and unexpired registration.

(b) As a condition of biennial renewal, a naturopathic doctor shall:

Submit a completed application, including payment of the biennial registration fee
 in § 16.13 (relating to licensure, certification, examination and registration fees).

(2) Disclose on the application any authorization to practice as a naturopathic doctor in another state, district, territory, possession or country.

(3) Disclose on the application 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.

(4) Affirm that the applicant holds a current basic cardio-pulmonary resuscitation (CPR) certificate issued by the American Heart Association, American Red Cross or a similar health authority or professional body approved by the Board.

(5) Certify that the applicant has completed at least 2 hours of approved continuing education in child abuse recognition and reporting as set forth in 23 Pa.C.S. § 6383(b)(3)(ii) AND IN CHAPTER 16 AT § 16.108(b) (RELATING TO CHILD ABUSE RECOGNITION AND REPORTING—MANDATORY TRAINING REQUIREMENT).

§ 18.905. Inactive status; reactivation of inactive or expired registration.

(a) A naturopathic doctor may request in writing that the Board place the registration on inactive status. Confirmation of inactive status will be forwarded to the registrant. A naturopathic doctor may not use the title of "naturopathic doctor," "doctor of naturopathic medicine," "REGISTERED NATUROPATHIC DOCTOR" or any other term implying that the individual is currently registered as a naturopathic doctor while on inactive status.

(b) To reactivate an inactive or expired registration, the registrant shall apply for reactivation by completing an application for reactivation on a form made available by the Board. The registrant shall:

(1) Pay the current biennial registration fee specified in § 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).

(2) Disclose whether the registrant used the title of "naturopathic doctor," "doctor of naturopathic medicine," "REGISTERED NATUROPATHIC DOCTOR" or any other term implying that the individual was currently registered as a naturopathic doctor in the Commonwealth of Pennsylvania while the registration was inactive or expired.

(3) Disclose on the application any authorization to practice as a naturopathic doctor in another state, district, territory, possession or country.

(4) Disclose on the application 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.

(5) Submit evidence the registrant holds a current basic cardio-pulmonary resuscitation (CPR) certificate issued by the American Heart Association, American Red Cross or a similar health authority or professional body approved by the Board.

(6) Verify completion of at least 2 hours of approved continuing education in child abuse recognition and reporting in the 2 years immediately preceding the application for reactivation as set forth in 23 Pa.C.S. § 6383(b)(3)(ii) (relating to education and training) AND IN CHAPTER 16 AT § 16.108(b) (RELATING TO CHILD ABUSE RECOGNITION AND REPORTING—MANDATORY TRAINING REQUIREMENT).

- (c) A registrant who has not had clinical contact with patients for 4 years or more shall demonstrate current competency and qualification to hold forth as a naturopathic doctor by demonstrating a passing score on the NPLEX PART II—CORE CLINICAL SCIENCE EXAMINATION—examination, completed within 12 months of the application to reactivate the registration.
- (d) Payment of applicable late fees required under section 225 of the Bureau of Professional and Occupational Affairs Fee Act (63 P.S. § 1401-225) does not preclude the Board from taking disciplinary action for utilizing the title of "naturopathic doctor," "doctor of naturopathic medicine" or any other term implying that the individual was currently registered as a naturopathic doctor while holding an inactive or expired registration.

§ 18.906. Display of registration.

A naturopathic doctor registrant shall prominently display the certificate of registration and evidence of biennial renewal in a publicly accessible location at the registrant's regular place of business. The registrant shall have evidence of current registration available for inspection by

authorized agents of the Board and by persons receiving services when the naturopathic doctor provides services at locations other than the registrant's regular place of business.

§ 18.907. Acceptable titles and professional designations by registrants and non-

registrants; prohibited titles.

(a) An individual must have a current, active and unsuspended registration to claim to be, or hold oneself out as, a naturopathic doctor, registered naturopathic doctor, doctor of naturopathic medicine or use any similar title implying that the individual holds a current registration as a naturopathic doctor in this Commonwealth.

(b) An individual who has not registered with the Board may claim to be, and hold oneself out as, a naturopath or a traditional naturopath 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.

(c) A naturopathic doctor who uses the designation "Dr." shall further identify himself or herself as a "naturopathic doctor," "registered naturopathic doctor" or "doctor of naturopathic medicine" and may not use any term or designation that would imply that the naturopathic doctor is licensed or authorized to practice medicine and surgery, dentistry, podiatry, optometry, psychology, nursing, physical therapy, acupuncture, chiropractic, genetic counseling, athletic training, massage therapy or any other health care profession, unless that individual also holds a current and active authorization to practice the other profession issued by the appropriate licensing authority of this Commonwealth.

§ 18.908. Informed consent and disclosure of financial interests.

(a) A naturopathic doctor shall obtain written informed consent from the patient prior to providing naturopathic services to the patient. The informed consent shall include notification to

the patient that the naturopathic doctor is not a physician. This subsection shall not apply to registrants who are also currently and actively licensed to practice as a physician in this Commonwealth.

(b) 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 ANY MARKETING ACTIVITY RELATING TO MERCHANDISE.

§ 18.909. Naturopathic records.

(a) A naturopathic doctor shall maintain patient records that accurately describe the patient's concerns, evidence the naturopathic doctor's plan of service and implementation of service and document the patient's response to any services provided.

(b) All patient records for minors and adults shall be retained for a minimum period of 7 years from the date of the service for which a naturopathic record entry is required. Patient records for minor patients shall also be retained until 1 year after the minor patient reaches majority, even if this means that the naturopathic doctor retains the record for a period of more than 7 years.

(c) Upon written request, a naturopathic doctor shall make true, correct and legible copies of the written records of service available to the patient or the person or persons designated by the patient.

(d) Payment for naturopathic services rendered may not be required as a condition to making the written records of service available to the patient or the patient's designee. A naturopathic doctor may require pre-payment of the costs to copy and produce the naturopathic records. The maximum applicable copying and reproduction costs for naturopathic service records shall be the

same as those costs applicable to production of health records as annually adjusted by the Secretary of the Department of Health and published in the *Pennsylvania Bulletin*.

§ 18.910. Advertising.

(a) Any advertisement by a naturopathic doctor shall contain both of the following:

- (1) The name of the naturopathic doctor as registered with the Board.
- (2) The words "naturopathic doctor" or "doctor of naturopathic medicine."

(b) Advertisements by a naturopathic doctor may not contain any of the following:

(1) The word "physician" unless the naturopathic doctor is also currently and actively licensed as a physician or physician assistant in this Commonwealth.

(2) Any words or phrases indicating or implying that the naturopathic doctor is "board certified" or "board eligible" unless the certification body is also disclosed.

- (3) Statements containing misrepresentations of facts.
- (4) Statements that cannot be verified by the Board for truthfulness.
- (5) Statements likely to mislead or deceive because of their context or because the statements make only a partial disclosure of relevant facts.

(6) Statements intended to, or likely to, create false or unjustified expectations of favorable results.

(7) Statements containing representations or implications that can reasonably be expected to cause an ordinary prudent person to misunderstand or be deceived.

(8) Statements that are untruthful and improbable or contain misstatements, falsehoods, misrepresentations, distorted or fabulous statements as to cures.

(9) Statements that misrepresent the nature, characteristics or qualities of natural substances MERCHANDISE or NATUROPATHIC services provided by a naturopathic doctor.

(10) Statements that a manifestly incurable condition can be cured or that guarantee a cure of any condition.

(11) Statements promoting herbal, natural or dietary supplements as drugs.

(12) Statements recommending any modality of service that is inconsistent with the health, safety and welfare of the public.

§ 18.911. Code of Ethics.

(a) Naturopathic doctors shall concern themselves primarily with the welfare of the patient.

(b) A naturopathic doctor who suffers from a physical, mental or emotional impairment, including substance abuse, that impacts the individual's ability to practice naturopathic medicine OR TO PROVIDE NATUROPATHIC SERVICES WITH REASONABLE SKILL AND SAFETY TO PATIENTS shall seek professional treatment and refrain from the practice of naturopathic medicine until the impairment no longer exists or reasonable accommodations can be made.

(c) A naturopathic doctor shall:

(1) Respect and maintain the privacy and confidentiality of the patient.

(2) Disclose the patient's records or information about the patient only with the patient's consent or as required by law.

(3) Adequately safeguard SAFEGUARD PATIENT PROTECTED HEALTH INFORMATION confidential patient information, including storage and disposal of records.

(4) Provide sufficient information to a patient to allow the patient to make an informed decision regarding care, including:

- (i) The purpose and nature of a naturopathic evaluation or NATUROPATHIC service regimen.
- (ii) Alternatives to naturopathic care.
- (iii) Side effects and benefits of a proposed NATUROPATHIC service regimen.
- (iv) The estimated cost of NATUROPATHIC services.
- (v) The right of the patient to withdraw from NATUROPATHIC services.

(5) Maintain professional boundaries, even when the patient initiates crossing the boundaries of the professional relationship.

(6) Decline to administer A NATUROPATHIC service if the naturopathic doctor believes that a THE service is contraindicated or unjustified.

(7) Make referrals only to registered naturopathic doctors or other qualified and duly licensed health care providers.

(8) Accurately inform INFORM the patient, other health care professionals and the public of the limitations of the practice of naturopathic medicine.

(9) Adequately assess ASSESS the patient to determine if contraindications against naturopathic service exist and refer the patient to an appropriate health care practitioner.

(10) At all times respect the patient's dignity, autonomy and privacy.

(11) Cooperate with any lawful investigation conducted by the Board, including:

(i) Furnishing information requested in a timely manner as directed by the Board.

(ii) Complying with a subpoena.

- (iii) Responding to a complaint at the request of the Board.
- (iv) Providing meaningful and timely access to relevant patient records.
- (12) Report to the Board misconduct COMMITTED BY A NATUROPATHIC DOCTOR in the practice of naturopathic medicine OR IN THE PROVISION OF NATUROPATHIC SERVICES.
- (d) A naturopathic doctor may not:

(1) Misrepresent credentials, qualifications or affiliations, and shall attempt to correct others who misrepresent the naturopathic doctor's credentials, qualifications or affiliations.

(2) Knowingly engage in or condone behavior that is fraudulent, dishonest or deceitful.

(3) Engage in a commercial MARKETING activity which conflicts with the duties of a naturopathic doctor SUBSECTION (c).

(4) Perform naturopathic medicine on OR PROVIDE A NATUROPATHIC SERVICETO a patient if a contraindication against naturopathic service exists.

(5) Intimidate, threaten, influence or attempt to influence any person regarding any violation of law or regulation.

(6) Aid or abet any individual violating or attempting to violate any provision of law or regulation.

(7) Accept a patient for A NATUROPATHIC service, or continue unnecessary service, when the patient cannot be reasonably expected to benefit from the service.

(8) 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.

(9) Make a guarantee or promise about the efficacy of a particular course of care, the naturopathic doctor's practice, PARTICULAR NATUROPATHIC SERVICE or the anticipated results of care.

(10) Exploit the professional relationship by either of the following:

- (i) Continuing NATUROPATHIC service unnecessarily.
- (ii) Charging for a NATUROPATHIC service not provided or different from what was actually provided.

(11) Exploit a relationship with a patient, staff member or student for the naturopathic doctor's personal advantage including, but not limited to, a personal, sexual, romantic or financial relationship.

(12) Engage in sexual misconduct.

(13) PROVIDE OR PERFORM A NATUROPATHIC SERVICE AT A LEVEL BENEATH THE ACCEPTED STANDARD OF CARE FOR A NATUROPATHIC DOCTOR WHICH WOULD BE NORMALLY EXERCISED BY THE AVERAGE PROFESSIONAL OF THE SAME KIND IN THIS COMMONWEALTH UNDER THE CIRCUMSTANCES, INCLUDING LOCALITY AND WHETHER THE NATUROPATHIC DOCTOR IS OR PURPORTS TO BE A SPECIALIST IN THE AREA.

(e) A naturopathic doctor may not perform a service or provide a NATUROPATHIC service that the naturopathic doctor is not qualified to perform, or which is beyond the scope of the naturopathic doctor's education, AND training., capabilities or experience.

(f) 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. A NATUROPATHIC DOCTOR MAY NOT ASSERT AS A DEFENSE TO A DISCIPLINARY ACTION UNDER SECTION 204 OF THE NDRA (63 P.S.§ 272.204) OR § 18.913 (RELATING TO GROUNDS FOR DISCIPLINE), THE ABSENCE OF A SPECIFIC ETHICAL, LEGAL OR PROFESSIONAL DUTY IN THIS SUBSECTION WHEN SUCH DUTY IS NORMALLY EXERCISED BY THE AVERAGE PROFESSIONAL OF THE SAME KIND IN THIS COMMONWEALTH UNDER THE CIRCUMSTANCES, INCLUDING LOCALITY AND WHETHER THE NATUROPATHIC DOCTOR IS OR PURPORTS TO BE A SPECIALIST IN THE AREA.

§ 18.912. Sexual misconduct.

(a) Sexual exploitation by a naturopathic doctor of a current or former patient, or of an immediate family member of a patient, constitutes unprofessional conduct, is prohibited and subjects the naturopathic doctor to disciplinary action under section 204(8) of the NDRA (63 P.S. § 272.204(8)).

(b) Sexual behavior that occurs with a current patient, other than the naturopathic doctor's spouse, constitutes unprofessional conduct, is prohibited and subjects the practitioner to disciplinary action under section 204(8) of the NDRA.

(c) When a naturopathic doctor was involved with the management or directly provided naturopathic services to a patient other than the naturopathic doctor's spouse for a mental health disorder, any sexual behavior with that patient which occurs prior to the 2-year anniversary of the termination of the professional relationship constitutes unprofessional conduct, is prohibited and subjects the naturopathic doctor to disciplinary action under section 204(8) of the NDRA.

(d) A practitioner who engages in conduct prohibited by this section will not be eligible for placement into an impaired professional program in lieu of disciplinary or corrective actions.

(e) Consent is not a defense to conduct prohibited by this section.

§ 18.913. Grounds for discipline.

(a) The Board shall have the authority to impose disciplinary or corrective measures on a naturopathic doctor or applicant for registration as a naturopathic doctor for the reasons set forth in section 204 of the NDRA (63 P.S. § 272.204) and any of the following:

(1) Fraudulently or deceptively obtaining, or attempting to obtain, or using a registration or assisting another in fraudulently or deceptively obtaining or using a registration.

(2) Using false, deceptive or misleading advertising.

(3) Advertising, practicing or attempting to practice under a name other than the naturopathic doctor's name as registered with the Board; provided, however, that a naturopathic doctor may advertise utilizing a business name if the advertisement also includes the naturopathic doctor's name as registered by the Board.

(4) Aiding, assisting, employing or advising any unregistered individual to hold himself or herself out in a manner which states or implies the unregistered individual is a naturopathic doctor.

(5) Paying or receiving any commission, bonus, kickback or rebate, or engaging in any split-fee arrangement in any form with a licensed physician, organization, agency or other person, either directly or indirectly, for patients referred to other health care providers.

(6) Promoting the sale of services, drugs, devices, appliances or goods to a patient so as to exploit the patient for financial gain.

(7) Failing to keep written records justifying the course of service of a patient.

(8) Offering, undertaking or agreeing to cure or treat a disease by a secret method, treatment, product or medicine. FAILING TO DISCLOSE THE CONTENTS OF MERCHANDISE OR THE NATURE AND DESCRIPTION OF NATUROPATHIC SERVICES RECOMMENDED, PROVIDED OR OFFERED TO A PATIENT.

(9) Failing to cooperate with a lawful investigation of the Board.

(b) When the Board is empowered to take disciplinary or corrective action under the provisions of the NDRA, the Board's regulations or other statutory or regulatory authority, the Board may impose one or more of the following disciplinary or corrective actions as set forth in section 206 of the NDRA (63 P.S. § 272.206), section 42 of the act (63 P.S. § 422.42) and 63 Pa.C.S. § 3108 (relating to civil penalties):

- (1) Deny the application for registration.
- (2) Administer a public reprimand with or without probation.
- (3) Revoke, suspend, limit or otherwise restrict a registration.

(4) Require the registrant to submit to the care, counseling or treatment of a physician or a psychologist designated by the board.

(5) Require the registrant to take refresher educational courses or demonstrate passage of the NPLEX examination, or both.

(6) Stay enforcement of any suspension and place the registrant on probation with the right to vacate the probationary order for noncompliance.

(7) Impose a civil penalty of up to \$1,000 in accordance with the NDRA.

(8) Impose a civil penalty of up to \$10,000 in accordance with 63 Pa.C.S. § 3108(b); provided, however, that the Board will not impose a civil penalty under the NDRA and

also impose a civil penalty under 63 Pa.C.S. § 3108(b) for the same violation, as prohibited by 63 Pa.C.S. § 3108(c)(2).

(9) Impose the costs of investigation underlying the disciplinary action.

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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) 772-8528

January 17, 2024

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

> Re: Final Regulation State Board of Medicine 16A-4953 Registration of Naturopathic Doctors

Dear Chairman Bedwick:

Enclosed is a copy of a proposed rulemaking package of the State Board of Medicine pertaining to 16A-4953 Registration of Naturopathic Doctors.

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

Sincerely,

Mark A. hadad

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

CKM/elb 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 Dana M. Wucinski, Counsel, State Board of Medicine

 From:
 Orchard, Kari L.

 To:
 Bennetch, Erica; Brett, Joseph D.; Barton, Jamie

 Subject:
 RE: DELIVERY NOTICE: REGULATION 16A-4953 REGISTRATION OF NATUROPATHIC DOCTORS

 Date:
 Thursday, January 18, 2024 9:53:38 AM

 Attachments:
 image001.png

Received the corrected packet.

Independent Regulatory Review Commission

January 18, 2024

Thanks!

Kari Orchard

Executive Director (D) | House Professional Licensure Committee Chairman Frank Burns, 72nd Legislative District

From: Bennetch, Erica <erbennetch@pa.gov>
Sent: Thursday, January 18, 2024 9:14 AM
To: Orchard, Kari L. <KOrchard@pahouse.net>; Brett, Joseph D. <JBrett@pahouse.net>; Barton,
Jamie <JBarton@pahouse.net>
Subject: RE: DELIVERY NOTICE: REGULATION 16A-4953 REGISTRATION OF NATUROPATHIC DOCTORS

Please reply confirmation of receiving the corrected rulemaking package. The attached corrected rulemaking package includes the missing forms, checklists, and fee report form omitted from the previous delivery.

Thank you,

Erica L. Bennetch | Legal Assistant 2 Office of Chief Counsel | Department of State Governor's Office of General Counsel P.O. Box 69523 | Harrisburg, PA 17106-9523 Office Phone 717.775.8145 | Fax: 717.787.0251 erbennetch@pa.gov | www.dos.pa.gov (preferred pronouns: she, her, hers) PRIVILEGED AND CONFIDENTIAL COMMUNICATION

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From: Bennetch, Erica
Sent: Wednesday, January 17, 2024 10:33 AM
To: korchard@pahouse.net; ibrett@pahouse.net; Barton, Jamie <JBarton@pahouse.net>

Subject: DELIVERY NOTICE: REGULATION 16A-4953 REGISTRATION OF NATUROPATHIC DOCTORS **Importance:** High

<u>Please provide a written (email) confirmation of receipt of delivery of the attached final</u> <u>rulemaking.</u>

Please be advised that the State Board of Medicine is delivering the below final rulemaking.

• 16A-4953 Registration of Naturopathic Doctors (final)

• This final-form rulemaking is needed to implement the Naturopathic Doctor Registration Act (NDRA) (63 P.S. §§ 272.101—272.301). The rulemaking sets forth necessary definitions utilized in the rulemaking; application, renewal and reinstatement requirements; requires the display of registration; sets forth acceptable professional titles and prohibited titles; requires informed consent and disclosure of financial interests in products and services; and requires the maintenance and production of naturopathic medical records. The rulemaking also sets forth standards for advertising; ethical conduct; prohibits sexual misconduct and sets forth potential grounds for discipline as well as the sanctions which may be imposed by the Board. Additionally, it establishes fees for initial registration and biennial renewal of registration.

Thank you for your attention to this matter.

RECEIVED

Erica L. Bennetch | Legal Assistant 2 Office of Chief Counsel | Department of State Governor's Office of General Counsel P.O. Box 69523 | Harrisburg, PA 17106-9523 Office Phone 717.775.8145 | Fax: 717.787.0251 erbennetch@pa.gov | www.dos.pa.gov (preferred pronouns: she, her, hers) PRIVILEGED AND CONFIDENTIAL COMMUNICATION

Independent Regulatory Review Commission

January 18, 2024

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From:	Nicole Sidle		
То:	Bennetch, Erica; Francesca Summa		
Subject:	RE: [EXTERNAL]: RE: DELIVERY NOTICE: REGULATION 16A-4953 REGISTRATION OF NATUROPATHIC DOCTORS		
Date:	Thursday, January 18, 2024 10:48:54 AM	RECEIVED	
Attachments:	image001.png	KECEIVED	

Received.

Independent Regulatory Review Commission January 18, 2024

From: Bennetch, Erica <erbennetch@pa.gov>

Sent: Thursday, January 18, 2024 9:15 AM

To: Nicole Sidle <Nsidle@pahousegop.com>; Francesca Summa <Fsumma@pahousegop.com> **Subject:** [EXTERNAL]: RE: DELIVERY NOTICE: REGULATION 16A-4953 REGISTRATION OF NATUROPATHIC DOCTORS

Please reply confirmation of receiving the corrected rulemaking package. The attached corrected rulemaking package includes the missing forms, checklists, and fee report form omitted from the previous delivery.

Thank you,

Erica L. Bennetch | Legal Assistant 2 Office of Chief Counsel | Department of State Governor's Office of General Counsel P.O. Box 69523 | Harrisburg, PA 17106-9523 Office Phone 717.775.8145 | Fax: 717.787.0251 erbennetch@pa.gov | www.dos.pa.gov (preferred pronouns: she, her, hers) PRIVILEGED AND CONFIDENTIAL COMMUNICATION

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?

From: Bennetch, Erica

Sent: Wednesday, January 17, 2024 10:33 AM

To: Sidle, Nicole <<u>nsidle@pahousegop.com</u>>; <u>fsumma@pahousegop.com</u>

Subject: DELIVERY NOTICE: REGULATION 16A-4953 REGISTRATION OF NATUROPATHIC DOCTORS **Importance:** High

<u>Please provide a written (email) confirmation of receipt of delivery of the attached final</u> <u>rulemaking.</u>

Please be advised that the State Board of Medicine is delivering the below final rulemaking.

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Independent Regulatory Review Commission January 18, 2024

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Independent Regulatory Review Commission January 18, 2024

Smeltz Jennifer	Keview Collin	
	January 18	
	CTORS	
image001.png		
	Smeltz, Jennifer Bennetch, Erica RE: DELIVERY NOTICE: REGULATION 16A-4953 REGISTRATION OF NATUROPATHIC DO Thursday, January 18, 2024 9:27:44 AM image001.png	

Received.

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

From: Bennetch, Erica <erbennetch@pa.gov>
Sent: Thursday, January 18, 2024 9:12 AM
To: Smeltz, Jennifer <jmsmeltz@pasen.gov>
Subject: RE: DELIVERY NOTICE: REGULATION 16A-4953 REGISTRATION OF NATUROPATHIC DOCTORS

● CAUTION : External Email ●

Please reply confirmation of receiving the corrected rulemaking package.

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Thank you,

Erica L. Bennetch | Legal Assistant 2 Office of Chief Counsel | Department of State Governor's Office of General Counsel P.O. Box 69523 | Harrisburg, PA 17106-9523 Office Phone 717.775.8145 | Fax: 717.787.0251 erbennetch@pa.gov | www.dos.pa.gov (preferred pronouns: she, her, hers) PRIVILEGED AND CONFIDENTIAL COMMUNICATION

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From: Bennetch, EricaSent: Wednesday, January 17, 2024 10:33 AMTo: <u>imsmeltz@pasen.gov</u>

Subject: DELIVERY NOTICE: REGULATION 16A-4953 REGISTRATION OF NATUROPATHIC DOCTORS **Importance:** High

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?

Erica,

Received.

Have a great day!

Enid Vazquez

State Senator Lisa M. Boscola One E. Broad Street – Suite 120 Bethlehem, PA 18018 O: 610-868-8667 F: 610-861-2184 www.senatorboscola.com Independent Regulatory Review Commission

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January 18, 2024

From: Bennetch, Erica <erbennetch@pa.gov>
Sent: Thursday, January 18, 2024 12:15 PM
To: Monoski, Jesse <jesse.monoski@pasenate.com>
Cc: Vazquez, Enid <Enid.Vazquez@pasenate.com>
Subject: RE: DELIVERY NOTICE: REGULATION 16A-4953 REGISTRATION OF NATUROPATHIC DOCTORS
Importance: High

EXTERNAL EMAIL

Please reply confirmation of receiving the corrected rulemaking package. Apologies, I need a reply for this email as I need to resend to IRRC asap. Thank you,

Erica L. Bennetch | Legal Assistant 2 Office of Chief Counsel | Department of State Governor's Office of General Counsel P.O. Box 69523 | Harrisburg, PA 17106-9523 Office Phone 717.775.8145 | Fax: 717.787.0251 erbennetch@pa.gov | www.dos.pa.gov (preferred pronouns: she, her, hers) PRIVILEGED AND CONFIDENTIAL COMMUNICATION

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Independent Regulatory Review Commission January 18, 2024

From: Bennetch, Erica
Sent: Thursday, January 18, 2024 9:13 AM
To: jesse.monoski@pasenate.com
Cc: Vazquez, Enid <<u>Enid.Vazquez@pasenate.com</u>>
Subject: RE: DELIVERY NOTICE: REGULATION 16A-4953 REGISTRATION OF NATUROPATHIC DOCTORS

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From: Bennetch, Erica Sent: Wednesday, January 17, 2024 10:33 AM To: jesse.monoski@pasenate.com

Cc: Vazquez, Enid <<u>Enid.Vazquez@pasenate.com</u>>

Subject: DELIVERY NOTICE: REGULATION 16A-4953 REGISTRATION OF NATUROPATHIC DOCTORS **Importance:** High

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January 18, 2024

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