Report to the Legislature



Prepared by Health Systems Quality Assurance



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Executive Summary

The Senate Health and Long Term Care committee requested the Department of Health (department) review a proposal under <u>chapter 18.120 RCW</u> to expand the scope of practice for licensed naturopathic physicians (ND)¹ in Washington to include Schedule II-V controlled substances, broaden the definition of "minor office procedures," and add the authority to sign forms that other primary care physicians are authorized to sign. The Washington Naturopathic Physicians Association (WANP) is the applicant for this proposal.

Recommendation:

Didactic training in naturopathic schools has evolved to include more curriculum based in pharmacology. In addition, the applicant has identified a need to expand ND's prescriptive authority to increase access to opioid use disorder (OUD) treatment, help patients taper off controlled substances, and treat acute or post-surgical pain.

However, the department recommends this proposal not be enacted because it does not meet the criteria in RCW 18.120.010.

- The proposal does not demonstrate sufficient minimum education and training to safely prescribe Schedule II-V controlled substances. Naturopathic programs have evolved to include more pharmacology focus. However, many of the courses that include pharmacology include topics that do not have foundations in the basic sciences that the other medical programs include, and pharmacology training on controlled substances is not standardized and consistent across programs. In addition, naturopathic clinical training can occur almost entirely in naturopathic clinics without exposure to a variety of providers, settings, and situations where they could experience treatment of patients on a broad array of controlled substances.
- The other states that grant authority to prescribe controlled substances limit NDs to Schedules III-V or specific formularies and/or include safeguards such as collaboration with MDs, additional or continuing education, an additional pharmacology examination, or include MD or DO members on the naturopathic board or formulary advisory committee.
- The proposed definition of "minor office procedures" is vague and subject to a wide range of interpretations. The department cannot evaluate adequate training without knowing what specific procedures would be included in this definition.

¹ Also referred to as "naturopath" and "doctor of naturopathic medicine." RCW 18.36A.030(2).

Summary of Information

Legislative Request

The proposed bill under review, Senate Bill 5411 (2023) makes the following changes to the naturopathic scope of practice:

- Broadens the definition of minor office procedures to include "primary care services."
- Adds the prescriptive authority for controlled substances contained in Schedules II through V of the uniform controlled substances act, chapter <u>69.50 RCW</u>, as necessary in the practice of naturopathy.
- Adds the authority for naturopathic physicians (ND) to sign forms and any documents physicians are authorized to sign (e.g., disability determinations) if they are within the ND scope of practice.
- Adds "or naturopathic physician" to the definition of naturopath in <u>RCW 18.36A.020</u> and changes "naturopath" to "naturopathic physician" in <u>RCW 18.36A.040</u> (Scope of practice).

Section 1 of the bill consists of findings which include:

- Washington has a primary care shortage and the pandemic "further expos[ed] the need to empower primary care providers to practice to the full scope of their training."
- Naturopathic medical training emphasizes behavioral health, counseling, and lifestyle medicine in addition to conventional medicine to include pharmaceutical prescriptions.
- Many patients seek care from naturopathic physicians to stop taking or lower their doses of prescription medications.

Background

Naturopaths have been licensed and regulated with autonomous practice in Washington since 1987.² Their original scope of practice included:³

The prescription, administration, dispensing, and use, except for the treatment of malignancies or neoplastic disease, of nutrition and food science, physical modalities, homeopathy, certain medicines of mineral, animal, and botanical origin, hygiene and immunization, common diagnostic procedures, and suggestion; however, nothing in this chapter shall prohibit consultation and

² Laws of 1987, ch. 447.

³ Id. at § 3.

treatment of a patient in concert with a practitioner licensed under chapter 18.57 or 18.71 RCW.

Prescriptive authority excluded legend drugs except vitamins, minerals, whole gland thyroid, and substances as exemplified in traditional botanical and herbal pharmacopoeia, and nondrug contraceptive devices excluding interuterine devices.⁴ The law also limited the use of intramuscular injections to vitamin B-12 preparations and combinations when clinical and/or laboratory evaluation has indicated vitamin B-12 deficiency and prohibited the use of controlled substances.⁵ It also prohibited ND's use of controlled substances.⁶

Minor office procedures meant "care incident thereto of superficial lacerations and abrasions, and the removal of foreign bodies located in superficial structures, not to include the eye; and the use of antiseptics and topical local anesthetics in connection therewith."⁷

Physical modalities were defined as "the use of physical, chemical, electrical, and other noninvasive modalities including, but not limited to heat, cold, air, light, water in any of its forms, sound, massage, and therapeutic exercise."⁸

ND's scope of practice was amended in 2005 to add controlled substances limited to codeine and Schedule III-V testosterone products, increase the scope of minor office procedures, add nondrug contraceptive devices, and change the term "naturopathy" to "naturopathic medicine" throughout the chapter. The bill required consultation with the Board of Pharmacy (now the Pharmacy Quality Assurance Commission) on education and training requirements.⁹

In 2011, the scope of practice was further amended to change the definition of "physical modalities" to remove the term "noninvasive" and add that the modalities cannot exceed those used as of the effective date of the bill (7/22/2011) in minor office procedures or common diagnostic procedures.¹⁰ The bill also removed "nondrug" from the contraceptive devices included in the practice of naturopathic medicine.¹¹

The current prescriptive authority for naturopaths encompasses "vitamins; minerals; botanical medicines; homeopathic medicines; hormones; and those legend drugs and controlled

⁴ Laws of 1987, ch. 447 § 4.

⁵ <u>Id.</u>

⁶ <u>Id.</u>

⁷ <u>Id.</u> ⁸ Id.

⁹ Laws of 2005, ch.158 § 1,2.

¹⁰ Laws of 2011, ch. 40 § 1.

¹¹ Id. at § 2.

substances consistent with naturopathic medical practice in accordance with rules established by the board. Controlled substances are limited to codeine and testosterone products that are contained in Schedules III, IV, and V in chapter 69.50 RCW (Uniform Controlled Substances Act).¹²

NDs in Washington have had a limited number of disciplinary actions related to prescribing under their current scope of practice. Between 2021-23, there were 1,620 licensed NDs in Washington.¹³ Since 2005, the department has taken disciplinary action in 22 cases involving controlled substance violations. Approximately 11 NDs voluntarily surrendered or gave up their DEA licenses as an act of good faith or due to disciplinary action imposed by the DEA.¹⁴

Summary of Applicant Report

The laws on sunrise reviews require the applicant group to explain several factors about the proposed legislation, including the problem it is attempting to fix, how it ensures competence of practitioners, and how it is in the public interest.¹⁵ The department refers to this as the "applicant report." The applicant report is intended to supplement the proposed legislation to help the department determine if the proposed change in scope of practice meets the criteria in <u>RCW 18.120.010(2)(Purpose – Criteria)</u>.

Once the department receives the proposed bill and applicant report, the department posts the materials online and solicits public comments. The department reviews all the data and comments received, drafts a report with initial recommendations, then solicits additional public comments on the draft recommendations. At the end of the public comment period, the department reviews comments received and adjusts the report and recommendations as necessary before submitting the final report to the legislature.

The applicant asserts Naturopathic Doctors (NDs) are recognized as primary care physicians and need the proposed scope of practice increase to adequately serve in this role, which is limited by: ¹⁶

1. Lack of full prescriptive authority:

¹² RCW 18.36A.020(12).

¹³ Health Systems & Quality Assurance (HSQA). (2023). *Report to the Legislature: 2021-23 Uniform Disciplinary Act (UDA) Report*. Washington State Department of Health. <u>https://doh.wa.gov/sites/default/files/2024-03/631093-UDAReport2021-2023.pdf</u>.

¹⁴ Health Systems & Quality Assurance (HSQA). (2023). *UDA Cases Received and Closed*. Washington State Department of Health Integrated Licensing and Regulatory System (ILRS). Retrieved November 15, 2023. ¹⁵ RCW 18.120.030.

¹⁶ "Proposal to Increase Scope of Practice," Washington Association of Naturopathic Physicians, Appendix B – Applicant Report. (Hereinafter referred to as "Applicant Report").

- a. Many ND patients are already taking or require prescriptions for controlled substances and expect their ND to be authorized to prescribe them. The ND must refer their patients to other providers for these medications, which the applicant asserts creates duplication of services and is a financial burden on the patients, NDs, and the health care system.
- b. Primary care physicians are expected to provide treatment for anxiety, insomnia, panic, ADHD, and addictions; provide temporary pain management; and provide medication assisted treatment (MAT) for opioid use disorder (OUD). NDs are not currently allowed to provide all forms of treatment for these issues. The applicant also provided examples of medications NDs would need authority to prescribe, including benzodiazepines, stimulant medications (e.g., methylphenidate to treat ADHD), and buprenorphine.
- c. Applicants state NDs should be included in the definition of an "other health care provider" who can terminate or assist in terminating a pregnancy, but "the current limitations in naturopathic prescriptive authority and outdated language in the minor office procedures section of naturopathic scope preclude their participation."
- 2. <u>Inability to sign all documents and certificates that primary care providers are routinely</u> <u>expected to sign</u>:
 - a. NDs have the authority to sign death certificates, but not Physician Orders for Life Sustaining Treatment (POLST), disability determinations, hospice orders, etc. This creates delays in obtaining this paperwork and a burden on patients to find another provider to sign these documents.
- 3. Exclusion from the Death with Dignity Act
 - a. The applicant asserts the limited prescriptive authority of naturopathic physicians resulted in an automatic exclusion of naturopathic physicians from the definition of "attending qualified medical provider," who is expected to be the patient's primary care provider. They state the list of qualified medical providers includes all statute-recognized primary care providers except for naturopathic physicians, who routinely provide primary care and support through end of life and occasionally receive requests for Death with Dignity from terminally ill patients.

What is Primary Care

There is not a consistent definition of primary care in Washington and the applicant report did not include a definition. However, the department found several sources that define or describe primary care that include serving as a patient's primary point of contact, providing continuous, integrated care to meet most health care needs, and care coordination. Here are some examples the department identified.

• RCW 74.09.010 – Medical Care

According to the applicant report, the legislature recognized NDs as primary care providers in 2011. They reference <u>RCW 74.09.010</u> (Definitions) on public assistance, which was amended in in 2011 to add a definition of primary care provider as "a general practice physician, family practitioner, internist, pediatrician, osteopath, naturopath, physician assistant, osteopathic physician assistant, and advanced registered nurse practitioner licensed under Title 18 RCW (Businesses and professions)." ¹⁷

• Office of Financial Management (OFM)

In its 2019 legislative report on annual primary care expenditures, the Office of Financial Management (OFM) defined primary care using the National Academy of Medicine's (formerly the Institute of Medicine) definition:¹⁸

The provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs including physical, mental, emotional, and social concerns, developing a sustained partnership with patients, and practicing in the context of family and community.

This report describes the four main features of primary care services as:¹⁹

- First-contact access (into the health care system) for each new need.
- Long-term person- (not disease-) focused care (also referred to as continuous care).
- Comprehensive care for most health needs.
- Coordinated care when it must be sought elsewhere.

• U.S. Department of Health and Human Services (HHS)

In 2023, HHS released an issue brief on primary care that describes it as providing health promotion, disease prevention, and disease treatment and management services for individuals across the lifespan. The brief states "[p]rimary care is founded on a longitudinal, trusted relationship between patients and their primary care clinicians and

https://ofm.wa.gov/sites/default/files/public/publications/PrimaryCareExpendituresReport.pdf. ¹⁹ <u>Id.</u> at 3.

¹⁷ Laws of 2011, ch.316 § 2.

¹⁸ Washington State Office of Financial Management (OFM). (2019) *Primary Care Expenditures: Summary of Current Primary Care Expenditures and Investment in Washington*.

associated care teams."²⁰ HHS recognizes "[o]ther essential elements of primary care include: serving as a patient's initial point of contact to the healthcare system, providing person- or family-centered, comprehensive, continuous, and coordinated care, and having a community orientation and engagement."²¹

The applicant asserts that because naturopathic physicians serve as primary care providers, limitations in their scope of practice create challenges in providing care, burdens on the health care system, and duplication of services. However, there are necessary statutory limitations in scopes of practice for different types of health care providers based on education and training.

Death with Dignity Act

According to Washington's Death with Dignity Act, prescribing and dispensing medications requires a diagnosis of a terminal illness by an attending qualified medical provider and confirmed by a consulting qualified medical provider.^{22,23} If either medical provider believes a patient may be suffering from a psychiatric or psychological disorder causing impaired judgment, they must refer the patient for counseling and cannot prescribe end-of-life medications until the person performing the counseling determines their judgment is no longer impaired.²⁴

Qualified medical provider:

Washington's Death with Dignity Act defines a consulting qualified medical provider as "a qualified medical provider who is qualified by specialty or experience to make a professional diagnosis and prognosis regarding the patient's disease."²⁵ These providers' responsibilities include examining the patient and relevant medical records, confirming in writing the attending qualified medical provider's diagnosis that the patient has a terminal disease, and verifying the patient is competent, acting voluntarily, and has made an informed decision.²⁶

The definition also includes allopathic and osteopathic physicians, physician assistants, and advanced registered nurse practitioners.²⁷

²¹ <u>Id.</u>

²⁰ Department of Health and Human Services. (2023). *HHS is Taking Action to Strengthen Primary Care*. <u>https://www.hhs.gov/sites/default/files/primary-care-issue-brief.pdf</u>.

²² RCW 70.245.010

²³ RCW 70.245.020.

²⁴ RCW 70.245.060.

²⁵ RCW 70.245.010(4).

²⁶ RCW 70.245.050.

²⁷ RCW 70.245.010(10).

Washington's Death with Dignity Act defines an attending qualified medical provider as "the qualified medical provider who has primary responsibility for the care of the patient and treatment of the patient's terminal disease."²⁸ Responsibilities include:²⁹

- Making the determination of whether a patient has a terminal disease,
- Ensuring an informed decision by notifying the patient of their diagnosis,
- Informing the patient of their prognosis, risks of the medications, probable result of the medication, and feasible alternatives,
- Prescribing and dispensing medication to the patient (including ancillary medications to ease discomfort),
- Referring the patient to a consulting qualified medical provider for confirmation of the diagnosis, and
- Signing a patient's death certificate listing the underlying terminal disease as cause of death.

Selection of qualified medical provider:

If a qualified patient selects an attending qualified medical provider who is a licensed professional other than a physician, the qualified patient must select a physician to serve as the qualified patient's consulting qualified medical provider.

A qualified patient may select a consulting qualified medical provider who is a licensed professional other than a physician, only if the qualified patient's attending qualified medical provider, is a physician.³⁰

Abortion

In Washington, the only health care providers allowed to perform abortions are physicians (allopathic or osteopathic),³¹ physician assistants, advanced registered nurse practitioners, or other health care providers acting within the provider's scope of practice.³² A health care provider may assist a physician, physician assistant, advanced registered nurse practitioner, or other health care provider acting within the provider's scope of practice in an abortion.³³ This includes surgical abortions, which require anesthesia, may require pain medications, and have small risks of cervical injury or uterine perforation or infection.

²⁸ RCW 70.245.010(2).

²⁹ RCW 70.245.040(1).

³⁰ RCW 70.245.230

³¹ RCW 9.02.170(4).

³² RCW 9.02.100.

³³ <u>Id.</u>

It also includes medical abortions, which require prescriptive authority for Mifepristone to block progesterone needed for a pregnancy to continue and Misoprostol (used through 10 weeks gestation).³⁴

Controlled Substances

Controlled substances are drugs, substances, or immediate precursors included in Schedules I through V of the state and federal Uniform Controlled Substances Acts (chapter 69.50 RCW and Title 21 USC). Drugs are scheduled based on acceptable medical use and potential for abuse or dependence, with the lowest number classifications indicating the most dangerous substances. Schedule I drugs have no accepted medical use and the highest abuse potential. Schedule II drugs have a high potential for abuse which may lead to severe psychological or physical dependence. Schedules III through V drugs have lesser potential for abuse and dependence than Schedule I and II drugs.

Opioid pain medications fall under Schedule II and III. Also included in Schedule II are methamphetamines, pentobarbital, and hallucinogenic substances. Drug overdose and opioid misuse is a serious public health crisis in the United States, including Washington state. This includes the use of prescription opioids.³⁵

Medication Assisted Treatment

Medication-assisted Treatment (MAT) is the use of medications in combination with counseling and behavioral therapies to treat substance use disorders, including opioid use disorders (OUD).^{36,37} MAT is used to treat both OUD and Alcohol Use Disorder (AUD), however the drugs used to treat OUD are different than the drugs used to treat AUD.

³⁴ United States Food & Drug Administration (FDA). (2023). *Questions and Answers on Mifepristone for Medical Termination of Pregnancy through Ten Weeks Gestation*. United States Food & Drug Administration. <u>https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-</u>

 $gestation \#: \cite{text} = Mifepristone \cite{20is} \cite{20a} \cite{20drug} \cite{20that}, of \cite{20last} \cite{20last} \cite{20drug} \ci$

³⁵ Washington State Department of Health. (n.d.). Opioid Data. Washington State Department of Health. <u>https://doh.wa.gov/data-and-statistical-reports/washington-tracking-network-wtn/opioids</u>. (accessed May 13, 2024).

 ³⁶ United State Food & Drug Administration. (2024). *Information about Medication-Assisted Treatment (MAT)*.
 U.S. Food & Drug Administration. <u>https://www.fda.gov/drugs/information-drug-class/information-about-medication-assisted-treatment-mat.</u>

³⁷ Substance Abuse and Mental Health Services Administration (SAMHSA). (2024). *Medications for Substance Use Disorders*. SAMHSA. <u>https://www.samhsa.gov/medications-substance-use-disorders</u>.

There are three drugs approved by the FDA for the treatment of OUD: buprenorphine, methadone, and naltrexone. They are safe to use for long periods of time and some people may be on them safely for their lifetime. All three of these medications operate to normalize brain chemistry, block the euphoric effects of opioids, relieve cravings, and relieve negative withdrawal symptoms.³⁸

Buprenorphine is the first medication to treat OUD that can be prescribed or dispensed in a primary care physician's office.³⁹ Methadone used to treat OUD can only be dispensed through a certified Opioid Treatment Program (OTP).⁴⁰ Naltrexone can be prescribed and administered by any practitioner licensed to prescribe medications, as it is not considered a controlled substance.⁴¹ However, for OUD, it is only available in an intramuscular injectable formula.⁴² A critical note is that for patients who discontinue naltrexone or relapse after a period of abstinence, they "may have a reduced tolerance to opioids. Therefore, taking the same, or even lower doses of opioids used in the past can cause life-threating consequences."⁴³

Program Comparisons

Because the skills and knowledge to prescribe controlled substances are intertwined across courses and clinical experience for each educational program, the department is unable to fully compare courses across professions. Instead, the department chose to compare major components of the programs. In some sections, the department used University of Washington Medical School, University of Washington DNP Program, University of Washington MEDEX NW PA program, and Bastyr University to illustrate specific requirements. Note that an in-depth description of education and practice requirements by program is included in Appendix D.

Requirements for entering training programs

³⁸ <u>Id.</u>

³⁹ Substance Abuse and Mental Health Services Administration (SAMHSA). (2024). *Buprenorphine*. SAMHSA. <u>https://www.samhsa.gov/medications-substance-use-disorders/medications-counseling-related-conditions/buprenorphine</u>.

⁴⁰ Substance Abuse and Mental Health Services Administration (SAMHSA). (2024). *Methadone*. SAMHSA. <u>https://www.samhsa.gov/medications-substance-use-disorders/medications-counseling-related-</u> <u>conditions/methadone</u>.

⁴¹ Substance Abuse and Mental Health Services Administration (SAMHSA). (2024). *Naltrexone*. SAMHSA. <u>https://www.samhsa.gov/medications-substance-use-disorders/medications-counseling-related-conditions/naltrexone</u>.

⁴² Id.

⁴³ <u>Id.</u>

All four professions require undergraduate degrees and similar prerequisite science courses, such as chemistry and biology. PAs are required to complete 2,000 hours of clinical patient care experience to enter their program.

MDs (Doctorate)	ARNPs (Doctorate)	PAs (Master's)	NDs (Doctorate)
Undergraduate degree Passage of the Medical College Admission Test [®] (MCAT [®])	Undergraduate degree Active RN license ⁴⁴ (which requires passage of the NCLEX examination)	Undergraduate degree 2,000 hours clinical patient care experience ⁴⁵ Prerequisite science courses	Undergraduate degree Prerequisite science courses
Prerequisite science courses	Prerequisite science courses (for RN program)		

Table 1. Comparison of requirements for entering training programs

Didactic Training

It is difficult to compare naturopathic educational programs to medical and nursing programs because the focus of each training program is so different. In addition, though all the programs had varying amounts of specific pharmacology-related courses, some also integrated pharmacological concepts throughout other courses. Therefore, the department could not compare specific credit amounts or hours.

According to the Washington State Medical Association (WSMA), medical students complete didactic courses in pharmacology, as well as learn the clinical application of pharmacology over approximately 1,352 hours of basic sciences course work. The UW Medical School's website states the program focuses on anatomy, embryology, pathology, histology, and pharmacology integrated into interdisciplinary blocks that cover all body systems, the lifecycle, behavioral health, infections & immunity, and the fundamentals of medical science and research.⁴⁶ Pharmacology is integrated across courses.⁴⁷

⁴⁵ MEDEX Northwest Physician Assistant Program. (2024). *Applicants*. University of Washington Medicine.

⁴⁴ University of Washington School of Nursing. (2024). *DNP - Doctor of Nursing Practice*. University of Washington. <u>https://nursing.uw.edu/academics/dnp/</u>. (Accessed October 7, 2024).

https://familymedicine.uw.edu/medex/applicants/. (Accessed May 13, 2024). (Under "Clinical Prerequisites" tab). ⁴⁶ University of Washington School of Medicine. (2022). *Summer and Autum Quarters*. University of Washington School of Medicine. <u>https://www.uwmedicine.org/sites/stevie/files/2023-02/Curriculum%20Visual.pdf</u>. (Accessed October 7, 2024).

⁴⁷ University of Washington School of Medicine. (2024). *Curriculum*. University of Washington School of Medicine. <u>https://www.uwmedicine.org/school-of-medicine/md-program/curriculum</u>. (Accessed September 2024).

UW's MEDEX NW PA program website states it focuses on basic scientific concepts, intensive history and physical examinstruction. Body systems are studied in blocks across courses, so the content of each is reinforced in the others. Curriculum courses include behavioral medicine, emergency medicine, adult medicine, and maternal and child health.⁴⁸ Pharmacology is integrated across courses.⁴⁹

ARNPs are required to hold an active license as an RN before entering an advanced practice program. According to the UW School of Nursing website, the BSN program focuses on the fundamentals in professional nursing practice, pharmacotherapeutics, and pathophysiology, as well as psychosocial nursing, and nursing practicums.⁵⁰ ARNPs take courses in pharmacotherapeutics and pathophysiology during their RN program, as well as in the DNP program.⁵¹ The DNP program focuses on advanced physical assessment, diagnosis, pathophysiology, and pharmacology.⁵¹

The dean of Bastyr University's Doctor of Naturopathic Medicine program states the program includes core principles in anatomy, histology, embryology, biochemistry, physiology, pathology, immunology, and infectious diseases in the context of body systems.⁵² Pharmacology content is integrated into psychopathology, naturopathic approaches to addiction, and medical procedures courses.⁵³ Bastyr's website shows the program also includes naturopathic therapeutics of body systems and conditions, minor medical/surgical procedures and multiple courses in hydrotherapy, homeopathy, electrotherapy, manipulation, and botanical medicine.⁵⁴ Regarding pharmacology training:

⁴⁸ MEDEX Northwest Physician Assistant Program. (2024). *Curriculum*. University of Washington Medicine. <u>https://familymedicine.uw.edu/medex/pa-program/curriculum/</u>. (Accessed September 2024).

⁴⁹ MEDEX Northwest Physician Assistant Program. (2024). *Didactic Year*. University of Washington Medicine. <u>https://familymedicine.uw.edu/medex/pa-program/curriculum/didactic-year/</u>. (Accessed September 2024).

⁵⁰ University of Washington School of Nursing. (2023). *Bachelor of Science in Nursing Program 2-Year Curriculum*. University of Washington. <u>https://students.nursing.edu/wp-content/uploads/2023/06/BSN-2023-Curriculum-Grid.pdf</u>. (Accessed September 2024).

⁵¹ University of Washington School of Nursing. (n.d.). *Doctor of Nursing Practice Family Nurse Practitioner Track 3-Year Program Curriculum*. University of Washington. <u>https://students.nursing.uw.edu/wp-</u>

content/uploads/2022/06/DNP-FNP-2022-Curriculum-Grid.pdf. (Accessed September 2024). ⁵² Bastyr University. (n.d.). *Doctor of Naturopathic Medicine*. Bastyr University.

https://bastyr.smartcatalogiq.com/en/2023-2024/academic-catalog/school-of-naturopathic-medicine/graduate-programs/doctor-of-naturopathic-medicine/. (Accessed September 2024).

⁵³ Kristina Conner, Dean, School of Naturopathic Medicine, Bastyr University, communication to the Washington State Department of Health, November 20, 2023. (See Appendix C, A-41).

⁵⁴ Doctor of Naturopathic Medicine.

- According to the dean at Bastyr, students receive 12.65 credits related to pharmacology. This
 includes specific pharmacology courses and an additional 3.15 credits within integrated
 management courses.⁵⁵
- The dean of the College of Naturopathic Medicine at NUNM stated the core curriculum contains 141.5 hours of pharmacology that are threaded through organ-based blocks.
- The dean of the College of Naturopathic Medicine at Sonoran University shared the program includes 13.5 credits in pharmacology, emergency medicine, and medical management of addiction, as well as 4.5 credits integrated into endocrinology and geriatrics courses.

The pharmacology curriculum does not appear standardized among ND programs. For example, Bastyr includes specific pharmacology courses, while NUNM does not include specific courses but integrates pharmacology into course blocks.

Clinical training

Allopathic and osteopathic physicians have the most extensive training, which includes required clerkships/rotations and specified patient encounters that must be experienced as part of their program. PAs train under allopathic or osteopathic physicians and are required to take clerkships and rotations in specific medical settings and populations. The UW MEDEX program includes 1,600 clinical training hours.⁵⁶

ARNPs have required clinical rotations in their underlying RN programs as well as advanced practice programs. Current national specialty certification, which includes passage of an examination is also required for ARNP licensure. ARNPs are required to obtain 500 hours of clinical training that includes advanced physical assessment, advanced pharmacology, and advanced pathophysiology,⁵⁷ as well as 1,000 clinically relevant practice hours obtained in their RN program.⁵⁸

The Council on Naturopathic Medicine Education (CNME) states that elements of the clinical education component include providing opportunities to treat patients of all ages, with a variety of conditions and diseases and a minimum number of patient encounters to ensure

⁵⁵ Kristina Conner, Dean, School of Naturopathic Medicine, Bastyr University, communication to the Washington State Department of Health, November 20, 2023. (See Appendix C, A-41).

⁵⁶ Kai Weng, Program Coordinator, MEDEX Northwest, UW School of Medicine, communication to the Washington State Department of Health, May 10, 2024 (see Appendix C, A-38).

⁵⁷ American Academy of Nurse Practitioners National Certification Board, Inc. (2021). *FNP, AGNP & PMHNP Certification Handbook*. American Academy of Nurse Practitioners National Certification Board, Inc. https://www.aanpcert.org/resource/documents/AGNP%20FNP%20Candidate%20Handbook.pdf.

⁵⁸ University of Washington School of Nursing. (204). *BSN—Bachelor of Science in Nursing*. University of Washington. <u>https://nursing.uw.edu/academics/bsn/</u>. (Accessed September 2024).

competency.⁵⁹ According to the Association of Naturopathic Medical Colleges and the Dean of Bastyr, naturopathic school faculty possess varied backgrounds with degrees in medicine, pharmacy, osteopathy, etc. However, CNME accreditation requires 900 of the 1,200 clock hours involving patient contact to occur in naturopathic clinics.⁶⁰ In addition, clinical training requirements reported by naturopathic programs show they can occur mainly in naturopathic clinics and do not appear to include requirements ensuring sufficient exposure to controlled substance prescribing. For example:

- Through Bastyr's and the National University of Natural Medicine's (NUNM) clinical experiences, students may manage patients on controlled substances during their required clinical rotations.⁶¹
- NUNM states students must demonstrate competency in pharmacological prescription through a total of only 12 prescriptions in at least eight different condition categories.⁶²
- Sonoran states it has two community clinics offering six clerkship opportunities per week where substance abuse disorders are common among the participants and that most student rotations are family practice, meaning many of the patients seen are taking medications the supervising physician has prescribed.⁶³

Sonoran University has elective site locations that are staffed by physicians in private practice, hospitals, ambulatory care facilities, long-term acute care facilities, etc., at the college's nine community clinics and more than 100 off-site clinics, including hospitals, medical centers, and medical mobile units. No more than 20 of 108 credits in direct patient care may be completed at elective off-site locations.⁶⁴

MDs	ARNPs	PAs	NDs
Required clerkships in	750 hours. ⁶⁷	Approximately 1,600	1,204 clinical training
family medicine,	(plus 1,000 clinically	hours. ⁶⁹	hours in a supervised
internal medicine,	relevant practice hours		setting. ⁷¹
obstetrics and	obtained in RN	Core family medicine	_
gynecology, pediatrics,	program). ⁶⁸	placement and required	Must pass a clinic exit
psychiatry, and surgery,		rotations in behavioral	

Table 2. Comparison of clinical training

⁵⁹ Council on Naturopathic Medical Education (CNME). (2024). *Handbook of Accreditation for Naturopathic Medicine Programs*. Council on Naturopathic Medical Education. <u>https://cnme.org/wp-</u>content/uploads/2024/01/CNME-Handbook-of-Accreditation-January-2024-edition.pdf.

⁶⁰ Id.

⁶¹ Applicant Report.

⁶² Applicant Report.

⁶³ Applicant Report.

⁶⁴ Sonoran University of Health Sciences. (2024). *Clinical Training*. Sonoran University of Health Sciences. <u>https://www.sonoran.edu/programs/college-of-naturopathic-medicine/clinical-training/</u>. (Accessed May 2024).

across urban and rural settings, hospital wards and outpatient clinics. ⁶⁵ According to WSMA, this is over two years.	medicine, emergency medicine, surgery, inpatient, and underserved populations. ⁷⁰	assessment ⁷²
Requires specific patient encounters and procedures. ⁶⁶		

Examination

All professions require passage of an examination prior to licensure. In addition, ARNPs must obtain and maintain national specialty certification, which requires passage of an examination.⁷³

Table 3. Comparison of examination requirements

MDs	ARNPs	PAs	NDs
Passage of all steps of	Passage of the National	Passage of the National	Passage of the
the United States	Council Licensure	Commission on	Naturopathic Physicians
Medical License	Examination (NCLEX) for	Certification of Physician	Licensing Examination
Examination (USMLE) or	RN license.	Assistants (NCCPA)	(NPLEX). ⁷⁴
the Licentiate of the		examination.	
Medical Council of	National specialty		NPLEX elective
Canada (LMCC).	certification which		pharmacology
	includes passage of an		examination.75
	examination.		

⁶⁷ American Academy of Nurse Practitioners National Certification Board, Inc. (2021).

⁶⁸ BSN—Bachelor of Science in Nursing.

⁶⁹ Kai Weng, Program Coordinator, MEDEX Northwest, UW School of Medicine, communication to the Washington State Department of Health, May 10, 2024 (see Appendix C, A-38).

⁷¹ Doctor of Naturopathic Medicine.

⁶⁵University School of Medicine. (2019). *PHASE 3: Explore & Focus*. University of Washington Medicine.

https://education.uwmedicine.org/curriculum/by-phase/clinical/explore-and-focus/. (Accessed September 202). 66 "PHASE 3: Explore & Focus."

⁷⁰ MEDEX Northwest Physician Assistant Program. (2024). *Clinical Year*. University of Washington Medicine. <u>https://familymedicine.uw.edu/medex/pa-program/curriculum/clinical-year/</u>. (Accessed September 2024).

⁷² Doctor of Naturopathic Medicine.

⁷³ WAC 246-840-302.

⁷⁴ WAC 246-836-030.

⁷⁵ North American Board of Naturopathic Examiners (NABNE). *Eligibility Requirements*. North American Board of Naturopathic Examiners. <u>https://nabne.org/eligibility-requirements/</u>. (Accessed October 2024).

Post-graduate requirements

MDs cannot be licensed to practice independently before completing a two-year residency in general medicine or surgery, or a specialty or subspecialty in the field of medicine or surgery as recognized by the American Board of Medical Specialties.⁷⁶ ARNPs must maintain their specialty certification and meet ongoing requirements for that certification. In addition, RNs are required to have a minimum of 96 hours of active nursing practice to maintain their license, where they practice under the supervision of MDs and other practitioners with prescriptive authority.⁷⁷

MDs	ARNPs	PAs	NDs
2-year residency in general medicine or surgery, or a specialty or subspecialty in the field of medicine or surgery. DEA-mandated 8 hours of CME training required for every provider prescribing controlled substances.	National specialty certification requires a minimum number of clinical hours, specific pharmacology courses, an exam, and renewal requirements. DEA-mandated 8 hours of CME training required for every provider prescribing controlled substances.	None. DEA-mandated 8 hours of CME training required for every provider prescribing controlled substances.	None. DEA-mandated 8 hours of CME training required for every provider prescribing controlled substances.

Table 4. Comparison of post-graduate requirements

Note: There are voluntary certification options available for NDs.

Prescriptive Authority

There are no restrictions on prescriptive authority for MDs/DOs or ARNPs.

PAs must have a practice agreement with a physician or physicians, which includes a supervising MD or DO. 78

NDs are limited in their prescriptive authority and for intravenous therapy, they must submit an attestation of training for at least sixteen hours of instruction.⁷⁹ At least eight hours must be part of a graduate level course.⁸⁰

⁷⁸ WAC 246-918-035.

⁷⁶ WAC 246-919-330(1).

⁷⁷ WAC 246-840-220

⁷⁹ WAC 246-836-220.

⁸⁰ WAC 246-836-220.

All professions who prescribe controlled substances are required to register with the Drug Enforcement Administration (DEA), which requires completion of a one-time, eight hours of addiction education and training.

MDs	ARNPs	PAs	NDs
No restrictions.	No restrictions.	Delegation agreement allows PAs to prescribe, order, administer and dispense legend drugs and Schedule II-V controlled substances. If a supervising or alternate physician's prescribing privileges are restricted, the physician assistant will be deemed similarly restricted.	No restrictions, except controlled substance prescriptions are limited to testosterone and codeine-containing substances in Schedules III-V. For intravenous therapy, must submit 16-hour training attestation.

Table 5. Comparison of prescriptive authority

Continuing education

Continuing education requirements vary substantially by profession. Only ARNPs and NDs have specific requirements for pharmacology continuing education.

Table 6. Comparison of continuing education requirements

MDs	ARNPs	PAs	NDs
200 hours every 4 years (average of 50 hours per year).	30 hours every two years (average of 15 hours per year) plus 15 hours in pharmacotherapeutics to retain prescriptive authority. National certification requires 100 contact hours of advanced CE, including 25 credits of advanced practice pharmacology every 5 years.	100 hours every 2 years (average of 50 hours per year).	60 hours every 2 years plus (average of 15 hours per year) 15 hours in pharmacotherapeutics for those with limited prescriptive authority.

In this review, the department must assess the minimum qualifications for NDs to practice or plan to practice in Washington. However, the department must note that it received public comments from several NDs who appear to exceed minimum qualifications such as by receiving clinical training from a variety of settings like hospitals, surgery centers, and federally qualified health clinics where broad patient populations and conditions were represented, and oversight was provided by a diversity of provider types. Some of these NDs held specialty certifications and/or completed residencies. The department also heard from several NDs who work in collaborative practices with MDs, DOs, ARNPs, and PAs.

Other States

The applicant report provided information on states with broad prescriptive authority. The department conducted additional research into each state's scope of practice and educational and practice requirements to gain prescriptive authority. Please note we use ND throughout this section for consistency.

Arizona

The Arizona Naturopathic Physicians Medical Board regulates NDs, who have limited authority to prescribe controlled substances if they are granted a certificate to dispense. This requires either graduation from an approved naturopathic school after January 1, 2005, or completion of a 60-hour pharmacological course on natural substances, drugs, or devices.⁸¹

Prescriptive authority includes Schedule III-V plus morphine in Schedule II.⁸² Intravenous administration of legend drugs is excluded from ND's prescriptive authority except vitamins, chelation therapy, drugs used in emergency resuscitation and stabilization, minerals, and nutrients.⁸³ In addition, NDs cannot prescribe cancer chemotherapeutics classified as legend drugs, or antipsychotics.⁸⁴

NDs must provide evidence of 30 credit hours of continuing medical education activities annually, which include ten credit hours in pharmacology relating to the diagnosis, treatment, or prevention of disease.⁸⁵

The department was unable to obtain information on disciplinary actions in Arizona.

⁸¹ A.A.C. R4-18-902.

⁸² A.R.S. § 32-1501(15).

⁸³ <u>Id.</u>

⁸⁴ <u>Id.</u>

⁸⁵ A.A.C. R4-18-205(A).

California

The California Board of Naturopathic Medicine (board) regulates NDs, who are authorized to prescribe Schedule III-V controlled substances, limited to drugs agreed upon by the naturopathic doctor and a supervising physician and surgeon.⁸⁶ The board includes two physician (MD/DO) members.⁸⁷ The ND must function under a standardized procedure or protocol developed and approved by the supervising physician and surgeon and the ND.⁸⁸ The protocol must include which drugs may be furnished or ordered under what circumstances, the extent of supervision, the method of periodic review of the naturopathic doctor's competence, and review of the standardized procedure.⁸⁹ When the NDs furnish or order Schedule III substances, there must be a patient-specific protocol approved by the supervising physician.⁹⁰

NDs must include the following in their licensure application: (1) whether they intend to furnish or order controlled substances, and (2) provide written evidence to the licensing authority that they have completed at least forty-eight hours of instruction in pharmacology that included the pharmacokinetic and pharmacodynamic principles and properties of the drugs they are furnishing or ordering.⁹¹

NDs are specifically prohibited from performing an abortion or surgical procedure.⁹²

The board also requires satisfactory completion of 60 hours of approved continuing education biennially, including at least 20 hours in pharmacotherapeutics.⁹³

Since the board's creation in 2004-05, there have been only three actions taken against NDs for patient harm and/or unprofessional conduct.⁹⁴

Vermont

The Office of Professional Regulation (OPR) regulates NDs in Vermont. There is an advisory committee that is tasked with studying and reporting on issues related to prescribing authority that is composed of seven member that include two naturopathic physicians, two allopathic or

⁸⁷ California Board of Naturopathic Medicine. (2024). *Board Members Bio*. California Department of Consumer Affairs. <u>https://www.naturopathic.ca.gov/about_us/members.shtml</u>. (Accessed 9/4/2024).

⁸⁶ Cal. Bus. & Prof. Code § 3640.5.

⁸⁸ Cal. Bus. & Prof. Code § 3640.5.

⁸⁹ <u>Id.</u>

⁹⁰ <u>Id.</u>

⁹¹ CAL. CODE REGS. § 4212.

⁹² CAL. BUS. & PROF. CODE § 3642.

⁹³ CAL. BUS. & PROF. CODE § 3635.

⁹⁴ R. Mitchell, Executive Director, California Board of Naturopathic Medicine, communication to the Washington State Department of Health, August 29, 2024. (See Appendix C, pp. A-48-50).

osteopathic physicians, a pharmacologist, a pharmacist, and a public member.⁹⁵ NDs must obtain a special endorsement for prescription medications. The endorsement requires passage of the National Board of Medical Examiners (NBME) pharmacology examination or a substantially equivalent examination.⁹⁶ According to the applicant, the "substantially equivalent examination" of choice in Vermont is the same elective pharmacology exam administered by NABNE and that is the preferred examination by the Vermont Office of Professional Regulation to demonstrate. The first 100 drug prescriptions issued by an ND must be reviewed by an independent supervising physician or a naturopath with the endorsement through a formal written agreement.⁹⁷

NDs are allowed to administer and provide for preventative and therapeutic purposes such things as: nonprescription medicines, topical medicines, homeopathic medicines, naturopathic physical medicine, therapeutic devices, barriers for contraception and certain prescription medicines.⁹⁸ Those prescription medicines are any human drug required by federal law or regulation to be dispensed only by prescription.⁹⁹ NDs are authorized to possess and control all controlled substances (referred to as "regulated drugs" in Vermont law) to the extent doing so is within their education, training, experience, and scope of practice.¹⁰⁰ There are currently no rules clarifying this scope of practice.¹⁰¹

For licensees possessing the special endorsement for prescription medications, Vermont requires 30 hours of continuing medical education every two years upon renewal, including ten hours in pharmacology of legend drugs.¹⁰²

There are 122 NDs holding a prescriptive authority endorsement out of 416 active, licensed NDs.¹⁰³ The department could not identify any disciplinary actions specifically related to ND's prescriptive authority.

New Mexico

https://secure.professionals.vermont.gov/prweb/PRServletCustom/app/NGLPGuestUser/V9csDxL3sXkkjMC FR2Hr <u>A*/!STANDARD?UserIdentifier=LicenseLookupGuestUser</u>. (Accessed May 14, 2024). (Search "Profession" = Naturopathic Physicians" and "Profession Type" = "Naturopathic Physician" and "Status" = "Active").

⁹⁵ 26 V.S.A. § 4125.

⁹⁶ CVR 04-030-380 § 3.5.

⁹⁷ <u>Id.</u>

⁹⁸ 26 V.S.A. § 4121.

⁹⁹ <u>Id.</u>

¹⁰⁰ Confirmed by the Vermont Office of Professional Regulation (OPR). (Lauren K. Layman, communication to Department of Health, March 29,2024) (See Appendix C, p. A-44).

 ¹⁰¹ Lauren K. Layman, communication to Department of Health, March 29, 2024. (See Appendix C, p. A-44).
 ¹⁰² CVR 04-030-380 §3.2.

¹⁰³ Vermont Office of Professional Regulation. (2021). *Find a Professional*. Vermont Office of Professional Regulation.

NDs are regulated by the New Mexico Medical Board.¹⁰⁴ A Naturopathic Doctors' Advisory Council advises the board. All licensees are required to pass the NPLEX biomedical science examination (Part I) and the core clinical science examination (Part II), as well as the clinical elective examination in minor surgery and pharmacology.¹⁰⁵

Under New Mexico's rules on naturopathic doctors, "primary care" is defined as: 106

Health care provided by a healthcare provider who typically acts as the first contact and principal point of continuing care for patients and coordinates other specialist care or services that the patient may require. Primary care providers are trained in non-specialty internal medicine and pediatrics, family medicine, general internal medicine, geriatrics (gerontology), general obstetrics and gynecology and general pediatrics, and refer to specialists when those services are warranted.

NDs must practice in collaboration with a medical or osteopathic physician and in alignment with naturopathic education.¹⁰⁷ "Collaboration" is defined under New Mexico rules as:¹⁰⁸

The process by which a licensed physician and a naturopathic doctor jointly contribute to the health care and treatment of patients, provided that: (a) each collaborator performs actions that the collaborator is licensed or otherwise authorized to perform, and (b) collaboration shall not be construed to require the physical presence of the licensed physician at the time and place services are rendered by the collaborating naturopathic doctor.

Section 16.10.22.11.B states, "This does not imply that supervision by a physician is required, rather that professional communication and collaboration is required between all healthcare providers for continuity of care in accordance with HIPAA regulations."

After passing a pharmacy examination authorized by board rules, NDs are authorized to prescribe all legend drugs, and testosterone products and all schedule III-V controlled substances, except all benzodiazepines, opioids, and opioid derivatives.¹⁰⁹ They are prohibited from performing surgical abortions.¹¹⁰ They are also required to take 75 hours of continuing

¹⁰⁴ New Mexico Medical Board. (2024). *Licensing and Renewal*. New Mexico Medical Board.

https://www.nmmb.state.nm.us/licensing/. (Accessed May 20, 2024). (The board regulates physicians, physician assistants, anesthesiologist assistants, genetic counselors, doctors or naprapathy, physician supervisors of pharmacist clinicians, polysomnographic technologists, naturopathic doctors, and podiatric physicians). ¹⁰⁵ N.M. Code R. § 16.10.22.9.

¹⁰⁶ N.M. Code R. § 16.10.22.7.

¹⁰⁷ N.M. Code R. § 16.10.22.11.

¹⁰⁸ N.M. Code R. § 16.10.22.11.

¹⁰⁹ LU

¹⁰⁹ <u>Id.</u>

¹¹⁰ N.M. Code R. § 16.10.22.12.

medical education every three years, including five hours in pain management and ten hours in pharmacology.¹¹¹

The department reached out to the New Mexico board to obtain information on disciplinary actions but were unable to obtain this information.

Oregon

Oregon NDs are regulated by the Oregon Board of Naturopathic Medicine.¹¹² Licensees are required to pass the Oregon Jurisprudence Examination and the NPLEX exams part I & II, as well as the NPLEX exams on clinical elective surgery and clinical elective pharmacology.¹¹³

Licensed Oregon NDs are defined as primary care physicians in statute and their scope of practice includes minor surgery, natural childbirth, and administering injection therapies.¹¹⁴ They are authorized to prescribe a large formulary of Schedules II-V controlled substances with no additional training.¹¹⁵ Two exceptions are ketamine therapy and injection and IV therapy, which have additional educating and reporting requirements.¹¹⁶ NDS are also prohibited from prescribing:¹¹⁷

- General anesthetics;
- Injectable ketamine for the purpose of general anesthesia;
- Mifepristone and misoprostol as an abortifacient;
- Barbiturates, except phenobarbital, butalbital, primidone; and
- Systemic oncology agents except for certain antineoplastic agents, in oral and topical form only.

The formulary was expanded in 2018 to include phenobarbital, butalbital, primidone; and again in 2023 to include prescription and administration of injectable and intravenous ketamine with additional training and education.

According to the executive director of the board of naturopathic medicine, Oregon licensees may prescribe medication from one of the most comprehensive formularies in the nation. Licensees may prescribe all pharmaceuticals needed in a primary care practice as well as the natural therapeutics.

¹¹¹ N.M. Code R. § 16.10.22.15.

¹¹² ORS § 685.145.

¹¹³ OAR 850-030-0020.

¹¹⁴ Mary-Beth Baptista, JD, Executive Director, Oregon Board of Naturopathic Medicine, communication to the Washington State Department of Health, August 31, 2024. (See Appendix C, pp. A-51-54).

¹¹⁵ OAR 850-060-0226.

¹¹⁶ OAR 850-060-0212.

¹¹⁷ OAR 850-060-0223.

The Naturopathic Formulary Council¹¹⁸ consists of seven members, one board member from the Oregon Board of Naturopathic Medicine, one naturopathic physician, two pharmacists, one allopathic physician, and two members with advanced degrees in either pharmacology or pharmacognosy. The council has adopted the current American Hospital Formulary Service Pharmacologic-Therapeutic Classification, which has been in use in hospitals and health systems for many years and is a logical way to group drugs for easy comparison and aggregate reporting on drugs for utilization and billing.^{119,120}

Licensees are required to obtain 32 hours of continuing education annually, including one hour in pain management and ten hours of pharmacology.¹²¹

There are 1,213 naturopathic physicians licensed in Oregon.¹²² Since 2017, there have been 19 disciplinary actions for conduct related to prescribing, including negligent prescribing, prescribing off the formulary, or not following state opioid prescribing guidelines appropriately. Since 2019, coinciding with the implementation of new Oregon Acute Opioid Prescribing Guidelines and associated resources, licensee discipline has been primarily for conduct that is "prescribing adjacent." These are mostly ethical violations for failing to follow the aforementioned prescribing guidelines, i.e., negligent charting, failing to check Prescription Drug Monitoring Program, boundary setting, and not entering pain contracts." ¹²³

2014 Sunrise Review

In a 2014 sunrise review of a similar proposal to include prescriptive authority for all Schedule II-V controlled substances for NDs, the department determined the proposal did not meet the sunrise criteria.¹²⁴

However, the Health Care Authority (HCA) argued in support of a limited expansion of prescriptive authority because expanded Medicaid coverage was expected to include an

https://doh.wa.gov/sites/default/files/legacy/Documents/2000/NaturopathFinal.pdf.

¹¹⁸ Oregon Board of Naturopathic Medicine. (n.d.). *Formulary Council*. Oregon Board of Naturopathic Medicine. <u>https://www.oregon.gov/obnm/Pages/Formulary%20Council.aspx</u>. (Accessed September 2024).

¹¹⁹ OAR 850-060-0226.

¹²⁰ American Society of Health-System Pharmacists, Inc. (2019). AHFS Pharmacologic-Therapeutic Classification System. American Society of Health-System Pharmacists, Inc.

https://www.oregon.gov/obnm/Documents/Formulary%20Information/AHFSClassificationwithDrugs2019.pdf. (Accessed May 20, 2024).

¹²¹ ORS § 850-040-0210.

¹²² Robin Crumpler, communication to the Department of Health, April 17, 2024. (See Appendix C, p. A-47).

¹²³ Mary-Beth Baptista, JD, Executive Director, Oregon Board of Naturopathic Medicine, communication to the Washington State Department of Health, August 31, 2024. (See Appendix C, pp. A-51-54).

¹²⁴ Health Systems & Quality Assurance (HSQA). (2014). *Naturopathic Scope of Practice Sunrise Review: Information Summary and Recommendations*. Washinton State Department of Health.

expanded demographic of patients with medical conditions requiring controlled substances in the naturopathic primary care setting. HCA also argued that: (1) deaths related to prescription opioids occurred almost without exception in patients on chronic therapy, (2) short-term treatment of acute conditions with controlled substances is considered safer, and (3) limited prescriptive authority may reduce the number of unnecessary emergency department visits.

The department suggested a less expansive scope increase option for the legislature to consider that included:

- Limiting ND prescriptive authority to controlled substances in Schedule III-V (and hydrocodone products in Schedule II),
- Limiting prescriptions to no more than seven days,
- Setting a maximum dosage,
- Instructing the Board of Naturopathy consult with the Pharmacy Quality Assurance Commission on rules to determine appropriate training and education,
- Requiring adoption of pain management rules, and
- Requiring registration in the Prescription Monitoring Program (PMP)¹²⁵ to access patient prescription history.

The legislature did not enact a scope expansion in response to these suggested options. The current ND scope expansion proposal has been updated from the 2014 version to include some additional pharmacology education. However, the department continues to believe the applicant proposal is too expansive and does not meet the Sunrise criteria.

The department also received comments from HCA on the current proposal.¹²⁶ While HCA shared it believes there could be positive impacts, HCA also shared concerns regarding the varying amounts of training and education NDs receive in pharmacology, specifically with stimulants and controlled substances, stating:

- "HCA does see the potential for this scope change to improve *access* to care, but retains concerns that it could impact the *quality* of care."
- "Medicaid managed care plans have concerns about the varying amounts of training and education naturopathic physicians receive in pharmacology, specifically with stimulates and controlled substances."

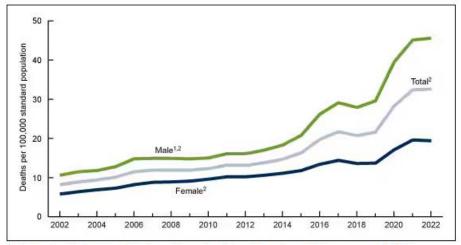
¹²⁵ The PMP allows the department to monitor the prescribing and dispensing of all Schedule II-V controlled substances. It is a secure online database that collects data on Schedules II-V controlled substances. RCW 70.225.020(1). Prescribers are authorized to access PMP data before prescribing or dispensing drugs to look for duplicate prescribing, possible misuse, drug interactions, and other potential concerns.

¹²⁶ Sandy Jaime, Legislative Review & Analysis Manager, Health Care Authority, communication to the Washington State Department of Health, November 20, 2023. (See Appendix C, pp. A-55-56).

In the 2014 ND Sunrise Review,¹²⁷ the department also noted that there was significant risk to increasing access without limitation to prescription opioid pain medication because:

- Prescription opioid related overdoses and deaths have reached epidemic levels,
- Data has shown a correlation between the rise in overdose deaths and states that have expanded prescription access to prescription opioids, and
- The state is currently engaged in intensive and effective efforts to curb the overuse of opioids in Washington. Granting broader prescribing authority for controlled substances is contrary to these efforts.

Since the 2014 ND Sunrise Review was completed, the opioid epidemic has gotten worse. According to the Centers for Disease Control and Prevention (CDC) in their March 2024 report,¹²⁸ "drug overdoses are one of the leading causes of injury death in adults and have risen over the past several decades in the United States." As illustrated in the table below from the March 2024 CDC report, in both 2015 and 2019 there was a significant increase in overdose deaths.





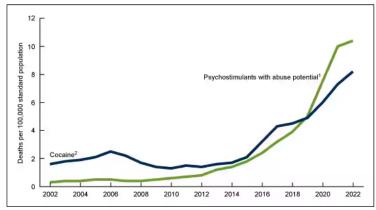
¹Rate significantly higher than for females for all years p < 0.05. ²Significant increasing trend from 2002 to 2022, with different rates of change over time, p < 0.05.

The CDC report also shows a similar significant increase in drug overdoses involving stimulants beginning around 2019.

¹²⁷ HSQA (2014).

¹²⁸ National Center for Health Statistics. (2024). *Drug Overdose Deaths in the United States, 2002–2022.* Center for Disease Control (CDC). <u>https://www.cdc.gov/nchs/products/databriefs/db491.htm</u>.

Figure 2. Age-adjusted rate of drug overdose deaths involving stimulants, by type of stimulant: United States, 2002-2022



¹Stable trend from 2002 to 2010, then significant increasing trend from 2010 to 2022, p < 0.05. ²Stable trend from 2002 to 2006, significant decreasing from 2006 to 2012, then significant increasing trend from 2012 to 2022, p < 0.05.

Given the increasing trend in overdose deaths involving controlled substances, especially opioids and stimulants, the department continues to be cautious in expanding the scope of prescriptive authority for these substances, especially when there is not clear evidence of sufficient training in prescribing and monitoring patients on opioids and stimulants.

Public Engagement

The department posted the applicant's proposal and all materials to the department's sunrise webpage and notified interested parties of the written comment period in the fall of 2023. The department received over 1,100 written comments. The department held a public comment meeting and accepted oral comments on April 24, 2024.

Here is a summary of the written and oral comments the department received.

Support

Commentors in support of the proposal stated that NDs are educated and trained in accredited naturopathic medical colleges to provide primary care. They argued this proposal would give Washington residents access to a broader range of healthcare options, particularly in rural and underserved areas, where access to conventional medical care can be limited or have long wait times. They also stated the proposal would decrease patient costs and make care timelier, as patients would not have to schedule a second office visit with another provider to fill or change a prescription. Requiring double visits delays care and increases costs due to insurance co-pays, time off work, and other cost shares, especially in rural communities.

NDs commented that natural medicine and conventional medicine are not mutually exclusive and there are circumstances that require both. NDs follow the least invasive approach first before introducing pharmaceuticals but are trained to identify when and whether a patient is overmedicated and when medications can be tapered off or discontinued.

Commentors also stated that inconsistencies in naturopathic regulation between Washington and Oregon places a burden on patients and doctors that travel across state lines for work or to seek care. Commentators claimed it is irrational for NDs who practice medicine in Oregon to be restricted or prohibited from providing the same level of care in Washington.

The department heard from numerous ND patients who wrote in support of the proposal. Many patients questioned why their ND could not write prescriptions for them since they are their primary care physician. They expressed concerns with the need to see multiple physicians for titrating medications and paying more than one co-pay, especially considering the long wait times to find another provider. Some patients wrote that they wished Medicare covered their naturopathic care, but they are willing to pay out of pocket because it is the care they trust. Many of the patients wrote specifically in support of having their ND prescribe ADHD and antianxiety medications.

The dean of Bastyr University wrote that the level of training by their graduates meets similar requirements as other healthcare practitioners who hold full prescriptive authority. The Bastyr program includes 300 credits, which equates to over 4,200 hours. The dean made some corrections to the education provided in the applicant report, which the department notes in the section on Bastyr training above. The dean attached updated information about Bastyr's current pharmacology and patient management courses on controlled substances, which include pharmacology, pharmaceutical management, and substance use disorders. According to these materials, Bastyr's ND program allocates 12.65 of curricular credits, which is equivalent to 141.75 hours of classroom time, specifically for didactic training and medication management. The latter is provided in a supervised setting throughout students' 1,204 hours of clinical training and is where students learn how to assess, manage, and refer substance use disorders. Bastyr emphasizes safe practice standards at every level of the student's education.

An instructor at Bastyr University who has also taught at Sonoran University stated their Bastyr graduates are well trained in the use of controlled substances, including having around 150 hours of classroom training and clinical training hours in pharmacology. They state NDs can simultaneously provide treatment on and support for managing controlled substances while ultimately reducing or eliminating the need for these medications. They attested that almost every patient encounter by their ND students involved pharmacological therapies.

The executive director of the Council on Naturopathic Medical Education (CNME) wrote to affirm that CNME-accredited naturopathic medical programs train naturopathic primary care physicians, and that training covers basic medical sciences, advanced clinical sciences, and

pharmacology. The program includes training on controlled substances and drug-herb-nutrient interactions, as well as public health, diagnostics, and non-pharmacologic therapeutics.

The executive director of the North American Board of Naturopathic Examiners (NABNE) wrote to confirm that the competencies tested in the NPLEX Part II – Core Clinical Sciences Examination are designed to test to the highest scope of practice available in any state, including medications used in primary care.

The Association of Accredited Naturopathic Medical Colleges (AANMC) wrote to confirm that ND training is similar to the biomedical and clinical requirements for other medical degrees such as MDs, ARNPs, and DOs. The AANMC's recommended core competencies outline stringent guidelines and expectations for clinical and professional practice among licensed NDs who have graduated from accredited naturopathic programs. Accredited naturopathic medical schools train their students to meet the AANMC's recommended clinical competencies and prepare them for the NPLEX exam. All accredited naturopathic medical schools in the US provide high-level pharmacology training, including coverage of controlled substances, pharmacology, pharmacognosy, drug-herb, and drug-nutrient interactions. They added that comparisons between naturopathic and conventional primary care programs (MD/DO, ARNP) demonstrate similarities in foundational medical training.

Other commentors noted that federal law requires that NDs who have DEA licenses, including those practicing in Washington, are required to obtain the same eight hours of training on Opioid Use Disorder (OUD) as all other practitioners who prescribe controlled substances. Washington NDs are also required by state law to take 15 hours of continuing education in pharmacology every two years.

One commenter who is both an ND and a family nurse practitioner (FNP)¹²⁹ stated that their FNP training did not include education on opioid prescriptions except to limit them, or on morphine equivalents. They also stated a third-party, rather than the program instructors, taught the buprenorphine section and that FNPs do not have mandatory residency requirements. They added that oftentimes FNPs never work as an RN or have clinical experience to support their success as an FNP.

The department also heard from an ND working in a primary care clinic that their ability to provide comprehensive primary care to their patients is impeded by their "limited prescriptive scope." This ND completed a residency in interventional pain management and serves as the medical director for an outpatient drug and alcohol treatment center. They stated they are constantly looking for providers to refer patients to for medication management and see regular lapses in care due to three-to-six-month waitlists. They state this proposal is critical for

¹²⁹ FNPs are a category of ARNP in Washington and are authorized to prescribe controlled substances.

their patients using medications commonly used to treat conditions like ADHD, insomnia, addiction, and acute pain.

The department heard from an ND working for a rural FQHC who discussed provider (especially mental health provider) shortages and burnout in their health center. They often see acute walk-in patients they would like to keep out of the emergency department for unnecessary visits. The closest urgent care is more than an hour away and local provider schedules are often booked out for weeks. The ND often must send patients to the emergency department or try to find another busy provider to help with prescriptions.

Other commentors stated NDs can help decrease opioid dependence, which is supported by the 2022 AANP Naturopathic Profession Benchmarking Survey that ranked NDs' treatment modalities. The study showed opioid prescribing ranked last of all modalities used in the five states that allow NDs to prescribe controlled substances. Without access to Suboxone and other formulations of buprenorphine, NDs are left trying to help patients with OUD "with one arm tied behind their back."

Commentors further stated many patients seek out naturopathic care to decrease dependence on addictive medications, and hospitals increasingly provide limited pain management. NDs often must refer patients to their primary care providers for follow- up and ongoing management of post-procedural pain. A primary care physician must have the authority to prescribe a medication both to manage patients in these situations and to safely taper them off.

The department also heard that patients turn to their primary care provider to sign hospice orders, POLST forms, various disability determinations, and other vital records. Restricting NDs from signing these documents creates an undue burden on patients forcing them to locate and establish care with additional providers to sign these documents.

An ND who worked with patients experiencing homelessness and behavioral health issues wrote in support of the proposal. They stated they frequently have patients request MAT treatment for OUD and, under current regulations, are forced to refer them out. They also argued the department should consider using NDs more since we are currently experiencing a fentanyl epidemic and individuals experiencing homelessness are some of the most affected, stigmatized, and vulnerable.

The department also heard from an MD who is the chief medical officer (CMO) at a medical center that hires NDs for their primary care team. The CMO stated they use an integrated model where these NDs work alongside MDs, ARNPs, and PAs. He researched the ND training, specifically in pharmacology, and stated NDs have substantially comparable training to nurse practitioners and PAs, and very similar training to MDs. The CMO stated they have a program where they select charts randomly from all their providers every quarter and send them out for outside review. The NDs consistently scored high for appropriate diagnosis and treatment. He

added there is no scientific evidence that ND prescribing would increase the risk of narcotics in our state. The CMO argued there is an adequate system of measuring controlled substance use, as well as prescribing rules and reporting tools to track their use.

The department further heard from NDs with patients who wanted to reduce or get off their medications. Without the authority to prescribe these medications, NDs are unable to help deprescribe their patients by giving them smaller and smaller dosages to wean off a medication.

Others stated the limitation in ND prescribing is more obvious in rural communities where the requirement to see a separate provider for a controlled substance is unreasonable, unfair, and inequitable for the patient. They argued NDs in other states have been safely prescribing controlled substances for years, with no reported increase in adverse events. In addition, they stated the concerns around the need for ND residencies are unfounded because nurse practitioners can prescribe these medications without a residency.

The department heard from one ND who stated their patients are all over the socioeconomic spectrum and those with the most precarious financial situations often had more complex medical needs that were greatly influenced by socioeconomic determinants of health. They argued these patients could save valuable time and money if they did not have to take additional unpaid time-off for health-related medical visits. They also stated NDs are not anti-conventional medicine but believe there is a time and a place for both approaches.

A pharmacist wrote they collaborated with nearly half of all licensed NDs this year and their interactions have consistently revealed ND's competence, compassion, and accessibility. They also worked at Bastyr University as affiliate faculty, contributing to the pharmacology series, specifically in dermatology. They stated it is routine that ND pharmacology training addresses specific medications, with a focus on mechanism of action, dosing and indications, contraindications and cautions, adverse reactions, and drug interaction.

The department heard from several NDs who practiced under Oregon's expanded scope of practice but now cannot prescribe and deprescribe pain medications like Tramadol, ADD meds like Adderall and anxiolytics like Xanax. They described situations where patients in Washington had a severe fear of air travel where they would benefit from the authority to prescribe a small number of Xanax pills for a trip, patients who are stable on their ADD medication would like the ND to take over their prescription, patients who are taking a benzodiazepine such as alprazolam for sleep or anxiety and are ready to taper off. Some of these NDs describe their education at the National University of Natural Medicine in Portland as including countless hours of training in pharmaceutical prescribing.

The department heard comments from an ND who completed a residency at Bastyr and is the Power of Providers ND representative, which is an advisory committee to the department. This group meets monthly with health care providers of all disciplines on topics like COVID vaccines and access to underserved populations. They are also adjunct faculty at Bastyr, where they

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train on the full scope of practice, including pharmaceuticals. They noted that when they were beginning their residency, they advocated for the Medicaid scope expansion and stated expertise and education in primary care has advanced since 2014. NDs are pivotal to addressing the concerns facing our state, including their holistic approach, which can include safe and practiced ways to use pharmaceuticals.

An ND who has practiced and held licenses in Oregon and has taught NDs and MDs for 30 years commented in support of the proposal. This ND is also a professor of pharmacology and clinical medicine and has taught physicians CME as well as naturopathic medical students, specifically in pharmacology, management and safe prescribing and deprescribing of controlled substances.

An ND and chief quality and compliance officer at a federally qualified health center (FQHC) serving the communities of Okanogan and Douglas counties wrote in support of the proposal. They were also chief resident of Bastyr in 2012, a trainer at McMaster University Evidence Based Clinical Practice program and served as a professor in evidence-based clinical practice at Bastyr prior to their current position. They said that states with expanded scope have NDs working in FQHCs, community clinics, rural clinics, and underserved areas. This scope expansion supports continuity of care for primary care relationships with NDs. They requested this proposal be evaluated against precedent set by the scope and training of other health professions in this state.

The department heard from MDs and others that they had misconceptions about naturopathic training and practice. They stated they had learned through working with NDs that they are supportive of vaccines and science-based decision making. They had also watched many traditionally biased MDs begin referring their patients to NDs. They added that the patients of the NDs they work with reported high patient satisfaction, high positive outcomes, and low incident reports.

Oppose

Those opposed to the proposal argued that naturopathic education and training is not equivalent to the education and training received by allopathic and osteopathic physicians. They cited how the CNME provides no standards around ND program course content and the incorporation of naturopathic principles with pharmacological sciences. They noted NDs take a two-part exam (NPLEX) covering basic sciences, diagnostic and therapeutic subjects, and clinical sciences that is written entirely by naturopaths and not subject to rigorous oversight or external review by experts in medical education. Furthermore, NDs are not required to complete a residency and only need to complete 850 hours of patient care with no requirement on treating specific conditions or patient populations.

Other commentors stated that naturopathic training does not prepare NDs to practice under the proposed increase in their scope of practice, including full prescriptive authority, minor

office procedures that could potentially include surgery such as vasectomies and abortions, and signing forms like disability determinations and hospice orders.

One person commented that the current ND scope of practice was achieved by misrepresentation of their education and training to lawmakers. They also stated naturopathic clinical training takes place in naturopathic teaching clinics that use patients with fake conditions and treatments like homeopathy, hydrotherapy, and botanical medicines. This commentor also stated NPs have no clinical training in hospital settings and their training hours are exaggerated and closer to 561 hours in direct patient care.

A surgeon and ophthalmologist spoke on behalf of the Washington Academy of Eye Physicians and Surgeons to oppose the proposal. They stated they have a unique insight from training various health professions – MDs, medical students, NDs, nurse practitioners, and physical therapists – and understand the distinct educational differences among these specialties. While there is importance to all health medical subspecialities, the commentator believed there is not appropriate expertise and training given in naturopathic schools.

Other commentors in opposition to the proposal state that MD and DO education includes:

- A highly regulated curriculum on the human body and its systems,
- Didactic courses and clinical training in pharmacology,
- Two years of patient care rotations through different specialties,
- Passage of a standardized, three-part licensing exam,
- Three to five years of accredited residency treating the acutely ill or injured in an emergency room setting, and
- Demonstration of competence at the end of the residency.

Some commenters argued the proposed scope of practice change is beyond NDs' knowledge and training, disregarding that care coordination is a critical part of patient care. They also stated that comprehensiveness of training, including residency, experience working as a team member with other physicians, and continued professional oversight allow board-certified physicians to stay current with professional standards and safely incorporate new treatments and medications into their practice.

Other commentors stated hospitals are already treating conditions that occurred due to naturopathic mismanagement. They argue NDs that practice independently cannot be compared to hospital-employed NDs who work in an integrated team-based care model with allopathic and osteopathic providers.

The department also heard that in-clinic abortions are safe when performed by practitioners with adequate clinical training in obstetrics and gynecology, including preprocedural preparation, performance of the procedure, and post-procedural patient care. Vasectomies are

delicate surgical procedures that involve injecting local anesthetics, incision into the scrotum, and tying, cauterizing, using surgical clips, or a combination of these.

Comments from pharmacists included they already see improper prescribing practices under the current naturopathic prescriptive authority. They do not believe naturopaths understand their current scope of practice and laws.

Others argued talented physicians in non-psychiatric specialties struggle with the treatment of serious mental illness and addiction and they have the benefit of much more extensive medical training and experience compared to NDs.

The department also heard that NDs do not have the training, guidance, and oversight to responsibly provide the level of care outlined in this bill. Commentators cited a 2018 study evaluating opiate prescribing patterns in Oregon found a greater percentage of high-risk opiate prescribing patterns by naturopaths. These commentors concluded that expanding opiate prescribing authority to naturopaths could undermine the progress Washington has made in reducing prescription opiate deaths.

Some opposing the proposal stated that while the idea of NDs playing a pivotal role in pain management is appealing, it lacks historical perspective. They argued there have been many regulations imposed on opioid prescribers who are attempting to find a balance between overand under-prescribing of these substances. Treating opioid use disorder is a daunting prospect even for experienced prescribers.

Others stated that in this era of addiction epidemics, the issue lies not in access to these medications, but in the lack of access to knowledgeable care regarding their safe use. They argue that decreasing prescribing standards will just worsen this issue and allowing NDs to prescribe these substances would only worsen the current opioid crisis.

Emergency medicine physicians stated they have seen harm caused by NDs, including patients who have died of strokes and had end-stage cancer that could have been prevented with appropriate care. They stated there has also been a growing number of adverse events in office-based settings associated with sedation and/or anesthesia care. This care should be based on nationally accepted standards, guidelines, and levels of care established by states that are consistent throughout dental offices, hospitals, ambulatory surgery centers, and clinics. When NDs are already failing to appropriately care for patients, these physicians argued expanding the ND scope of practice seems at best ill-advised and at worst dangerous.

The department also heard that NDs do not have standards of care based on medical science. They argued naturopathic medicine is philosophically and foundationally different than allopathic and osteopathic medical practice, not science-based and, does not follow medically accepted standards of care. Commentors stated that botanical and homeopathic medications lack compelling evidence of their therapeutic efficacy and national standards for primary care physicians consider these interventions medically unnecessary and substandard care. These medications are also not approved for medical use by the FDA.

Some commentors were concerned about assertions that referrals to specialists or other practitioners for medications are administrative red tape and that NDs must explain limitations to their prescriptive authority. They argued these referrals are intentional to protect patient safety and ensure care is provided only by those with adequate education and training. NDs cannot be considered comprehensive primary care providers due to the naturopathic community's lack of consensus around vaccines. They stated that the Naturopathic Medicine Institute opposed mandatory COVID-19 vaccines.

The department also heard there was no evidence to support the applicant's assertion that NDs may be the only health care providers in some rural communities. NDs generally practice in the same areas as allopathic and osteopathic physicians. In addition, there are safer options to address workforce challenges, including increased funding for student loan repayment programs, the workforce, retention initiatives, residencies, and continued use of telemedicine.

Others stated that while the applicant report highlights the ongoing mental health crisis as the rationale for expansion of ND prescribing authority, psychiatric care is much more than just prescribing medications. NDs have limited medical education, and this proposal disregards the training needed to understand the complex interactions between mental and physical health.

Other commentors argued that being recognized as a primary care provider does not equate to being qualified to provide the full scope of primary care services, nor justify scope expansion. The scope of practice for primary care MDs, DOs, PAs, ARNPs, NDs, and others is differentiated based on education and training. While overlaps may exist, there are necessary limitations to ensure patient safety.

The department also heard the proposed vague definition of minor office procedures could lead to troubling interpretations. The definition could be interpreted to include surgery, which may involve using lasers, scalpels, and needles; cutting and burning tissue; and making injections into body cavities, internal organs, and the central nervous system. It could also be interpreted to include injections in eye structures, which require specialized anatomical and procedural knowledge learned through surgical training.

Commentors stated the Board of Naturopathy already interprets minor office procedures to include the use of in-office nitrous oxide without guardrails, as well as procedures using Botox. There has been a growing number of adverse events in office-based settings associated with sedation or anesthesia care. This care should be based on nationally accepted standards and the proposal does not adhere to these standards.

Others reported that some Arizona naturopaths interpret the practice of naturopathy to include liposuction and gluteoplasty (Brazilian butt lifts) and the Arizona board has failed to

clarify the definition or discipline naturopaths who have performed "botched surgeries." This may also happen in Washington.

In addition, the department heard concerns that the Board of Naturopathy does not have the expertise to determine adequate education and training for this size of scope of practice increase, including full prescriptive authority.

The department also received comments from two NDs who opposed the proposal because of issues with existing continuing education rules. These included how NDs are not able to provide continuing education on pharmaceutical drugs they are not currently allowed to prescribe in Washington. In addition, they assert that graduates of naturopathic doctoral programs have some of the worst debt to earnings ratios in the entire country, which makes them vulnerable. They state the proposal is intended to increase the earnings of naturopathic physicians.¹³⁰

Concerns/Other:

The department also heard from people with concerns about the proposal, stating:

- It is unclear what percentage of NDs embrace the use of legend (prescribed) drugs and believe it is essential to obtain controlled substance prescriptive authority.
- The proposed bill makes changes to the definitions of minor office procedures and physical modalities. However, the applicant report does not address these changes and what education NDs obtain on these procedures.
- The applicant report referenced the passage of House Bill 1851 in 2022, which added PAs, ARNPs, and other clinicians as providers who perform or assist in the termination of pregnancy. However, it does not address what training naturopathic physicians receive on pregnancy termination.
- No disciplinary data was provided to support the applicant's claim that NDs have been safely prescribing since 2005.
- It is time for open, transparent communication between naturopathy and the greater healthcare community. They stated concerns that the foundational support for increased authority is not in place and included meeting notes from the Board of Naturopathy's CE rules update process over the last 3 years as evidence.

Some commentors noted only one NP program's pharmacology content is included in the curricula comparison, omitting the pharmacology content of pre-licensure nursing programs and neglecting the integration of pharmacology content into other clinical courses.

¹³⁰ Please note that many of the comments in opposition were form letters.

An anesthesiologist stated they have heard success with NDs in multidisciplinary practices where there's teamwork and cultural norms and the practices hold practitioners accountable for the care they provide. However, the anesthesiologist does not believe most NDs are practicing in these types of teams, but rather independently.

An ND provider in Tacoma with 20 years of experience as a professor in the training program stated that as more and more ND providers are moving into the FQHC and urgent care setting, it is not acceptable they cannot prescribe this important medication. In addition, the lack of clear parameters on what can be administered as an intravenous medication allows for providers to inject patients with any item obtained through a compounding pharmacy, even if this item lacks basic safety or efficacy research. This is an easy risk to address by adding a caveat to the ND scope of practice that stipulates that only FDA-approved medications can be administered. In addition, adding a restriction on off-label medication prescribed to patients with a current cancer diagnosis would be helpful.

The department also heard comments from NDs who would support a residency or additional exam requirement for NPs to qualify for full prescriptive authority.

The HCA provided comments that Medicaid managed care plans have concerns about the varying amounts of training and education NDs receive in pharmacology, specifically on stimulants and controlled substances. Regardless of the potential for addressing health care provider shortages, the HCA wants to ensure NDs caring for their clients have the level of training needed to provide quality care. HCA recognizes the potential of this proposal to impact access to care for Washington residents. However, they expressed concerns about the quality of care that might result from increasing the scope of practice without additional training requirements for the expanded prescriptive authority.

Comments from boards and commissions

The **Washington State Board of Naturopathy** wrote in support of the proposal because it would increase public safety and health by granting a wider range of options, as well as reducing costs associated with unnecessary duplicative care. They stated that an ND's approach starts with the least invasive method possible and includes a wide variety of treatment modalities on a case-by-case basis. Their position is that treatment options available to NDs should be the same as those available to and routinely used by all other recognized primary care providers. This should include controlled substances.

The Board added that the applicant report makes it clear ND's foundational training already meets or exceeds that of other providers with an advanced and autonomous scope of practice. In addition, the bill requires registration with the prescription monitoring program (PMP), which adds an additional safeguard and visibility into ND prescribing trends. They conclude that the board has a demonstrated history of careful and cautious rulemaking and will continue those efforts with a focus on keeping the public safe. In addition, there has

been little evidence of safety concerns regarding ND's current prescribing practices and the board is confident that this will continue once expanded prescriptive authority is granted.

The **Washington Medical Commission (WMC)** wrote with concerns about the adequacy of naturopathic training in the diagnosis of serious health conditions that may require use of controlled substances and the prevalence of overdose deaths from prescription opioids. They stated underlying conditions have evolved over the nine years since the last sunrise review, but the fundamental issues remain regarding training and the significant public health challenges with mitigating addiction and abuse of opioids.

They also expressed concerns that the proposed change to the definition of minor office procedures is meant to authorize vasectomies and dilation and curettage, adding that it is notable that the 2023 bills regarding who can perform abortions and participate in the death with dignity act excluded naturopathic physicians.

The **Washington State Board of Nursing (WABON)** stated they believe the proposal meets the sunrise criteria and may increase overall access to primary care. They stated a few areas of the applicant report needed correction. For example, the comparison of ARNP preparation to other providers in pharmacology credits did not include the pharmacology background completed in all nurses' baccalaureate education. WABON requested this be corrected to represent the full ARNP education. In addition, they stated the continuing education hours required for all providers who prescribe opioids is a one-time four-hour course. New opioid prescribers may require more continuing education depending on the individual provider. They added that there needs to be more clarity around the definition of office procedures.

Comments on draft report

The department posted the draft report online with initial recommendations and shared it with interested parties for review and comment. Interested parties were given a month to provide any comments. In this section the department summarizes the comments received and any changes to initial recommendations. Please note that the department piloted a survey to capture comments on the draft recommendations. However, the department received feedback that the survey questions were confusing and because the survey responses could be anonymous, there were concerns about including tallies of responses. Due to this input, the department is providing summaries of themes of the survey comments that are distinct from the separate letters the department received.

Comments in opposition to draft recommendations

Commenters wanted to ensure the final report accurately reflected that patients responded favorably to an expansion of scope of practice in prescribing for NDs. The majority stated they received more time with their ND and therefore believe they received better care. Most referred to their ND as their primary care provider and were often frustrated by the

requirement to also have a general practitioner (MD/DO) to prescribe suggested medications. Commentors also noted frustration regarding the extended time frame and cost that patients undergo in these situations due to current prescribing regulations.

The applicant and other commenters also stated the characterization of public comments was not reflective of the comments received, including not ensuring form letters were clearly identified and patient voices clearly communicated.

Response: The department has clarified its characterization of public comments.

The applicant and other organizations stated the disciplinary actions in Washington and other states is low in comparison to other professions. Some states included additional information on low numbers of disciplinary actions and regulations in their states. The California Naturopathic Doctors Association sent comments that it is burdensome for an MD to assume the extra responsibilities and malpractice risks associated with supervision, which is why only a small fraction of the 1,000 practicing NDs in California have established such relationships. They stated this impacts access to care, delayed treatment, and increased healthcare costs, as well as dual utilization of healthcare resources.

The applicant and other organizations commented that the report misrepresented physician supervision in other states. They also included additional information from other states on their regulations and disciplinary data.

Response: The department has clarified statements about disciplinary actions in Washington and other states and added new information submitted during the final comment period.

The applicant and other organizations referenced the 1999 and 2014 sunrise reports that acknowledged strong support from ND patients for an increase in scope of practice. They also pointed out that the department supported a narrower scope increase in 2014.

Response: The department has included additional information about the 2014 sunrise, but did not believe changes were needed to the draft report related to the 1999 sunrise.

The applicant and other organizations, including the Board of Naturopathy (board) stated the draft report appears to question whether NDs are qualified to educate and regulate themselves. The board wanted to ensure the report accurately reflects the current board expertise related to prescribing.

Response: The department has ensured this information was reflected in the final recommendations.

The applicant and other organizations, including Bastyr University, commented that the statement in the draft report "courses and treatment options in botanical medicine, exercise therapy, hydrotherapy, nature cure, acupuncture/traditional Chinese medicine, and homeopathy... leaves less time and focus on pharmacology related training and sciences." is not supported and does not consider the length of the ND programs.

Some commenters stated the draft comment "based on their limited training and education, NDs run a greater risk of making incorrect diagnoses, evaluations, or recommendations on

treatment options, which could result in serious life or death impacts for patients" is not accurate based on data demonstrating NDs practice safely.

Response: The department has clarified these statements in the education, assessment of sunrise criteria, and final recommendations sections.

Commenters asserted that the draft report does not present consistent, accurate, and unbiased data on ND education and in comparing it to other prescribing professions. They also state that the draft report failed to include much of the details the applicant and naturopathic schools provided in written comments, including that pharmacology content is woven into the curriculum outside specific pharmacology courses like other healthcare professions state.

Response: The department inadvertently posted the draft report without the appendices, where Appendix D provided details about education and training and additional information submitted by the dean of Bastyr University. The department has added the appendices and clarified the credit comparisons as much as possible given the information the department was able to obtain.

Some commenters wanted to add a primary care definition.

Response: The department did not believe changes were needed to this section of the report.

The applicant and other organizations commented that the draft report's statement that the clinical training for NDs occurs mainly in naturopathic clinics under supervision of naturopathic physicians is normal practice across all healthcare professions.

Response: The department clarified this statement in the final recommendations.

The Naturopathic Academy of Primary Care Physicians (NAPCP) wrote that they have been providing continuing education that includes guidance and education on the controlled substances proposed in the scope expansion for many years.

The CNME wanted the report to recognize that similar to the LCME, which accredits MD programs, the CNME is a U.S. Department of Education-recognized accrediting agency for ND doctoral programs with accreditation standards and processes that promote high quality naturopathic medical education and training with the goal of ensuring safe and effective practice. They list their accreditation standards on pharmacology.

Response: This information was presented in Appendix D of the report but was inadvertently left off the posting of the draft report.

One commenter added that NDs work extensively with patient populations on an extensive list of pharmaceuticals and are already called upon to manage complex cases, be wary of drug interactions, screen for nutritional deficiencies caused by drugs, etc. They are already weaning people off pharmaceuticals, managing the side effects of controlled substances, and helping reduce harm from these agents. Improving ND prescriptive authority will improve the ease with which such tasks can be managed, improve patient access to care and burdens on the healthcare system, and streamline care for those patients who must see a variety of clinicians, or have long waits to access care.

A commenter serving community and migrant health centers stated that NDs play a vital role addressing the underlying conditions or structural determinants of health that contribute to poor health outcomes, especially in marginalized and vulnerable communities and the integration of naturopathic medicine with conventional medicine has strengthened their capacity to provide whole-person care in a multidisciplinary team-based care environment. expand and modernize the naturopathic physician scope of practice in Washington.

Response: The department did not believe these comments required changes to the draft report.

Comments in support of draft recommendations

The WMC commented that without the multi-modal education with trainees and trainers from other professions, ND training cannot be considered equivalent to other professions with prescriptive authority. They ask that the final report refrain from characterizing the NDs education as having a strong foundation in pharmacology. They also request the final report reflect that scope expansions may only occur through legislation, rather than through rulemaking efforts.

Response: The department has clarified the pharmacology training in response to a number of comments. The rest of this request is outside the scope of the sunrise statute.

WSMA wrote in support of the draft recommendations.

One commenter stated that expanding opioid scope should require the supervision of the boards that currently manage this skill. The board of naturopathy is not able to regulate this and is not served by people sufficiently trained to do so.

Response: The department did not make any changes in response to these comments.

Other comments on draft recommendations

Some NDs appreciated comments focused on increasing and/or requiring additional training to prescribe additional controlled substance medications and support a required additional exam or continuing education for additional prescribing authorization. They state they expect the profession to continue to have high standards for a broader scope.

The randomized chart reviews from integrative clinics points out that NDs are on par with MDs regarding diagnosis and treatment. Therefore, other MDs who point out a lack of training are usually not fully aware of ND training.

An ND who provides gender affirming care states this type of scope expansion could help gender diverse people who have difficulty accessing competent care because a large percentage of gender diverse people avoid medical care due to negative experiences with medical providers. They add that some patients have been refused care from medical practitioners so referring out for controlled substance medications would make them more comfortable. They also state that gender diverse people are often diagnosed with ADHD so NDs could provide bridge scripts for these patients when they have gaps in psychiatric management.

One commenter stated that this scope of expansion should at the very least be considered for NDs who have completed residency trainings. Other commenters indicated the department should support a scope expansion for NDs who have post-doctoral training.

A few commenters stated the Board of Naturopathy should determine minimum training for the proposed scope expansion.

One commenter stated NDs should consider a partnership with a professional organization of pharmacists to determine adequate training and bring their recommendations to the board jointly.

Response: The department did not believe changes were needed to the final report in response to these comments.

Review of Proposal Using Sunrise Criteria

The Sunrise Act, in <u>RCW 18.120.010</u>, states that a health care profession should be regulated, or the scope of practice expanded only when:

- Unregulated practice can clearly harm or endanger the health, safety, or welfare of the public and the potential for the harm is easily recognizable and not remote or dependent upon tenuous argument;
- The public needs and can reasonably be expected to benefit from an assurance of initial and continuing professional ability; and
- The public cannot be effectively protected by other means in a more cost-beneficial manner.

Because the above criteria focus on new professions, the department directs applicant groups to demonstrate the following for proposals to increase a profession's scope of practice. The proposal benefits the public by:

- Protecting the public from harm;
- Providing assurance of sufficient education, training, and professional ability to perform the scope of practice; and
- Demonstrating the proposal is the most cost-beneficial option to protect the public.

First Criterion: Protecting the public from harm.

The proposal does not meet this criterion.

Naturopaths are currently a thoroughly regulated profession. The proposal, as written, does not offer adequate protections to meet this criterion. Controlled substances are drugs that have potential benefits but also carry substantial risks, which is why they are scheduled based on their potential for misuse, abuse, and dependence. The proposal's vague definition of minor office procedures also leaves the door open for broad interpretation. Without knowing what specific procedures are intended, the department cannot evaluate whether NDs have adequate training for those procedures.

The department acknowledges that pharmacology training in naturopathic schools has clearly evolved, adding a stronger didactic foundation in basic sciences and pharmacology. However, compared to other prescribers with full prescriptive authority, the minimum clinical requirements on pharmacology training and surgical procedures for NDs do not provide sufficient education and experience for NDs to warrant full prescriptive authority. In addition, many of the courses, including pharmacology, include components that do not have foundations in the basic sciences that the other medical programs do.

Second Criterion: Providing assurance of sufficient education, training, and professional ability to perform the scope of practice.

The proposal does not meet this criterion.

There are adequate laws and rules in place to assure the public of initial and continued professional ability for the current naturopath scope of practice. The proposal, as written, does not offer adequate protections to meet this criterion. The applicant has not shown adequate minimum core training requirements, especially clinical requirements, to ensure the public of their ability to safely prescribe Schedule II-V controlled substances. The proposed expanded definition of minor office procedures is too broad for the department to evaluate naturopathic school training since the department cannot determine what procedures need to be included in that training.

Third Criterion: The public cannot be effectively protected by other means in a more cost-beneficial manner.

This criterion was not fully evaluated because the applicant did not provide data or information that could be analyzed with a cost-benefit approach. In addition, the department did not fully evaluate these claims because the applicant did not demonstrate the proposal met the first two criteria to protect the public.

Detailed Recommendations

The applicant report identifies a need to expand ND's prescriptive authority to increase access to OUD treatment like Buprenorphine, help patients taper off controlled substances, treat acute or post-surgical pain, treat ADHD, and sign documents like hospice orders or POLST (portable medical orders) forms.

However, the department recommends this proposal not be enacted because it does not meet the criteria in , demonstrating it provides assurance of initial and continuing ability to protect patients from harm.

Rationale:

The department must be able to confirm sufficient education to perform increases to scope of practice. This proposal:

- Does not demonstrate sufficient minimum education and training to safely prescribe Schedule II-V controlled substances:
 - Naturopathic programs have evolved to include more pharmacology focus. However, many of the courses that include pharmacology include topics that do not have foundations in the basic sciences that the other medical programs include. Pharmacology, especially focused on controlled substances, is also not standardized and consistent across programs.
 - NDs' clinical training can occur almost entirely in naturopathic clinics without exposure to a variety of providers, settings where they could experience treatment of patients on a broad array of controlled substances. Naturopathic programs do not require:
 - Clinical training in settings such as hospitals or involving behavioral health medicine, emergency medicine, surgery, inpatient procedures, etc., or
 - Exposure to specific patient populations or conditions, such as pediatric patients, patients with specific behavioral health conditions, and patients on pain management.
 - The other states that grant authority to prescribe controlled substances limit NDs to Schedules III-V or specific formularies and/or include safeguards such as collaboration with MDs, additional or continuing education, an additional pharmacology examination, or inclusion of MD or DO members on the naturopathic board or formulary advisory committee.
 - The proposed definition of "minor office procedures" is vague and subject to a wide range of interpretations. The department cannot evaluate adequate training without knowing what specific procedures would be included in this definition.

• Many primary care providers refer patients requiring long term use of controlled substances to specialists because the significant risks of overdose, abuse, and misuse require additional training to prevent and mitigate.

The proposal includes language requiring the Board of Naturopathy to establish education and training requirements. However:

- Chapter <u>18.120 RCW</u> requires the department to analyze whether a proposal to increase a profession's scope of practice currently demonstrates it protects the public from harm and provides assurance of sufficient education, training, and professional ability to perform the expanded scope of practice.
- Without clearly stated education and training requirements, the department cannot determine whether they meet the sunrise criteria.
- Though the board currently has members with prescribing expertise, it is not a requirement and future board members may not have that expertise.