Information Summary and Recommendations

Naturopathic Scope of Practice Sunrise Review

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THE SUNRISE REVIEW PROCESS

A sunrise review is an evaluation of a proposal to change the laws regulating health professions in Washington. The Washington State Legislature's intent, as stated in chapter 18.120 RCW, is to permit all qualified people to provide health services unless there is an overwhelming need for the state to protect the interests of the public by restricting entry into the profession. Changes to the scope of practice should benefit the public.

The Sunrise Act (RCW 18.120.010) says a health care profession should be regulated or 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.

If the legislature identifies a need and finds it necessary to regulate a health profession not previously regulated, it should select the least restrictive alternative method of regulation, consistent with the public interest. Five types of regulation may be considered as set forth in RCW 18.120.010(3):

1. *Stricter civil actions and criminal prosecutions.* To be used when existing common law, statutory civil actions, and criminal prohibitions are not sufficient to eradicate existing harm.
2. *Inspection requirements*. A process enabling an appropriate state agency to enforce violations by injunctive relief in court, including, but not limited to, regulation of the business activity providing the service rather than the employees of the business, when a service being performed for people involves a hazard to the public health, safety or welfare.
3. *Registration.* A process by which the state maintains an official roster of names and addresses of the practitioners in a given profession. The roster contains the location, nature and operation of the health care activity practices and, if required, a description of the service provided. A registered person is subject to the Uniform Disciplinary Act (chapter 18.130 RCW).
4. *Certification.* A voluntary process by which the state grants recognition to a person who has met certain qualifications. Non-certified people may perform the same tasks, but may not use "certified" in the title.[1] A certified person is subject to the Uniform Disciplinary Act.
5. *Licensure.* A method of regulation by which the state grants permission to engage in a health care profession only to people who meet predetermined qualifications. Licensure protects the scope of practice and the title. A licensed person is subject to the Uniform Disciplinary Act.

[1] Although the law defines certification as voluntary, many health care professions have a mandatory certification requirement such as nursing assistants-certified, home care aides, and pharmacy technicians.

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EXECUTIVE SUMMARY
Background and Proposal

Naturopaths have been licensed to practice naturopathy or naturopathic medicine in Washington since 1987 under chapter 18.36A RCW.[2] The Naturopathic Advisory Committee was under the authority of the secretary of the Department of Health (department) until 2011. At that time, the legislature replaced the advisory committee with the Board of Naturopathy (board) and transferred licensing and disciplining authority from the secretary to the board.[3] Prior to 1987, naturopaths were regulated under the Drugless Healing statute (chapter 18.36 RCW) to practice "drugless therapeutics."

The original naturopathic scope of practice excluded the use[4] of legend drugs[5] with the exception of vitamins, minerals, whole gland thyroid, and substances included in traditional botanical and herbal pharmacopoeia. Non-drug contraceptive devices were allowed, except for intrauterine devices. Intramuscular injections were limited to vitamin B-12 preparations and combinations for indication of B-12 deficiency. The use of controlled substances was specifically prohibited.

The scope of practice was amended in 2005 to expand prescriptive authority for naturopaths. The current prescriptive authority is limited to "those legend drugs and controlled substances consistent with naturopathic medical practice in accordance with rules established by the board"[6] and includes:

- Legend drugs under WAC 246-836-210, excluding botulinum toxin and inert substances for cosmetic purposes; and
- Controlled substances, limited in RCW to codeine products[7] and testosterone products[8] contained in Schedules III, IV, and V of chapter 69.50 RCW. WAC 246-836-211 requires a naturopath to be approved by the board before being authorized to prescribe, dispense, or order the approved controlled substances.

On April 24, 2014, Representative Eileen Cody, chair of the House Health Care and Wellness Committee, requested that the department consider a sunrise application. The request was to review a proposal "that would allow naturopaths to prescribe legend drugs and controlled substances contained in Schedules II through V of the Uniform Controlled Substances Act" and included draft bill H-4573.4, an act relating to prescriptive authority of naturopaths (Appendix A). The draft bill removes the limitation on controlled substances in RCW 18.36A.020(10), and amends the practice of naturopathic medicine in RCW 18.36A.040(2) to include "legend drugs and controlled substances contained in Schedules II through V of the uniform controlled substances act, chapter 69.50 RCW, necessary in the practice of naturopathy."

[2] Naturopaths were originally regulated under the Department of Licensing and moved to the Department of Health when it was created in 1991 (Chapter 3, laws of 1991).
[3] Chapter 41, laws of 2011.
[4] "Use" means prescribing, administering, or dispensing.
[5] Legend drugs are required to be dispensed on prescription only or are restricted to use by practitioners (RCW 69.41.010).
[6] Changed in 2011 from "rules established by the secretary" by Chapter 41, Laws of 2011.
[7] For example, Tylenol #3 (acetaminophen with codeine) or expectorant cough syrup with codeine.
[8] Male hormone supplements, products to treat low testosterone levels.

On May 30, 2014, the Washington Association of Naturopathic Physicians (WANP, applicant) submitted its applicant report to assess the criteria required in chapter 18.120 RCW (Appendix B). The applicant suggests the following changes to draft bill H-4573.4:

- A section requiring the board to adopt pain management rules that conform with HB 2876 (chapter 209, laws of 2010); and
- Amendments to the proposed changes to RCW 69.41.030(1) to add "a naturopathic physician under chapter 18.36A RCW when authorized by the board of naturopathy" and to RCW 69.45.010(12) "a naturopathic physician under chapter 18.36A RCW when authorized to prescribe by the board of naturopathy…"

In subsequent follow up at the public hearing and in written correspondence, the applicant indicated the desire to include additional changes in the draft bill, such as inclusion in the prescription monitoring program, a one-time addition of eight hours of supplemental education and training focused on controlled substances in Schedules II-V, and 10 additional hours annually of continuing education in pharmacology.

RECOMMENDATION

The department doesn't support the proposal to expand the prescriptive authority of naturopaths to include *all* Schedule II-V controlled substances without limitations.

Rationale:

- The applicant has not demonstrated problems with the current prescriptive authority that would justify unlimited expansion of the naturopathic prescriptive authority for controlled substances.
- Unlimited prescriptive authority isn't necessary for naturopaths to practice as primary care physicians under Medicaid.
- Referrals for controlled substances are often necessary, especially in long-term opioid therapy, to ensure the most qualified health care professionals are prescribing these substances, which are controlled because of their significant risks to public health due to overdose, abuse and misuse.
- The applicant hasn't demonstrated that naturopaths receive adequate education in clinical pharmacotherapy of prescribing opioid, antianxiety, sedative, hypnotics, and amphetamine substances to treat various disease states to safely prescribe controlled substances.
- The department doesn't see a benefit to increasing access without limitation to prescription opioid pain medications included in this proposal 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 prescribed opioids.
    - The state is currently engaged in intensive and effective efforts to curb the overuse of opioids in Washington. Granting unlimited prescribing authority for controlled substances is contrary to these efforts.

Although the department doesn't support unlimited expansion of prescriptive authority, the sunrise review process surfaced new information and perspectives that the legislature should consider. Notably, the HCA has provided the following arguments in support of a limited expansion of naturopathic prescriptive authority, with which the department agrees:

- The HCA recognizes the potential benefit of more convenient and comprehensive health care of clients whose primary care provider is a naturopath.
- Naturopaths currently have a narrower range of prescriptive authority than other designated primary care providers in Washington.
- It is likely that patients with acute non-life or limb-threatening injuries will seek care in their places of practice, and there is a subset of the population for whom codeine is not effective and/or not tolerated.
- The HCA agrees with the applicant that expanded Medicaid coverage is expected to include an expanded demographic of patients with medical conditions requiring controlled substances in the naturopathic primary care setting.
- Deaths related to prescription opioids have occurred almost without exception in patients on chronic therapy. Short-term treatment of acute conditions with controlled substances is considered safer.
- Limited prescriptive authority may reduce the number of unnecessary emergency department visits.

In addition, Bastyr University has indicated a willingness to develop and offer a continuing medical education program on controlled substances to address deficiencies in core training, and has offered assistance in developing necessary educational requirements.

Should the legislature consider exploring expanded prescriptive authority for naturopaths, the department recommends:

- Limiting prescriptive authority to controlled substances in Schedule III-V[9], and hydrocodone products in Schedule II.[10] All other Schedule II controlled substances should be prohibited.
- Limiting controlled substance prescriptions to no more than seven days when treating a particular patient for a single trauma, episode, or condition or for pain associated with or related to the trauma, episode, or condition.
- Maximum dosage of 120 milligrams morphine equivalent dose (MED) per day.[11]

[9] This would include Tramadol, which naturopaths had prescriptive authority to prescribe as a legend drug until the FDA recently reclassified it as a Schedule IV controlled substance.

[10] Hydrocodone products are short-acting opioids, which meet the HCA's stated goal of providing naturopaths an additional tool to treat acute pain. These products were rescheduled from Schedule III to Schedule II in October of 2014.

[11] Morphine equivalent dose means a conversion of various opioids to a morphine equivalent dose by the use of accepted conversion tables. 120 MED is the mandatory consultation threshold for adult patients set in the administrative codes of providers with full prescriptive authority (as required in Chapter 209, Laws of 2010).

- Authorization for the Board of Naturopathy, in consultation with the Pharmacy Quality Assurance Commission, to undergo rulemaking to determine appropriate training and education.
- Requiring the board to adopt pain management rules appropriate for acute pain treatment, including, but not limited to, patient examination and screening for comorbidities and risk factors.
- Requiring naturopaths with prescriptive authority for controlled substances to register in the Prescription Monitoring Program (PMP)[12] database to access patient prescription history.

[12] The PMP is a secure online database that collects data on Schedules II-V controlled substances. 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 (chapter 70.225 RCW).

SUMMARY OF INFORMATON

Background

Naturopaths have been licensed to practice naturopathy or naturopathic medicine in Washington since 1987 under chapter 18.36A RCW. The Naturopathic Advisory Committee was under the authority of the secretary of the department until 2011. At that time, the legislature replaced the advisory committee with the Board of Naturopathy (board) and transferred licensing and disciplining authority from the secretary to the board.[13] Prior to 1987, naturopaths were regulated under the Drugless Healing law (chapter 18.36 RCW) to practice "drugless therapeutics."

The original naturopathic scope of practice excluded the use of legend drugs with the exception of vitamins, minerals, whole gland thyroid, and substances as exemplified in traditional botanical and herbal pharmacopoeia, and non-drug contraceptive devices excluding intrauterine devices. Intramuscular injections were limited to vitamin B-12 preparations and combinations for indication of B-12 deficiency. The use of controlled substances was specifically prohibited.

The naturopath's scope of practice was amended in 2005 to expand the prescriptive authority. The current prescriptive authority is limited to "those legend drugs and controlled substances consistent with naturopathic medical practice in accordance with rules established by the board"[14] and includes:

- Legend drugs under WAC 246-836-210, excluding botulinum toxin and inert substances for cosmetic purposes; and
- Controlled substances, limited to codeine and testosterone products contained in Schedules III, IV, and V of chapter 69.50 RCW. WAC 246-836-211 requires naturopaths to be approved by the board before they are authorized to prescribe, dispense, or order controlled codeine and testosterone products.[15]

As of November 1, 2014, there were 1,215 naturopaths licensed in Washington.[16] Requirements for licensure under RCW 18.36A.090 and WAC 246-836-150 include successful completion of a board-approved doctoral degree program in naturopathy (at least 3,000 hours of instruction) and passage of the basic science, clinical science, and minor surgery portions of the Naturopathic Physicians Licensing Examination. The board has approved seven schools in the United States and Canada that are accredited by the Council on Naturopathic Medical Education. The Council on Naturopathic Medical Education has stricter standards than Washington law, including that the program be a minimum of 4,100 hours, with at least 1,200 hours devoted to clinical training.

Proposal for Sunrise Review

On April 24, 2014, Representative Eileen Cody, chair of the House Health Care and Wellness Committee, requested the department consider a sunrise application. The request was to review a proposal "that would allow naturopaths to prescribe legend drugs and controlled substances contained in Schedules II through V of the Uniform Controlled Substances Act" and included draft bill H-4573.4, an act relating to prescriptive authority of naturopaths (Appendix A). The draft bill

[13] Chapter 41, laws of 2011.
[14] Changed in 2011 from "rules established by the secretary"
[15] Naturopathic physicians must sign an attestation of completion of at least four hours of graduate-level instruction in specific pharmacology topics before being granted this limited prescriptive authority.
[16] Department of Health Integrated Licensing and Regulatory System.

amends the practice of naturopathic medicine in RCW 18.36A.040(2) to include "legend drugs and controlled substances contained in Schedules II through V of the uniform controlled substances act, chapter 69.50 RCW, necessary in the practice of naturopathy."

On May 30, 2014, the applicant submitted its applicant report to assess the criteria required in chapter 18.120 RCW (Appendix B). The applicant suggests the following changes to draft bill H-4573.4:

- A pain management section that conforms with HB 2876 (chapter 209, laws of 2010); and
- Amendments to the proposed changes to RCW 69.41.030(1) to add "a naturopathic physician under chapter 18.36A RCW when authorized by the board of naturopathy" and to RCW 69.45.010(12) "a naturopathic physician under chapter 18.36A RCW when authorized to prescribe by the board of naturopathy…"

At the public hearing and in written correspondence, the applicant indicated the desire to include additional changes to its proposal, such as inclusion in the prescription monitoring program , eight additional hours of supplemental education and training focused on controlled substances in Schedules II-V, and addition of 10 hours of continuing education in pharmacology.

Public Participation and Hearing

The department received the request from the legislature to conduct this sunrise review on April 24, 2014, and received the applicant report on May 30, 2014. On June 9, 2014, the department posted the proposal and all applicant materials to the sunrise webpage and notified interested parties of the public hearing scheduled for July 17, 2014. Written comments were accepted until the conclusion of the public hearing, with an additional comment period for follow up after the hearing.

At the hearing, the applicant presented the sunrise proposal and responded to questions from the hearing panel. The applicant presenters included Robert May, ND, from Washington Association of Naturopathic Physicians; Jane Guiltinan, ND, dean of the Naturopathic Program at Bastyr University; and Chris Krumm, ND, from HealthPoint (community health organization). Dr. May testified that he recognizes the draft legislation from Representative Cody does not include requirements for rulemaking on education and training necessary for expanding prescriptive authority to include controlled substances. He stated he wanted it to be very clear that WANP intends to ask the legislature to include education and training necessary to ensure public safety and optimal care by naturopaths who wish to have this expanded prescriptive authority. He also indicated he intends to request amendments to bring the bill into conformity with the Controlled Substances Act and to include a requirement for pain management rules similar to those in place for other prescribers. He added that naturopath physicians have been safely prescribing legend drugs and limited controlled substances (testosterone and codeine products) since 2005.

Dr. Guiltinan provided information on Bastyr's four-year doctoral residency program (see page 16 under Pharmacology Training for details provided at the hearing). She also addressed questions about naturopathic residencies, stating they are optional at this time. Bastyr offers the largest number of opportunities with 25 residency slots per year. She also stated there is a requirement for 20 hours per year of continuing education. Dr. Guiltinan indicated support of rulemaking to identify where additional education and training requirements would be

appropriate for naturopaths. However, Dr. Guiltinan stated that if the proposal were enacted by the legislature, she does not think Bastyr would add hours to the current training but would adjust the existing pharmacology hours to incorporate controlled substance training. During the rebuttal period, Dr. Guiltinan revised her statements and indicated Bastyr would be "willing to develop and offer a continuing medical educational program on controlled substances… that could address any current deficiencies in core training…" (see summary of rebuttals on page 33 and Appendix F).

Dr. Krumm gave some background on HealthPoint, which is a large, multi-center, community health organization that serves primarily low-income and underserved King County patients. HealthPoint is an important provider of Medicaid services. Many of HealthPoint's patients struggle with additional physical, mental and psychosocial stressors that complicate their care. He shared one recent example where a patient needed pain medication, but the prescription was delayed because Dr. Krumm wasn't authorized to write a controlled substance prescription; instead, he had to refer the patient to another doctor. He also discussed how reduction in dual utilization and time spent consulting unnecessarily within a busy primary care practice would be better for the patients. All three applicant presenters responded to questions from the department hearing panel regarding the proposal. (See Appendix C for summary of hearing).

In addition, three members of the public testified at the hearing. One testified in support of the proposal and two in opposition.

We received 14 letters in support of the proposal from naturopaths and other health care providers, including allopathic physicians advanced registered nurse practitioners (ARNPs), and osteopathic physicians.

We received 15 letters in opposition to the proposal from organizations, including the Washington State Medical Association that was undersigned by a number of organizations representing physicians in various specialties; Washington Osteopathic Medical Association; Washington Academy of Family Physicians; Providence Health and Services; Washington State Medical Quality Assurance Commission; and other health care providers.

We received three letters offering comments from the Association of Washington Health Plans (AWHP), Washington State Health Care Authority (HCA), and the Washington East Asian Medicine Association). (See Appendix D for written comments received).

The following themes were found in the written and oral public comments we received during our review.

Themes in support of proposal

- Naturopaths have been practicing safely with their current prescriptive authority.
- Patients would benefit from increased authority in the primary care setting, including continuity of care and avoid dual utilization of providers.
- This change is needed for naturopaths to fully participate as primary care providers in response to the growing shortage.
- Oregon already has broad controlled substance prescriptive authority, and naturopaths are practicing safely there.

- Naturopaths have adequate training for this increase in prescriptive authority.
- A federally funded organization that employs naturopaths as part of a multi-disciplinary team that serves Medicaid patients and uninsured patients stated that the naturopaths it employs are competent and compassionate, and expansion of prescriptive authority would improve services to patients. It would also reduce unnecessary visits and time spent consulting that drains resources and costs money.
- An advanced registered nurse practitioner wrote to state she has worked with naturopaths in an integrated medicine clinic and has sometimes collaborated with the naturopaths in her clinic to have patients referred to her for prescriptions outside of the naturopath's authority. She wrote that the referrals were always appropriate and warranted.

Themes in opposition to proposal

- The fundamental teaching of naturopaths is rooted in the belief that it is an alternative approach to traditional medicine.
- Naturopaths have their place in the health care system as providers with a philosophy that seeks to restore and maintain optimum health by emphasizing nature's inherent self-healing process. According to the American Association of Naturopathic Physicians, this is accomplished through education and the rational use of natural therapeutics.
- Expanding prescriptive authority for controlled substances will add to the problem of over-prescribing that has led to the epidemic of overdose deaths in Washington.
- Expanding prescriptive authority to include controlled substances is not in the best interest of the public and will not increase access to care in a meaningful way.
- There will be negative consequences from the proposal, posing a public threat because naturopaths lack training in clinical pharmacology, as well as practical knowledge of drug effects. Medical doctors seek to master this throughout their careers, not just through continuing medical education.
- Medical and osteopathic doctors have substantially more pharmacology training, including the additional years of residency training.
- Granting providers with less training the authority to prescribe dangerous controlled substances is unnecessary and contrary to the intent of pain management legislation such as ESHB 2876 (Chapter 209, Laws of 2010).
- Designation as a primary care provider is an insufficient argument to support this expansion.

Other

The Association of Washington Health Plans stated the following:

- The applicant should be required to provide details about naturopathic educational curriculum, particularly in relation to controlled substances and dealing with addiction.
- Because of the prescription drug abuse epidemic and high rate of opioid deaths, the department should exercise significant caution in extending prescriptive authority for these substances without ensuring appropriate training and education.
- Consider inclusion of specific training on acute and long-term chronic pain management, starting with Washington State Medical Association's practitioner education on this topic.

- The applicant should be required to provide information on the frequency of occurrences where naturopaths must refer patients for controlled substance prescriptions since that was used to define the problem.

The HCA stated it recognizes the potential benefit of more convenient and comprehensive health care of clients whose primary care provider is a naturopath if appropriate pharmacology education and training are clearly defined. It initially recommended a one-year residency requirement, but when the HCA found out the rarity of naturopathic residencies and reviewed the supplemental education requirements submitted by the applicant, had less concern about the adequacy of naturopath pharmacology training. The HCA recommends expanding prescriptive authority for naturopaths for controlled substances limited to treatment of acute conditions for a limited amount of time. It states this will reduce disruption in treatment and may reduce the number of unnecessary emergency department visits.

Washington East Asian Medicine Association sent a letter with a concern that is outside the scope of this sunrise review. It was regarding citations the applicant submitted with its applicant materials so we are including the comment. The reference was to a Department of Labor and Industries (L&I) definition regarding coverage of health practitioners not covered by another classification who diagnose, treat, and care for patients (WAC 296-17A-6109). L&I included acupuncture in the list of remedies these naturopaths may use. The association requested to go on record in this report to state that acupuncture is not within the naturopathic scope of practice.

Applicant's Definition of the Problem and Proposed Solution

The applicant relies heavily on the fact that naturopaths have been designated as primary care providers in several sections of law and rule. In defining the problem, it has stated the current limitation on prescriptive authority interferes with naturopaths' ability to provide the whole spectrum of primary care to their patients. The need for referral to other providers disrupts continuity and coordination of care and results in dual utilization and increased costs to the health care system. As evidence of this disruption in care, a member of the applicant group who is a naturopath gave one example at the public hearing where he had to refer a patient to another provider for a controlled substance prescription. His patient faced a one-day delay in receiving pain medications due to the referral to a medical doctor.

In addition, the dean of Bastyr University's naturopathic program estimated at the public hearing that about five percent of the population at the Bastyr teaching clinic in Wallingford has a need for controlled substances. Several naturopaths and their patients sent comments sharing challenges they have faced with the need for referrals for controlled substances. Challenges included the need to develop relationships with several providers who were not as invested in their care as their naturopath, delays in accessing prescriptions, and using emergency departments for acute pain needs. Some included stories about poor care they received from other providers, such as MDs, influencing their decisions to see naturopaths as their primary care physicians.

Expansion of Medicaid includes an expanded demographic of patients with medical conditions that require controlled substances in the naturopathic primary care setting. The increasing shortage of primary care providers in response to Medicaid expansion and increased coverage under the Patient Protection and Affordable Care Act (ACA) is making referrals more

challenging. In response to department questions about the primary care shortage and how it relates to the proposal, the applicant provided numerous references (see Appendix B). It also included references to support the anticipated new shortage with the expansion of Medicaid.

The applicant has asserted there are parallels to the advanced registered nurse practitioner expansion in prescriptive authority and to the circumstances that existed during a 1992 sunrise review on their prescriptive authority. These were listed as:

- Naturopaths have a history of safe prescribing under existing authority evidenced by increased demand for their services, high patient satisfaction, and no complaints about prescribing.[17]
- Restricting availability of controlled substances to certain segments of the population creates a lack of access to care and serious risk to the public. Because naturopaths already serve in primary care roles, failure to expand prescriptive authority creates the same risks.
- Public benefit from the availability of qualified providers to function in an expanded practice capacity may be more appropriate and less costly. Naturopaths are well positioned to provide these same benefits to the public with the inclusion of controlled substances in their scope of practice.
- The circumstances in effect when advanced registered nurse practitioners were granted expanded prescriptive authority are very similar to current circumstances regarding the need for increased access in many areas of Washington.

The applicant has stated naturopaths require unlimited controlled substance prescriptive authority in order to provide optimal care for their patients. They believe most controlled substances are rarely, if ever, used by any primary care provider, as evidenced by the department's Prescription Monitoring Program's "top 20" list of the most prescribed controlled substances. The applicant submitted the top 20 list in response to the department's question about what medications naturopaths would most likely prescribe. This list includes Schedule II opioid pain medications such as oxycodone, methadone and hydromorphone; Schedule II amphetamine (Adderall) to treat Attention Deficit Hyperactivity Disorder (ADHD); and Schedule IV anti-anxiety and sedative medications like Ambien and lorazepam. After the public hearing, the applicant submitted an additional list of anticipated medications naturopaths may need in primary care practice. These included sedatives like Xanax and Valium on Schedule IV, Vicodin on Schedule III,[18] ADHD medications like Ritalin, and opioids like morphine on Schedule II.

The applicant stated that the eight hours of additional pharmacology education (in addition to the four hours required for current prescriptive authority) and10 hours of additional continuing education in pharmacology that it proposes as amendments to the draft bill will ensure public safety. Naturopaths have been prescribing legend drugs since 2007, many with significant potential for drug interactions. These medications require more knowledge and monitoring in order to prescribe within safe parameters and have serious potential side effects and

[17] The department would like to make a correction to this statement. There are a small number of complaints about naturopathic prescribing, and even more about improper authorizations of medical marijuana, a Schedule I controlled substance under both state and federal law.
[18] Vicodin and other hydrocodone combination products became Schedule II controlled substances as of October 6, 2014.

complications. Naturopaths have incorporated these drugs into their primary care practices successfully. In addition, naturopaths spend more time in office visits and have an emphasis on the doctor-patient relationship. In combination with the wide array of other traditional non-drug naturopathic modalities like clinical nutrition, lifestyle counseling, body work techniques, and stress management; naturopaths create a foundation where use of controlled substance prescriptions can be used in lower dosages and for shorter periods of time, which limit abuse and addiction potential. (See Appendix B for full applicant report).

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. The Centers for Disease Control and Prevention (CDC) reports that abuse of prescription and nonprescription opioid painkillers is a public health epidemic that can lead to unintentional poisoning deaths. People in rural counties are about twice as likely to overdose on prescription painkillers as people in large cities.[19] Data shows that states with higher sales of prescription opioids have higher rates of overdose deaths. In addition:

- The three opioids most often involved in overdose deaths are methadone, oxycodone, and hydrocodone.
- Medicaid clients are twice as likely to receive an opioid prescription compared to non-Medicaid clients and are six times more likely to have a fatal overdose involving prescription opioids.
- One in 20 people in the United States use prescription painkillers non-medically to get high.
- By 2010, enough opioid pain relievers were sold in the United States to medicate every adult with a typical dose of five milligrams of hydrocodone every four hours for one month.[20]
- According to the CDC, in 2013 the United States made up about four percent of the world's population but consumed 80 percent of the world's oxycodone and 99 percent of the world's hydrocodone.[21]

Because of the health risks associated with opioid use, the legislature passed ESHB 2876 (chapter 209, Laws of 2010) requiring boards and commissions with prescriptive authority for opioids[22] to

[19] http://www.cdc.gov/Features/VitalSigns/PainkillerOverdoses/, accessed August 12, 2014.
[20] Ibid.
[21] http://www.npr.org/2013/11/02/242594489/with-rise-of-painkiller-abuse-a-closer-look-at-heroin, accessed August 19, 2014.
[22] Podiatric Medical Board, Dental Quality Assurance Commission, Board of Osteopathic Medicine and Surgery, Medical Quality Assurance Commission, and Nursing Care Quality Assurance Commission.

adopt rules on chronic, non-cancer pain management. The legislation required adoption of rules related to clinical assessment tools and tracking the use of opioids. It specifically required rules outlining the criteria for when a practitioner must refer a patient to, or seek a consultation with, a pain specialist.

The need for referral for controlled substance prescriptions is often a necessary coordination, rather than a disruption, of health care. It is necessary to ensure the most qualified healthcare professionals are prescribing these substances, which are controlled because of their risks. Naturopathic training has a major focus on treatments such as homeopathy, botanical medicines, and physical medicine techniques like hydrotherapy and soft tissue manipulation. Less time is focused on pharmacology and little on controlled substances.

With the growing access to prescription opioid medications and the epidemic of overdose deaths, a very cautious approach should be taken in considering expanding access to these medications. We must always consider patient safety. This is particularly true when considering controlled substances and pain management, where the data shows a correlation between the rise in overdose deaths and states that have expanded the use of controlled substances such as opioids.

Safe and effective chronic opioid therapy for chronic non-cancer pain requires clinical skills and knowledge in both the principles of opioid prescribing and on the assessment and management of risks associated with opioid abuse, addiction, and diversion.[23] The applicant hasn't shown that the current educational standards for clinical pharmacotherapy relating to prescribing opioid, antianxiety, sedative, hypnotics, and amphetamine substances for various disease states is sufficient to provide for patient safety and good clinical outcomes.

Current Regulation and Practice of Naturopathic Physicians

The scope of practice of naturopaths has been amended twice since 1987:

- Chapter 158, laws of 2005, expanded the scope of practice to:
    - Expand the prescriptive authority to include "those legend drugs and controlled substances consistent with naturopathic medical practice in accordance with rules established with the secretary," limiting controlled substances to codeine and testosterone products contained in Schedules III, IV, and V of chapter 69.50 RCW.
    - Amend the definition of minor office procedures to add treatment of lesions and intramuscular, intravenous, subcutaneous, and intradermal injections of substances according to rules established by the secretary.[24]
    - The secretary, in consultation with the former Naturopathy Advisory Committee and the former Board of Pharmacy[25] were required to develop education and training requirements that the naturopaths must meet before being granted prescriptive authority for testosterone and codeine controlled substance products.

[23] Roger Chou, et al, *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain, The Journal of Pain, vol. 10, Issue 2, pp. 113-130,* http://www.jpain.org/article/S1526-5900(08)00831-6/fulltext.
[24] Consistent with department recommendations in a 1999 sunrise review.
[25] Now the Pharmacy Quality Assurance Commission.

- Chapter 40, laws of 2011, changed the limitation that physical modalities must be noninvasive, replacing it with those physical modalities that don't exceed those used as of July 22, 2011, in minor office procedures or common diagnostic procedures. This legislation also removed the limitation that only non-drug contraceptive devices could be used in treatment.
- Chapter 41, Laws of 2011, transferred authority from the secretary to the Board of Naturopathy to adopt rules regarding naturopaths' authority to prescribe testosterone and codeine controlled substances.

Naturopaths' current scope of practice is defined in RCW 18.36A.040 as "the practice by naturopaths of the art and science of the diagnosis, prevention, and treatment of disorders of the body by stimulation or support, or both, of the natural processes of the human body." This includes:

- Manual manipulation
- Nutrition and food science
- Homeopathy
- Minor office procedures such as treating superficial lacerations, lesions, and abrasions
- Injections of substances consistent with the practice of naturopathic medicine; and
- Naturopathic medicines, including legend drugs and controlled substances limited to codeine and testosterone products (such as Tylenol with codeine or male hormone supplements), consistent with naturopathic medical practice as set in rule by the board.

Naturopaths who wish to prescribe codeine or testosterone must first submit an attestation that they have completed at least four hours of graduate-level instruction in specific pharmacology topics and be granted authority by the board. There are currently 717 out of 1,215 licensed naturopaths who hold this authorization.

The applicant states that naturopaths have been practicing within their current prescriptive authority safely. This authority includes many legend drugs that have significant risks such as potential for drug interactions or serious potential side effects and complications such as Coumadin, lithium, and insulin. (Note: No data was provided to support or refute this assertion).

Naturopathic Theory

Naturopathic medicine is described as a distinct primary health care profession, emphasizing prevention, treatment, and optimal health through the use of therapeutic methods and substances that encourage individuals' inherent self-healing process. The practice of naturopathic medicine includes modern and traditional, scientific, and empirical methods. It focuses on holistic, proactive prevention and comprehensive diagnosis and treatment that help to facilitate the body's inherent ability to restore and maintain optimal health. Naturopaths identify and remove barriers to good health by creating a healing internal and external environment.[26] According to the board, this care should include the full range of medical options, including the use of controlled substances, to ensure greater options for patients.

[26] American Association of Naturopathic Physicians (AANP), http://www.naturopathic.org/education.

Naturopathic Physician Education and Training

The board has approved seven Council on Naturopathic Medical Education (CNME) accredited schools in the United States and Canada for licensure in Washington. The council requires programs to be a minimum of 4,100 clock hours, with at least 1,200 hours devoted to clinical training. Naturopaths are trained in four- or five-year, graduate-level programs in basic and clinical sciences. Naturopathic curriculum includes many courses in clinical nutrition, homeopathic medicine, botanical medicine, psychology and counseling.[27] There are residency options at schools, such as Bastyr University, but there is no residency requirement for graduation or state licensure.

The currently accredited naturopathic schools provide a range of 60 to 96 hours dedicated to pharmacology, with additional hours of medication management.[28] The Naturopathic Physicians Licensing Examination, which is required for licensure in Washington, includes a pharmacology section that is described in more detail below.

Pharmacology Training

There is no consistency in pharmacology training across the various health professions with full or limited prescriptive authority for controlled substances in Washington (MDs, osteopathic doctors, advanced registered nurse practitioners, dentists, podiatrists, and optometrists). The educational programs for these professions, including that of naturopaths, incorporate basic science courses and clinical experience. However, there is a broad range of theories and focuses in each type of school and health profession. Pharmacological concepts are taught throughout many courses, making it difficult to parse out exactly how many credits or hours focus on pharmacology, the topics covered, and the depth of the education.

The department requested the applicant identify how naturopathic pharmacology training compares to other licensed professions with full prescriptive authority. The applicant provided information on naturopathic training but recommended the department and other prescribers provide information on other professions for comparison purposes. The department has summarized the information received from multiple sources on the pharmacology training for other professions with prescriptive authority below (see written comments in Appendix D for full comments).

Bastyr University states its program includes 88 hours dedicated to pharmacology, with additional hours included in the clinical sciences modules that cover medication management. In her presentation at the public hearing, Jane Guiltinan, ND, dean of Bastyr University's Naturopathic Medicine program, stated that about half of the pharmacology hours are included in basic sciences during the first two years, and the other half are learned as part of the clinical sciences. The current pharmacology training does not focus on controlled substances since they are not in the Washington scope of practice for naturopaths. Dr. Guiltinan stated that if controlled substances were added to the prescriptive authority, Bastyr would not add additional hours to the current training but would instead adjust the current hours to incorporate appropriate training. During the rebuttal period, Dr. Guiltinan revised her statements and indicated Bastyr would be "willing to develop and offer a continuing medical educational program on controlled substances… that could address any current deficiencies in core training…"

[27] Bastyr University curriculum, http://www.bastyr.edu/academics/areas-study/study-naturopathic-medicine/naturopathic-doctor-degree-program#Curriculum, accessed 7/1/2014.
[28] Applicant report.

The applicant submitted information from four other approved naturopathic programs in the United States showing a range of 70-96 hours of pharmacology training. This information was cited from a 2013 Vermont report[29] that reviewed naturopaths' education and clinical training to determine whether it includes sufficient academic and clinical training in pharmacology for additional prescriptive authority (including controlled substances). The report concluded that Council on Naturopathic Medical Education accredited programs include didactic and clinical pharmacology training that varies from program to program, "ranging from sufficient to wanting."

The Vermont report recommended a conservative approach to naturopath prescribing that "errs on the side of public protection," including a number of recommendations to be completed as a condition of enacting expanded prescriptive authority. These included passage of a naturopathic pharmacology examination, a period of prescription review by another authorized prescriber for new practitioners, and continuance of a formulary of substances that may be prescribed for patients and the conditions naturopaths are competent to treat based on that naturopathic training and experience. According to Sam Russo, naturopathic advisor to the Vermont Office of Professional Regulation, the formulary will sunset in 2015 and naturopaths will be authorized to prescribe within their scope of training. This will accommodate for the variation in training among naturopathic programs.

The College of Osteopathic Medicine at Pacific Northwest University of Health Science and WOMA provided information about osteopathic medicine pharmacology training. They indicated osteopathic doctor training includes 163 contact hours in pharmacology in the first and second years, focusing on mechanism of action, potential adverse effects, and appropriate applications. The following two years incorporate clinical training in pharmacology, including diagnosis directing medication selection, dosing, and alternative therapies. This is followed by a minimum of three-year residencies, where DOs hone these skills while overseen by an attending physician.[30]

Washington State Medical Association (WSMA) provided information about allopathic physician pharmacology training. The University of Washington requires two quarters specific to pharmacology, equaling 180 hours of class time. Pharmacology is covered in many other courses during the final two years of medical school. In addition, during their residency training, MDs continue to learn clinical pharmacology, indications and contraindications for prescribing medications for disease and conditions working with experienced physicians.[31]

Since the applicant has cited parallels to Advanced Registered Nurse Practitioners (ARNPs) throughout its proposal, we are providing more detail regarding Advanced Registered Nurse Practitioner practice, education, and training. Advanced Registered Nurse Practitioners are licensed to practice independently with a broad scope of practice based on education, certification, standards of care, and competencies developed by professional organizations. For example, the National Organization of Nurse Practitioner Faculties has developed a set of Nurse

[29] Vermont Office of Professional Regulation report to the legislature, *Prescriptive Authority for Naturopathic Physicians*, February 5, 2013, https://www.sec.state.vt.us/media/389803/Naturopath_Prescribing_2013.pdf
[30] Information submitted by Assistant Dean of Clinical Education at Pacific Northwest University of Health Sciences College of Osteopathic Medicine, and WOMA (See Appendix D – Written Comments).
[31] Letter submitted by WSMA, July 24, 2014 (See Appendix D – Written Comments).

Practitioner Core Competencies.[32] WAC 246-840-300 requires the ARNP scope of practice to be within the individual ARNP's knowledge, experience and practice.

Advanced Registered Nurse Practitioners are required to hold a Registered Nurse (RN) license and to have graduated from an accredited advanced nursing education program. They must also acquire and maintain certification in a nurse practitioner specialty, such as the American Nurses Credentialing Center Academy of Nurse Practitioners, American Midwifery Certification Board or Council on Certification of Nurse Anesthetists. Education to become an RN includes pharmacology education and principles to appropriately and safely administer medications and assess patients' responses to them.

Initial application for advanced registered nurse practitioner prescriptive authority requires at least 30 contact hours of education in pharmacotherapeutics related to the applicant's scope of practice and includes pharmacokinetic principles and their clinical application and the use of pharmacological agents in the prevention of illness, restoration, and maintenance of health (WAC 246-840-410). Most programs provide more than the minimum hours.

WAC 246-840-360 requires that advanced registered nurse practitioners meet the following requirements to renew their licenses every two years:

- Minimum of 250 hours of independent clinical practice in the advanced registered nurse practitioner role; and
- Completion of 30 continuing education hours relevant to the area of certification and scope of practice.

Many national certification organizations, such as American Nurses Credentialing Center and Academy of Nurse Practitioners, require 1,000 clinical practice hours for renewal every five years, or the advanced registered nurse practitioner must retest and pass the certification examination again. Renewal of the prescriptive authority is separate and requires 15 hours of continuing education in pharmcotherapeutics relevant to the area of certification and scope of practice, in addition to the 30 hours of continuing education required for licensure renewal (WAC 246-840-451).[33]

Prescriptive Authority in Other States

Seven states and Washington DC grant naturopaths a limited prescriptive authority that does not include controlled substances.[34] In Alaska, Connecticut,[35] Minnesota, and North Dakota, naturopaths are regulated but don't have prescriptive authority for legend drugs or controlled substances. Naturopaths aren't regulated or licensed in more than 30 states.

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[32] http://c.ymcdn.com/sites/www.nonpf.org/resource/resmgr/competencies/npcorecompetenciesfinal2012.pdf.

[33] Provided by Louise Kaplan, PhD, ARNP, FNP-BC, FAANP, Director, Nursing Program, Saint Martin's University, at the department's request.

[34] Hawaii, Idaho, Kansas, Maine, Montana, New Hampshire and Utah have varying levels of prescriptive authority for legend drugs.

[35] Connecticut reviewed a proposal dated March 20, 2014, to add prescriptive authority for naturopaths but concluded it did not provide enough information to demonstrate adequate education. The report can be found at: http://www.ct.gov/dph/lib/dph/practitioner_licensing_and_investigations/scope_of_practice_2014/report_to_the_general_assembly-naturopaths_3_21_14_final_report.pdf.

The department identified four states where naturopaths have varying levels of prescriptive authority for controlled substances: Arizona, Oregon, California, and Vermont. Arizona and Oregon have the broadest authority for controlled substances (Appendix F). Arizona's authority is limited to Schedules III-V and morphine in Schedule II (excluding cancer and antipsychotic medications). Oregon operates from a large formulary that includes many Schedule II controlled substances. All four states are uniform in the requirement of continuing education in pharmacology for license renewal. However, each state also has unique requirements, which include:

- Arizona, Oregon, and Vermont require additional pharmacology courses and/or pharmacology/formulary examinations for licensure.
- Oregon includes a one-time mandatory pain management course.
- California requires supervision by an allopathic or osteopathic physician for Schedule IV-V controlled substances and a patient-specific protocol checked by a supervising physician for Schedule II substances.
- Vermont requires a period of prescription review by an authorized prescriber for new providers.

Primary Care

The applicant submitted definitions regarding primary care from the American Association of Family Physicians. The association defines primary care as being performed by a physician[36] who manages care and collaborates with other health professionals, using consultation and referral when appropriate. Primary care physicians are described as generalist physicians who are the first point of contact and take continuing responsibility for providing a patient's care, which includes coordinating the use of the entire healthcare system to benefit the patient.

The applicant has asserted that to provide primary care effectively, naturopaths need prescriptive authority for the full range of controlled substances in Schedules II-V. It states that their use will be limited to those appropriate to the naturopathic scope of practice and within the context of naturopathic philosophy and training. When asked to elaborate on the conditions naturopaths are likely to treat under the expanded Medicaid demographic, many of the applicant's responses focused on pain management.

Primary care includes coordinating care that is outside of the provider's scope of practice, education, and training, and includes referral to an appropriate provider. Naturopathic physicians are approved under Medicaid to provide primary care services. However, they are authorized to provide only those services that are within their scope of practice. There is no indication that unlimited prescriptive authority is necessary or expected by Medicaid to act as primary care providers. The Medicaid population is shown to be in a high-risk category for opioid pain medications, with data showing they are twice as likely to receive an opioid prescription compared to non-Medicaid clients, and are six times more likely to have a fatal overdose involving prescription opioids. The Health Care Authority has indicated naturopaths may offer a

[36] AAFP use of the term "physician" refers to MDs and DOs.

valuable contribution to Medicaid patients through alternative methods to decrease the need for opioid medications.

Primary Care Shortage

The department acknowledges there are shortages of primary care physicians in Washington and across the country. This is a complicated issue, with disparities in primary care capacity across different regions and populations, and was an issue long before the Affordable Care Act. Some of the reasons for the smaller pool of primary care physicians include a high workload, lower reimbursement rates, and less competitive salaries. Strategies to increase the supply of primary care providers have included utilizing advanced registered nurse practitioners in an expanded capacity to help fill gaps in primary care. Their prescriptive authority has evolved in response to specific needs in the healthcare system. These have included evidence that advanced registered nurse practitioners have filled specific voids in rural and underserved areas, and their numbers and distribution have made them effective in filling these gaps. In contrast, the applicant testified that the vast majority of naturopaths practice within King, Pierce and Snohomish counties. A map provided by the applicant shows that more than half of all naturopaths licensed in Washington are in King County alone, and 10 counties have none.

The expansion of Medicaid in the Affordable Care Act has caused anticipation that shortages may be exacerbated as the primary care workforce must take on many new patients. The Washington State Office of Financial Management conducted a research project on the availability of primary care physicians to serve this newly expanded Medicaid population. This report stated that findings have been unclear on the ability of Washington's primary care capacity to absorb the expanded Medicaid population. It concluded that it appears the state has sufficient capacity overall, with disparities appearing to lie in specific rural areas.[37]

Parallels to ARNPs

The department finds that this proposal doesn't parallel the 1992 sunrise review and subsequent expansion of advanced registered nurse practitioner prescriptive authority. During the sunrise review, the ARNP sunrise applicant was able to demonstrate that not expanding their prescriptive authority would severely restrict access to primary and specialty care in rural areas. It provided information regarding access to care challenges in rural areas and how advanced registered nurse practitioner's prescriptive authority was tied to addressing those challenges. It also showed that these providers had been put into a situation where they had the responsibility, but not the authority, to prescribe controlled substances.

The applicant hasn't demonstrated these same conditions exist or that expansion of naturopath prescriptive authority would have the same impact. In addition, the advanced registered nurse practitioner report was conducted prior to the expanded use of opioids for chronic, non-cancer pain. Many significant changes in the political and health care landscape have occurred since 1992.

[37] *Availability of Primary Care Physicians to Serve the Affordable Care Act's Medicaid Expansion Population*, Washington State Office of Financial Management, Research Brief No. 65, June 2012.

REVIEW OF PROPOSAL USING SUNRISE CRITERIA

The Sunrise Act, chapter 18.120 RCW includes regulated professions seeking to substantially increase their scope of practice; however it does not provide specific criteria for evaluating these proposals. RCW 18.120.010(2) includes the following criteria for evaluating proposals to regulate a health profession for the first time: "A health profession should be regulated by the state 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.

First Criterion: Unregulated practice can harm or endanger health or safety.

Naturopaths are currently a thoroughly regulated profession. The proposal as written does not offer adequate protections to meet this criterion. Controlled substances are often dangerous drugs and are scheduled based on their potential for misuse, abuse and dependence. Opioids are used at epidemic levels, with a correlation shown between the rise in overdose deaths and states that have expanded prescription access of these substances.

Naturopathic schools include training in pharmacology that varies in content and length. The proposal does not include sufficient training specific to controlled substances, and Bastyr University, a primary educator of naturopaths in this region, has indicated it will revise the current pharmacology training to include controlled substances rather than add hours to the training if the draft bill is enacted. It will also develop and offer continuing medical education programs on controlled substances.

If the legislature decides to expand the naturopathic scope of practice to include prescriptive authority for additional controlled substances, it will be necessary for additional protections to ensure the public's health and safety. The department believes the additional education and training the applicant proposes isn't sufficient for an expanded prescriptive authority for controlled substances. We would want the Board of Naturopathy, in consultation with the Pharmacy Quality Assurance Commission, to undergo rulemaking to determine appropriate training and education.

Second Criterion: The public needs and will benefit from assurance of professional ability.

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 core training or that the additional education proposed will ensure the public of professional ability to safely prescribe controlled substances.

If the legislature considers expanding the naturopathic scope of practice to include prescriptive authority for additional controlled substances, then the Board of Naturopathy will need authority to undergo rulemaking.

Third Criterion: Public protection cannot be met by other means in a more cost beneficial manner.

The current naturopathic scope of practice protects the public. The proposal as written does not offer adequate protections to meet this criterion. If the legislature considers expanding the naturopathic scope of practice to include prescriptive authority for additional controlled substances, then the Board of Naturopathy will need authority to undergo rulemaking as there is no other more cost beneficial manner to protect the public.

DETAILED RECOMMENDATIONS TO LEGISLATURE

The department doesn't support the proposal to expand the prescriptive authority of naturopaths to include *all* Schedule II-V controlled substances without limitations.

Rationale:

- The applicant has not demonstrated problems with the current prescriptive authority that would justify unlimited expansion of the naturopathic prescriptive authority for controlled substances.
- Unlimited prescriptive authority isn't necessary for naturopaths to practice as primary care physicians under Medicaid.
- Referrals for controlled substances are often necessary, especially in long-term opioid therapy, to ensure the most qualified health care professionals are prescribing these substances, which are controlled because of their significant risks to public health due to overdose, abuse and misuse.
- The applicant hasn't demonstrated that naturopaths receive adequate education in clinical pharmacotherapy of prescribing opioid, antianxiety, sedative, hypnotics, and amphetamine substances to treat various disease states to safely prescribe controlled substances.
- The department doesn't see a benefit to increasing access without limitation to prescription opioid pain medications included in this proposal 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.
    - 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.

Although the department doesn't support unlimited expansion of prescriptive authority, the sunrise review process surfaced new information and perspectives that the legislature should consider. Notably, the HCA has provided the following arguments in support of a limited expansion of naturopathic prescriptive authority, with which the department agrees:

- The HCA recognizes the potential benefit of more convenient and comprehensive health care of clients whose primary care provider is a naturopath.
- Naturopaths have a narrower range of prescriptive authority than other designated primary care providers in Washington.
- It is likely that patients with acute non-life threatening or limb-threatening injuries will seek care in their places of practice, and there is a subset of the population for whom codeine is not effective and/or not tolerated.
- The HCA agrees with the applicant that expanded Medicaid coverage is expected to include an expanded demographic of patients with medical conditions requiring controlled substances in the naturopathic primary care setting.

- Deaths related to prescription opioids have occurred almost without exception in patients on chronic therapy. Short-term treatment of acute conditions with controlled substances is considered safer.
- Limited prescriptive authority may reduce the number of unnecessary emergency department visits.

Bastyr University has indicated a willingness to develop and offer a continuing medical education program on controlled substances to address deficiencies in core training, and has offered assistance in developing necessary educational requirements.

If this alternative is considered, the department recommends:

- Limiting prescriptive authority to controlled substances in Schedule III-V,[38] and only hydrocodone products in Schedule II.[39]
- Limiting controlled substance prescriptions to no more than seven days when treating a particular patient for a single trauma, episode, or condition or for pain associated with or related to the trauma, episode, or condition.
- Maximum dosage of 120 milligrams morphine equivalent dose (MED) per day.[40]
- Authorizing the Board of Naturopathy, in consultation with the Pharmacy Quality Assurance Commission, to undergo rulemaking to determine appropriate training and education.
- Requiring the board to adopt pain management rules appropriate for acute pain treatment, including, but not limited to, patient examination and screening for comorbidities and risk factors.
- Requiring naturopaths with prescriptive authority for controlled substances to register in the Prescription Monitoring Program (PMP)[41] database to access patient prescription history.

[38] This would include Tramadol, which naturopaths had prescriptive authority to prescribe as a legend drug until the FDA recently reclassified it as a Schedule IV controlled substance.
[39]Hydrocodone products are short-acting opioids, which meet the HCA's stated goal of providing naturopaths an additional tool to treat acute pain. These products were rescheduled from Schedule III to Schedule II in October of 2014.
[40] Morphine equivalent dose means a conversion of various opioids to a morphine equivalent dose by the use of accepted conversion tables. 120 MED is the mandatory consultation threshold for adult patients set in the administrative codes of providers with full prescriptive authority (as required in Chapter 209, Laws of 2010).
[41] The PMP is a secure online database that collects data on Schedules II-V controlled substances. 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 (chapter 70.225 RCW).

REBUTTALS TO DRAFT REPORT

The department shared a draft report with sunrise participants and interested parties and invited rebuttal comments or suggested corrections. We received 37 letters of rebuttal, correction, or support that are summarized below. The full rebuttals are included in Appendix F. We have summarized the topics of rebuttals and suggested corrections, along with our response or actions.

Applicant

We received rebuttals from the applicant on the follow topics and statements in the draft report.

1. **The applicant didn't prove the current prescriptive authority is inadequate, problematic, or that it causes disruption of continuity and coordination of care.**

   The applicant disagreed with this rationale, citing:

   - A 1992 sunrise report supporting expansion of advanced registered nurse practitioner prescriptive authority.
   - The example provided at the hearing where a patient's pain medication was delayed (page 9). The applicant stated this example didn't simply demonstrate inconvenience, but a patient self-medicating with an inappropriate drug that had dire implications. This example wasn't unique for naturopaths in smaller or rural practices.
   - Naturopaths don't have access to the common controlled substance medications the applicant submitted with the applicant materials that are necessary for primary care. This proves the current prescriptive authority is problematic for naturopathic physicians and patients.
   - The HCA report, *Emergency Department Utilization: Assumed Savings from Best Practices Implementation*[42]. The applicant states the current prescriptive authority contributes to unnecessary utilization of emergency room services which are contrary to goals outlined by the HCA in its report. The report states that if a client does not have a primary care physician or can't be seen in a reasonable amount of time for a low acuity need, he or she may turn to the emergency department.

   Department Response: The applicant relies heavily on a 22-year old sunrise report that occurred prior to the opioid epidemic this state and nation faces currently. The political and health care landscape was very different than what exists today. In addition, the few isolated examples provided by the applicant are not evidence of a problem that would rise to the level of substantially expanding a profession's scope of practice. The HCA report may make a case for a limited expansion of prescriptive authority for acute conditions.

   The department received several rebuttal letters from naturopaths and naturopathic patients citing challenges they have faced with the lack of prescriptive authority for controlled substances. In addition, we received a rebuttal letter from the HCA stating the proposal (with

[42] Washington State Health Care Authority, http://www.hca.wa.gov/Documents/legreports/3ESHB2127C7L2012E2PVEmergencyDepartmentUtilizationReport.pdf.

specific limitations) may reduce unnecessary emergency department visits for controlled substances. The report has been revised to reflect these comments.

2. **Prescriptive authority isn't necessary for naturopaths to practice as primary care physicians under Medicaid.**

   The applicant disagreed with this rationale, citing a conclusion in Vermont's Report on Education and Clinical Training of Naturopathic Physicians that the evolution of the naturopathic profession necessitates the ability to prescribe primary care pharmaceuticals to fulfill their role as primary care physicians when it falls within the scope of a naturopath's education and training. Primary care is not defined by provider type but by a core set of services, including management of acute conditions. The applicant also stated that patients who select a naturopath as their primary care provider shouldn't be subject to discrimination as to services they can receive, including prescribing controlled substances for acute conditions and for chronic conditions such as ADHD.

   Department Response: The department doesn't consider scope limitations based on education and training to be discrimination because the patient has a choice between different types of primary care providers with different levels of training and scopes of practice. HCA's letter of rebuttal supporting limited prescriptive authority for naturopaths in order to effectively treat Medicaid patients stated that allowing naturopaths to prescribe controlled substances for acute and time limited periods is patient centered and appropriate (with additional education). Their letter didn't indicate that the scope expansion is required or necessary for naturopaths to maintain primary care provider status. The report has been revised to reflect these comments.

3. **Referrals for controlled substances are necessary to ensure the most qualified health care professionals are prescribing these substances, which are controlled because of their significant risks to public health due to overdose, abuse and misuse.**

   The applicant stated that referrals for chronic opioid therapy are well described in the Interagency Guidelines on Opioid Dosing for Chronic Non-Cancer Pain and other literature and agrees these patients should be co-managed with a board certified pain specialist. However, it disagreed that referrals are appropriate for controlled substances for acute cases, which require timely treatment and when delays for referral can put patients at risk.

   Department Response: The department agrees that acute cases require timely treatment and delays can put patients at risk. However, the statement that the most qualified health care professionals should be prescribing these substances is accurate, especially for chronic opioid therapy. This rationale has been slightly revised for clarification.

4. **The applicant has not demonstrated naturopaths receive adequate education to safely prescribe controlled substances and the additional education and continuing education are not sufficient to overcome the deficiencies.**

   The applicant reiterated that the four hours of supplemental education naturopaths are required to complete to apply for the current prescriptive authority works, and that naturopaths have a safe record of prescribing. This includes pain medications like tramadol and affirms that the current continuing education model was built on a strong core education

in pharmacology and pharmacotherapeutics. The applicant requested that if the department believes alternate educational requirements would better protect the public, we should identify this education in the final report for consideration for rulemaking.

Department Response: It is the applicant's responsibility to demonstrate adequate training to increase a profession's scope of practice. The department requested the applicant provide detailed information comparing the pharmacology training of current controlled substance prescribers to that of naturopaths, including length of training and specific content; however sufficient information wasn't provided. No changes were made to the report in response to these comments.

5. **The department doesn't see a need to increase access to prescription opioid pain medications because of the prescription opioid epidemic, the link between the rise in overdose deaths and states that have expanded the use of prescription opioids, and granting broader prescribing authority for controlled substances is contrary to the current efforts to curb the overuse of opioids.**

   The applicant disagreed with this rationale, stating that naturopathic medicine offers an alternative approach and a unique perspective that includes more time with patients and emphasis on alternative non-drug therapeutics that will lessen the need for controlled substances. However, in some acute cases a short-term opioid prescription for a carefully screened patient may be the most medically appropriate treatment.

   The applicant stated that the department suggests a moratorium on new prescriptive authority for any type of provider, including MDs, osteopathic doctors, advanced registered nurse practitioner and physician assistants, which would not serve the public and would compound the problems occurring now. It also suggests the department identify the states with an increase in overdose deaths to review whether they include licensure for naturopaths and whether this data is relevant. The applicant included citations of studies supporting the efficacy of the "naturopathic approach."

   Department Response: The department did not suggest a link between opioid –related deaths and naturopath prescriptive authority. We were recognizing the current problems with opioids and stating that adding more provider types who can prescribe controlled substances is contrary to efforts to curb the overuse of opioids. However, the Centers for Disease Control and Prevention (CDC) has released information showing that Oregon and Arizona, where naturopath prescriptive authority is broadest, had 82.2.-95 painkiller prescription per 100 people in 2012, compared to 72-82.1 per 100 people in Washington.[43] In addition, efficacy of the naturopathic approach isn't the subject of this review, so the additional citations are irrelevant to this sunrise. In light of additional information provided during the rebuttal period of the sunrise review, the department has amended the rationale to indicate we don't see a benefit to increasing access *without limitation* to prescription opioid pain medications.

[43] http://www.cdc.gov/vitalsigns/opioid-prescribing/infographic.html#map.

6. **Speculation that naturopaths have a safe prescribing record.**

   The applicant disagreed with the statement that it "speculated" naturopaths have been prescribing legend drugs with significant risks, such as Coumadin, lithium, and insulin safely and provided no data to support this assertion. It cited:

   There have been no complaints against naturopaths for issues with prescribing within the current scope of practice. The applicant asked the department to provide data on the number of complaints against naturopaths for issues related to prescribing authorized controlled substances, testosterone and codeine. The department responded that there have been 24 complaints related to prescribing outside the statutory scope of practice with four closed with no action, nine with issuance of Stipulations of Informal Disposition, and 11 in process.

   Department Response: The department considers the above statements to be speculation because the applicant provided examples of dangerous legend drugs currently within the naturopath prescriptive authority but did not provide data on what naturopaths are actually prescribing. In addition, prescribing outside the statutory scope of practice is a serious problem. No changes were made to the report in response to these comments.

7. **Review of first sunrise criterion: unregulated practice can harm or endanger health or safety.**

   The applicant disagreed with the department's assessment of this criterion, stating that naturopaths have an established safety record for their current prescriptive authority. It provided evidence of the primary care shortage and references supporting the anticipated increased shortage due to Medicaid expansion. This establishes the readily apparent potential for public harm due to lack of access to primary care.

   Department Response: Naturopaths are already considered primary care providers. However, the HCA agreed in its rebuttal that some prescriptive authority for controlled substances may be beneficial to the Medicaid population that naturopaths are now authorized to treat. The report was revised to add this information.

8. **Review of second sunrise criterion: the public needs and will benefit from assurance of professional ability.**

   The applicant disagreed with the department's assessment of this criterion, stating the current model for naturopath prescriptive authority forms the basis for the supplemental and continuing education in this proposal, and that the proposed additional education meets or exceeds that of other provider types with full prescriptive authority.

   Department Response: The applicant has not provided sufficient information for the department to adopt this conclusion. However, in light of additional information provided during the sunrise review process, the department added that if the legislature considers limited expansion of prescriptive authority, rulemaking by the Board of Naturopathy in consultation with the Pharmacy Quality Assurance Commission will be necessary.

9. **Review of third sunrise criterion: public protection cannot be met by other means in a more cost beneficial manner.**

The applicant repeated the parallels it cited in their applicant materials to the 1992 advanced registered nurse practitioner sunrise review and added that referral to the emergency department or other to other primary care providers for acute conditions requiring controlled substances would not be considered best practices.

Department Response: The department agrees that referrals for acute conditions can be problematic and has made changes to indicate this in the report.

10. Report of Dr. Guiltinan's testimony from public hearing that Bastyr would not add hours to the current pharmacology training but would incorporate controlled substances into existing training.

The applicant stated Bastyr University has confirmed it is interested in and has the ability to develop and offer supplemental education to fulfill requirements enacted by the legislature and Dr. Guiltinan has provided comments to this effect. In addition, due to a curriculum change in process at Bastyr, the number of contact hours for naturopath pharmacology was inaccurately reported as 60.5, while the correct number is actually 88 hours with an elective for an additional 20 hours available.

Department Response: This is new information and the report has been revised accordingly.

11. Placement of public comments in the draft report.

The applicant stated it was unclear why the department included a Health Care Authority (HCA) letter in the paragraph about letters of opposition when the HCA recognized potential benefit of the proposal. It also questioned inclusion of the letter from Washington East Asian Medicine Association, which didn't address topics covered in the sunrise review.

Department Response: These two letters were clearly identified in the report as letters of concern, rather than opposition. However, changes have been made to the public testimony section to ensure these comments are clearly and accurately reported.

12. Public comments the applicant mistook for department statements.

The applicant had concerns about the following statements in the report:

- The department implies naturopathy is limited to natural therapeutics in the statement, "NDs have their place in the health care system as providers with a philosophy that seeks to restore and maintain optimum health… according to the American Association of Naturopathic Physicians…" It directed us to reference the current AANP website for correct statements.
- The department suggests prescriptive authority for providers with less training that MDs is dangerous through the statement, "MDs and DOs having substantially more pharmacology training and residencies, and that granting providers with less training controlled substance prescriptive authority is unnecessary and contrary to legislative efforts…"

Department Response: These statements are represented under public comments, not the department's position. No changes were made to the draft report in response to these comments.

13. Department reports of concerns from the AWHP and HCA regarding naturopathic education.

The applicant states that these comments were made before it provided additional details about naturopathic education in follow up to the department.

Department Response: The report has been revised to clarify these comments.

14. Reporting of the expanded demographic of Medicaid population.

The applicant disagreed with the department's statement that it "has speculated that the expansion of Medicaid will include an expanded demographic of patients with medical conditions that require controlled substances in the naturopathic primary care setting." It stated that the department's citation of CDC reports on page 13 showing Medicaid clients are twice as likely to receive an opioid prescription compared to non-Medicaid clients confirms Medicaid expansion will include an increased percentage of patients requiring opioid prescriptions in the naturopathic primary care setting.

Department Response: The term "speculated" was changed to "asserted" in the report.

15. Department criticism of naturopathic core education and characterization of applicant's recommendation for supplemental education.

The applicant pointed to the 2005 legislative change granting their current prescriptive authority and the additional education to obtain this prescriptive authority, along with the safe record of prescribing. It also requested a correction needed to the report where the department reported the applicant recommended eight hours of supplemental education, rather than the actual 12 hours.

Department Response: The report has been revised to clarify that the applicant recommends eight hours in addition to the four hours required for current prescriptive authority.

16. Department statement that the Council on Naturopathic Medical Education has no standard pharmacology training.

The applicant argued this is an untrue statement and provided a statement from Council on Naturopathic Medical Education.

Department Response: The report has been revised to remove this statement.

17. Naturopathic educational standards for clinical pharmacology.

The applicant reiterated its willingness to ask the legislature to require the Board of Naturopathy to initiate formal rulemaking to develop the most appropriate process and regulatory means for Washington and request the department identify the recommendations that would protect the public in this regard.

Department Response: This isn't new information. No changes were made to the report in response to this comment.

18. **Registered Nurses and Advanced Registered Nurse Practitioner pharmacology education.**

The applicant reported the following observations on training of other prescribers:

- In assessing the core nursing education related to pharmacology, it doesn't appear that the bachelor's level education includes diagnosis or prescription of medications, which naturopathic education includes both didactically and clinically.
- Initial application for advanced registered nurse practitioner's prescriptive authority requires 30 contact hours of pharmacotherapeutics, while core naturopathic education includes 70-90 hours, with Bastyr reporting 88 hours of pharmacology course work and an elective for 20 additional hours.
- Advanced registered nurse practitioner renewal of prescriptive authority requires 15 hours of continuing education in pharmacotherapeutics relevant to the area of certification and scope of practice, whereas the naturopathic requirements are proposed in the applicant report to increase from 20 to 30 hours per year with 10 specific to pharmacology, exceeding the ARNP requirements.

Department Response: Comparison of mere numbers of hours without comparing course content isn't helpful to this review. No changes were made to the report in response to these comments.

HEALTH CARE AUTHORITY

The department received a letter requesting the following clarifications and updates about the Health Care Authority's initial letter of comment:

1. **Modification of the characterization of the HCA's perspective.** Revise this statement to "recognizes the potential benefit of more convenient and comprehensive health care of clients whose primary care provider is a naturopath, if appropriate and clearly defined pharmacology education and training for naturopaths were required in conjunction with this change in the scope of practice authority for naturopaths."
2. **Clarification of the HCA's concerns.** The HCA's primary concern is than an increase in prescriptive authority must include adequate pharmacology education and training. It was concerned with the vagueness in the original applicant report and suggested a one-year residency. However, after reading follow up comments from the applicant, finding out the rarity of naturopathic residencies, and reviewing the proposed supplemental education and continuing education submitted, the HCA has less concern with the adequacy of pharmacology training as it relates to the limited prescriptive authority it suggests.
3. **Concerns in the report over prescription and overuse in patients on Medicaid**. Almost without exception, the deaths from opioids have occurred in patients on chronic therapy. Short-term treatment with controlled substances is much safer and at times indicated.
4. **Medicaid's expanded demographic.** The HCA agreed with the applicant that Medicaid will include an expanded demographic of patients with medical conditions requiring controlled substances in the naturopathic primary care setting and that naturopaths can offer valuable contributions with alternatives that may decrease the need for opioid medications.

5. **Support proposal with limitations.** The HCA would support the applicant's proposal if prescriptive authority for controlled substances was limited to the treatment of acute conditions and for a limited amount of time. Treatment for chronic condition should be done in collaboration with specialists.
6. **Benefits.** Expanded prescriptive authority will allow naturopaths to manage primary care patients when they have acute and time limited conditions requiring controlled substances. In the acute setting, this will reduce disruption of care and may also reduce unnecessary emergency department visits.

Department Response: The report has been revised to include the requested clarifications, corrections, and updates. It has also been revised to address the potential benefit of limited prescriptive authority for acute conditions, including reduction in delays in care and unnecessary emergency department visits. This is a similar approach to the prescriptive authority for optometrists. However, the complex prescriptive authorities for various professions cause confusion for prescribers and place pharmacists in an awkward position of gatekeeper when filling prescriptions. Clear parameters must be set for pharmacists to effectively play this role.

SAM RUSSO, ND, Lac, RMSK, CONTRIBUTOR TO VERMONT REPORT

The department received a letter from one of the contributors to the Vermont report cited in the draft sunrise requesting the following clarifications and corrections to the draft report:

1. Naturopathic Physicians Licensing Examination**.** It didn't review the Naturopathic Physicians Licensing Examination, but received information from the organization about its exam. After the report was published, Dr. Russo stated that he revisited the information on the exam core clinical science examination and found that it does evaluate the clinical aspects of pharmacology.
2. **Corrections to information on Vermont in Appendix E.** Requested correction to the table of pharmacology education/continuing education to indicate the information was taken from the administrative rules, not statute.
3. **Pharmacology examination.** The Vermont rules will be updated to strike the requirement to pass the National Board of Medical Examiners pharmacology exam or the exam given at the University of Vermont's College of Medicine… and will be replaced with "an examination created by the Office of Professional Regulation." Vermont found that naturopaths aren't eligible to take the National Board of Medical Examiners and the University of Vermont exams were not appropriate because they test for introductory pharmacology training. A new exam is available.
4. **Vermont formulary.** Requested corrections on page 16, fourth paragraph to 1) show that the current formulary will sunset in 2015 and naturopaths will either be able to pursue a license endorsement to prescribe within their scope of training or have no prescriptive authority; and 2) expand on "errs on the side of public protection." One of the reasons Vermont chose a two tiered system was to accommodate for the variation in training among naturopath programs.
5. **Oregon and Arizona schools.** Requested the department address more in the report about Oregon's and Arizona's naturopathic colleges that provide training in controlled substances, rather than focusing on Bastyr.

Department Response: The report has been revised to reflect these clarifications and corrections. However, no changes were made to the report regarding Oregon and Arizona pharmacology training because detailed information on these schools wasn't provided by the applicant.

Jane Guiltinan, ND
Dean and Professor, School of Naturopathic Medicine, Bastyr University

Dr. Guiltinan wrote that Bastyr is willing and able to develop and offer a continuing medical educational program on controlled substances through its continuing education department to address any deficiencies in core training required by the legislature and Board of Naturopathy. She offered Bastyr's assistance in developing the education and training requirements to ensure public safety and optimal care by naturopaths in using controlled substances. In addition, she corrected the number of pharmacology hours she provided at the sunrise hearing, stating it is actually 88 didactic hours, rather than 60.5.

Department Response: This was new information so the report has been revised accordingly.

Board of Naturopathy

The board wrote in support of the applicant's proposal, stating:

- The practice of naturopathic medicine seeks to restore and maintain health by emphasizing the natural and inherent self-healing process, starting with the least invasive method possible. The continuum of care and treatment modalities should include the full range of medical options, including controlled substances, which ensures greater health care options for Washington residents.
- The board supports the applicant's intent to include rulemaking authority for the board, which would be similar to the efforts in 2005 when legend drugs, codeine, and testosterone were added to the naturopathic scope of practice.
- The foundation of naturopath education is sound and the academic standards include a strong curriculum in clinical pharmacology, prescription drug management, and patient safety monitoring. It recognized the example of the University of Washington School of Medicine's significant pharmacology training and stated that Bastyr also has a curriculum robust in pharmacology that meets or exceeds that of other prescribers.
- The board agreed that an increase in prescriptive authority to include controlled substances would require additional specific training to a degree comparable to that of other prescribers.
- The board stated it supports the applicant's intent to include additional continuing education hours specific to pharmacology.
- The board stated it supports the applicant's intent for adoption of pain management rules to address concerns about opioid abuse and misuse and ensure public and patient safety.
- The board stated it is confident the history of safe prescribing supported by naturopathic-complaint history will continue with expanded prescriptive authority.

Department Response: Since these comments are not rebuttals to the report, no changes were made to the report except to include the board's support for the proposal.

Additional Rebuttals to Draft Sunrise from Providers and Patients

We received rebuttal letters from 13 naturopath patients supporting the applicant's proposal, and agreeing that the current need for referral to another health care provider for controlled substance prescriptions causes problems. These include increased costs to patients to see another provider such as multiple co-pays; loss of time from work or family; and disruption in coordination of care. These patients indicated trust in their naturopathic primary care providers and the relationship they have developed, and that they often distrust other types of providers they have been required to see in order to receive controlled substances. Some patients indicated they were forced to stop taking necessary medications due to high medical bills and challenges with being referred.

We received eight rebuttal letters from naturopaths, their staff, and other health care providers indicating support for the applicant's proposal. These comments agreed with the applicant that naturopaths are qualified to prescribe controlled substances, and that the principles of naturopathic medicine allow for these types of prescriptions when less invasive methods do not work. These comments also agreed with the applicant's assertions that the current prescriptive authority causes challenges, including dual utilization and additional costs. They also cited issues with titrating patients off of controlled substances (reducing dosage) when implementing an alternative treatment plan.

The department received four comments generally supporting the applicant's proposal and asking the department to reconsider the draft recommendations.

Department Response: The report has been revised to include this information.

Additional Comments Supporting Department's Draft Recommendations

We also received seven additional letters supporting the recommendations in the draft report. Three were from health care providers – an advanced registered nurse practitioner in psychiatric practice and two pharmacists. One of the letters was from the American Naturopathic Medical Association opposing expanded prescriptive authority for naturopaths (and stating the current prescriptive rights of naturopaths should be rescinded). It stated it receives many complaints regarding naturopaths prescribing, Council on Naturopathic Medical Education approved naturopathic schools don't train at the same level as allopathic medical schools, and to grant prescriptive authority for any drug is confusing to the public and dangerous due to the naturopath level of education.

Department Response: No changes were made to the report in response to these comments.