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.

Appendix A

Request from Legislature and Draft Bill

State of Washington
House of Representatives

April 24, 2014

John Wiesman, Secretary
Washington State Department of Health
P.O. Box 47890
Olympia, Washington 98504-7890

Dear Secretary Wiesman,

I am requesting that the Department of Health consider a Sunrise Review application for 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.

A copy of the proposal is attached. The House Health Care and Wellness Committee would be interested in an assessment of whether the proposal meets the sunrise criteria for expanding the scope of practice for a regulated health profession in Washington.

I appreciate your consideration of this application, and I look forward to receiving your report. Please contact my office if you have any questions.

Sincerely,

Eileen Cody

EILEEN CODY, Chair
House Health Care and Wellness Committee

Cc: Karen Jensen, Washington State Department of Health
Robert May, Washington Association for Naturopathic Physicians
Alexa Silver, Office of Program Research

BILL REQUEST - CODE REVISER'S OFFICE

BILL REQ. #: H-4573.4/14 4th draft

ATTY/TYPIST: AL:eab

BRIEF DESCRIPTION: Concerning prescriptive authority of naturopaths.

AN ACT Relating to prescriptive authority of naturopaths; amending RCW 18.36A.040 and 69.43.135; and reenacting and amending RCW 18.36A.020, 69.41.030, 69.45.010, and 69.50.101.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

Sec. 1. RCW 18.36A.020 and 2011 c 41 s 3 and 2011 c 40 s 1 are each reenacted and amended to read as follows:

Unless the context clearly requires otherwise, the definitions in this section apply throughout this chapter.

(1) "Board" means the board of naturopathy created in RCW 18.36A.150.

(2) "Common diagnostic procedures" means the use of venipuncture consistent with the practice of naturopathic medicine, commonly used diagnostic modalities consistent with naturopathic practice, health history taking, physical examination, radiography, examination of body orifices excluding endoscopy, laboratory medicine, and obtaining samples of human tissues, but excluding incision or excision beyond that which is authorized as a minor office procedure.

(3) "Department" means the department of health.

(4) "Educational program" means an accredited program preparing persons for the practice of naturopathic medicine.

(5) "Homeopathy" means a system of medicine based on the use of infinitesimal doses of medicines capable of producing symptoms similar to those of the disease treated, as listed in the homeopathic pharmacopeia of the United States.

(6) "Hygiene and immunization" means the use of such preventative techniques as personal hygiene, asepsis, public health, and immunizations, to the extent allowed by rule.

(7) "Manual manipulation" or "mechanotherapy" means manipulation of a part or the whole of the body by hand or by mechanical means.

(8) "Minor office procedures" means care and procedures incident thereto of superficial lacerations, lesions, and abrasions, and the removal of foreign bodies located in superficial structures, not to include the eye; and the use of antiseptics and topical or local anesthetics in connection therewith. "Minor office procedures" also includes intramuscular, intravenous, subcutaneous, and intradermal injections of substances consistent with the practice of naturopathic medicine and in accordance with rules established by the secretary.

(9) "Naturopath" means an individual licensed under this chapter.

(10) "Naturopathic medicines" means vitamins; minerals; botanical medicines; homeopathic medicines;((~~hormones; and those legend drugs and controlled substances consistent with naturopathic medical practice in accordance with rules established by the board. Controlled substances are limited to codeine and testosterone products that are contained in Schedules III, IV, and V in chapter 69.50 RCW~~)) and other nutrients and compounds, other than legend drugs or controlled substances, that are consistent with naturopathic medicine.

(11) "Nutrition and food science" means the prevention and treatment of disease or other human conditions through the use of foods, water, herbs, roots, bark, or natural food elements.

(12) "Physical modalities" means use of physical, chemical, electrical, and other modalities that do not exceed those used as of July 22, 2011, in minor office procedures or common diagnostic procedures, including but not limited to heat, cold, air, light, water in any of its forms, sound, massage, and therapeutic exercise.

(13) "Radiography" means the ordering, but not the interpretation,

of radiographic diagnostic and other imaging studies and the taking and interpretation of standard radiographs.

(14) "Secretary" means the secretary of health or the secretary's designee.

(15) "Suggestion" means techniques including but not limited to counseling, biofeedback, and hypnosis.

Sec. 2. RCW 18.36A.040 and 2011 c 40 s 2 are each amended to read as follows:

(1) Naturopathic medicine is 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. A naturopath is responsible and accountable to the consumer for the quality of naturopathic care rendered.

(2) The practice of naturopathic medicine includes manual manipulation (mechanotherapy), the prescription, administration, dispensing, and use, except for the treatment of malignancies, of nutrition and food science, physical modalities, minor office procedures, homeopathy, naturopathic medicines, hygiene and immunization, contraceptive devices, common diagnostic procedures, and suggestion; however, nothing in this chapter shall prohibit consultation and treatment of a patient in concert with a practitioner licensed under chapter 18.57 or 18.71 RCW. A naturopath may prescribe and administer 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.

(3) No person licensed under this chapter may employ the term "chiropractic" to describe any services provided by a naturopath under this chapter.

Sec. 3. RCW 69.41.030 and 2013 c 71 s 1 and 2013 c 12 s 1 are each reenacted and amended to read as follows:

(1) It shall be unlawful for any person to sell, deliver, or possess any legend drug except upon the order or prescription of a physician under chapter 18.71 RCW, an osteopathic physician and surgeon under chapter 18.57 RCW, an optometrist licensed under chapter 18.53 RCW who is certified by the optometry board under RCW 18.53.010, a dentist under chapter 18.32 RCW, a podiatric physician and surgeon

under chapter 18.22 RCW, a naturopathic physician under chapter 18.36A RCW, a veterinarian under chapter 18.92 RCW, a commissioned medical or dental officer in the United States armed forces or public health service in the discharge of his or her official duties, a duly licensed physician or dentist employed by the veterans administration in the discharge of his or her official duties, a registered nurse or advanced registered nurse practitioner under chapter 18.79 RCW when authorized by the nursing care quality assurance commission, a pharmacist licensed under chapter 18.64 RCW to the extent permitted by drug therapy guidelines or protocols established under RCW 18.64.011 and authorized by the board of pharmacy and approved by a practitioner authorized to prescribe drugs, an osteopathic physician assistant under chapter 18.57A RCW when authorized by the board of osteopathic medicine and surgery, a physician assistant under chapter 18.71A RCW when authorized by the medical quality assurance commission, or any of the following professionals in any province of Canada that shares a common border with the state of Washington or in any state of the United States: A physician licensed to practice medicine and surgery or a physician licensed to practice osteopathic medicine and surgery, a physician licensed to practice naturopathic medicine and authorized to prescribe legend drugs, a dentist licensed to practice dentistry, a podiatric physician and surgeon licensed to practice podiatric medicine and surgery, a licensed advanced registered nurse practitioner, a licensed physician assistant, a licensed osteopathic physician assistant, or a veterinarian licensed to practice veterinary medicine: PROVIDED, HOWEVER, That the above provisions shall not apply to sale, delivery, or possession by drug wholesalers or drug manufacturers, or their agents or employees, or to any practitioner acting within the scope of his or her license, or to a common or contract carrier or warehouse operator, or any employee thereof, whose possession of any legend drug is in the usual course of business or employment: PROVIDED FURTHER, That nothing in this chapter or chapter 18.64 RCW shall prevent a family planning clinic that is under contract with the health care authority from selling, delivering, possessing, and dispensing commercially prepackaged oral contraceptives prescribed by authorized, licensed health care practitioners.

(2)(a) A violation of this section involving the sale, delivery, or

possession with intent to sell or deliver is a class B felony punishable according to chapter 9A.20 RCW.

(b) A violation of this section involving possession is a misdemeanor.

Sec. 4. RCW 69.43.135 and 2011 c 336 s 838 are each amended to read as follows:

(1) The definitions in this subsection apply throughout this section unless the context clearly requires otherwise.

(a) "Iodine matrix" means iodine at a concentration greater than two percent by weight in a matrix or solution.

(b) "Matrix" means something, as a substance, in which something else originates, develops, or is contained.

(c) "Methylsulfonylmethane" means methylsulfonylmethane in its powder form only, and does not include products containing methylsulfonylmethane in other forms such as liquids, tablets, capsules not containing methylsulfonylmethane in pure powder form, ointments, creams, cosmetics, foods, and beverages.

(2) Any person who knowingly purchases in a thirty-day period or possesses any quantity of iodine in its elemental form, an iodine matrix, or more than two pounds of methylsulfonylmethane is guilty of a gross misdemeanor, except as provided in subsection (3) of this section.

(3) Subsection (2) of this section does not apply to:

(a) A person who possesses iodine in its elemental form or an iodine matrix as a prescription drug, under a prescription issued by a licensed veterinarian, physician, or advanced registered nurse practitioner;

(b) A person who possesses iodine in its elemental form, an iodine matrix, or any quantity of methylsulfonylmethane in its powder form and is actively engaged in the practice of animal husbandry of livestock;

(c) A person who possesses iodine in its elemental form or an iodine matrix in conjunction with experiments conducted in a chemistry or chemistry-related laboratory maintained by a:

(i) Public or private secondary school;

(ii) Public or private institution of higher education that is accredited by a regional or national accrediting agency recognized by the United States department of education;

(iii) Manufacturing facility, government agency, or research facility in the course of lawful business activities;

(d) A veterinarian, physician, naturopathic physician, advanced registered nurse practitioner, pharmacist, retail distributor, wholesaler, manufacturer, warehouse operator, or common carrier, or an agent of any of these persons who possesses iodine in its elemental form, an iodine matrix, or methylsulfonylmethane in its powder form in the regular course of lawful business activities; or

(e) A person working in a general hospital who possesses iodine in its elemental form or an iodine matrix in the regular course of employment at the hospital.

(4) Any person who purchases any quantity of iodine in its elemental form, an iodine matrix, or any quantity of methylsulfonylmethane must present an identification card or driver's license issued by any state in the United States or jurisdiction of another country before purchasing the item.

(5) The Washington state patrol shall develop a form to be used in recording transactions involving iodine in its elemental form, an iodine matrix, or methylsulfonylmethane. A person who sells or otherwise transfers any quantity of iodine in its elemental form, an iodine matrix, or any quantity of methylsulfonylmethane to a person for any purpose authorized in subsection (3) of this section must record each sale or transfer. The record must be made on the form developed by the Washington state patrol and must be retained by the person for at least three years. The Washington state patrol or any local law enforcement agency may request access to the records.

(a) Failure to make or retain a record required under this subsection is a misdemeanor.

(b) Failure to comply with a request for access to records required under this subsection to the Washington state patrol or a local law enforcement agency is a misdemeanor.

Sec. 5. RCW 69.45.010 and 2013 c 19 s 81 are each reenacted and amended to read as follows:

The definitions in this section apply throughout this chapter.

(1) "Commission" means the pharmacy quality assurance commission.

(2) "Controlled substance" means a drug, substance, or immediate

precursor of such drug or substance, so designated under or pursuant to chapter 69.50 RCW, the uniform controlled substances act.

(3) "Deliver" or "delivery" means the actual, constructive, or attempted transfer from one person to another of a drug or device, whether or not there is an agency relationship.

(4) "Department" means the department of health.

(5) "Dispense" means the interpretation of a prescription or order for a drug, biological, or device and, pursuant to that prescription or order, the proper selection, measuring, compounding, labeling, or packaging necessary to prepare that prescription or order for delivery.

(6) "Distribute" means to deliver, other than by administering or dispensing, a legend drug.

(7) "Drug samples" means any federal food and drug administration approved controlled substance, legend drug, or products requiring prescriptions in this state, which is distributed at no charge to a practitioner by a manufacturer or a manufacturer's representative, exclusive of drugs under clinical investigations approved by the federal food and drug administration.

(8) "Legend drug" means any drug that is required by state law or by regulations of the commission to be dispensed on prescription only or is restricted to use by practitioners only.

(9) "Manufacturer" means a person or other entity engaged in the manufacture or distribution of drugs or devices, but does not include a manufacturer's representative.

(10) "Manufacturer's representative" means an agent or employee of a drug manufacturer who is authorized by the drug manufacturer to possess drug samples for the purpose of distribution in this state to appropriately authorized health care practitioners.

(11) "Person" means any individual, corporation, government or governmental subdivision or agency, business trust, estate, trust, partnership, association, or any other legal entity.

(12) "Practitioner" means a physician under chapter 18.71 RCW, an osteopathic physician or an osteopathic physician and surgeon under chapter 18.57 RCW, a dentist under chapter 18.32 RCW, a podiatric physician and surgeon under chapter 18.22 RCW, a naturopathic physician under chapter 18.36A RCW, a veterinarian under chapter 18.92 RCW, a pharmacist under chapter 18.64 RCW, a commissioned medical or dental officer in the United States armed forces or the public health service

in the discharge of his or her official duties, a duly licensed physician or dentist employed by the veterans administration in the discharge of his or her official duties, a registered nurse or advanced registered nurse practitioner under chapter 18.79 RCW when authorized to prescribe by the nursing care quality assurance commission, an osteopathic physician assistant under chapter 18.57A RCW when authorized by the board of osteopathic medicine and surgery, or a physician assistant under chapter 18.71A RCW when authorized by the medical quality assurance commission.

(13) "Reasonable cause" means a state of facts found to exist that would warrant a reasonably intelligent and prudent person to believe that a person has violated state or federal drug laws or regulations.

(14) "Secretary" means the secretary of health or the secretary's designee.

Sec. 6. RCW 69.50.101 and 2014 c 192 s 1 are each amended to read as follows:

Unless the context clearly requires otherwise, definitions of terms shall be as indicated where used in this chapter:

(a) "Administer" means to apply a controlled substance, whether by injection, inhalation, ingestion, or any other means, directly to the body of a patient or research subject by:

(1) a practitioner authorized to prescribe (or, by the practitioner's authorized agent); or

(2) the patient or research subject at the direction and in the presence of the practitioner.

(b) "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. It does not include a common or contract carrier, public warehouseperson, or employee of the carrier or warehouseperson.

(c) "Commission" means the pharmacy quality assurance commission.

(d) "Controlled substance" means a drug, substance, or immediate precursor included in Schedules I through V as set forth in federal or state laws, or federal or commission rules.

(e)(1) "Controlled substance analog" means a substance the chemical structure of which is substantially similar to the chemical structure of a controlled substance in Schedule I or II and:

(i) that has a stimulant, depressant, or hallucinogenic effect on the central nervous system substantially similar to the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance included in Schedule I or II; or

(ii) with respect to a particular individual, that the individual represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system substantially similar to the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance included in Schedule I or II.

(2) The term does not include:

(i) a controlled substance;

(ii) a substance for which there is an approved new drug application;

(iii) a substance with respect to which an exemption is in effect for investigational use by a particular person under Section 505 of the federal Food, Drug and Cosmetic Act, 21 U.S.C. Sec. 355, to the extent conduct with respect to the substance is pursuant to the exemption; or

(iv) any substance to the extent not intended for human consumption before an exemption takes effect with respect to the substance.

(f) "Deliver" or "delivery," means the actual or constructive transfer from one person to another of a substance, whether or not there is an agency relationship.

(g) "Department" means the department of health.

(h) "Dispense" means the interpretation of a prescription or order for a controlled substance and, pursuant to that prescription or order, the proper selection, measuring, compounding, labeling, or packaging necessary to prepare that prescription or order for delivery.

(i) "Dispenser" means a practitioner who dispenses.

(j) "Distribute" means to deliver other than by administering or dispensing a controlled substance.

(k) "Distributor" means a person who distributes.

(l) "Drug" means (1) a controlled substance recognized as a drug in the official United States pharmacopoeia/national formulary or the official homeopathic pharmacopoeia of the United States, or any supplement to them; (2) controlled substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in individuals or animals; (3) controlled substances (other than food)

intended to affect the structure or any function of the body of individuals or animals; and (4) controlled substances intended for use as a component of any article specified in (1), (2), or (3) of this subsection. The term does not include devices or their components, parts, or accessories.

(m) "Drug enforcement administration" means the drug enforcement administration in the United States Department of Justice, or its successor agency.

(n) "Electronic communication of prescription information" means the transmission of a prescription or refill authorization for a drug of a practitioner using computer systems. The term does not include a prescription or refill authorization verbally transmitted by telephone nor a facsimile manually signed by the practitioner.

(o) "Immediate precursor" means a substance:

(1) that the commission has found to be and by rule designates as being the principal compound commonly used, or produced primarily for use, in the manufacture of a controlled substance;

(2) that is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance; and

(3) the control of which is necessary to prevent, curtail, or limit the manufacture of the controlled substance.

(p) "Isomer" means an optical isomer, but in subsection (z)(5) of this section, RCW 69.50.204(a) (12) and (34), and 69.50.206(b)(4), the term includes any geometrical isomer; in RCW 69.50.204(a) (8) and (42), and 69.50.210(c) the term includes any positional isomer; and in RCW 69.50.204(a)(35), 69.50.204(c), and 69.50.208(a) the term includes any positional or geometric isomer.

(q) "Lot" means a definite quantity of marijuana, useable marijuana, or marijuana-infused product identified by a lot number, every portion or package of which is uniform within recognized tolerances for the factors that appear in the labeling.

(r) "Lot number" shall identify the licensee by business or trade name and Washington state unified business identifier number, and the date of harvest or processing for each lot of marijuana, useable marijuana, or marijuana-infused product.

(s) "Manufacture" means the production, preparation, propagation, compounding, conversion, or processing of a controlled substance, either directly or indirectly or by extraction from substances of

natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container. The term does not include the preparation, compounding, packaging, repackaging, labeling, or relabeling of a controlled substance:

(1) by a practitioner as an incident to the practitioner's administering or dispensing of a controlled substance in the course of the practitioner's professional practice; or

(2) by a practitioner, or by the practitioner's authorized agent under the practitioner's supervision, for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale.

(t) "Marijuana" or "marihuana" means all parts of the plant Cannabis, whether growing or not, with a THC concentration greater than 0.3 percent on a dry weight basis; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin. The term does not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture, or preparation of the mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of the plant which is incapable of germination.

(u) "Marijuana concentrates" means products consisting wholly or in part of the resin extracted from any part of the plant Cannabis and having a THC concentration greater than sixty percent.

(v) "Marijuana processor" means a person licensed by the state liquor control board to process marijuana into useable marijuana and marijuana-infused products, package and label useable marijuana and marijuana-infused products for sale in retail outlets, and sell useable marijuana and marijuana-infused products at wholesale to marijuana retailers.

(w) "Marijuana producer" means a person licensed by the state liquor control board to produce and sell marijuana at wholesale to marijuana processors and other marijuana producers.

(x) "Marijuana-infused products" means products that contain marijuana or marijuana extracts, are intended for human use, and have

a THC concentration greater than 0.3 percent and no greater than sixty percent. The term "marijuana-infused products" does not include either useable marijuana or marijuana concentrates.

(y) "Marijuana retailer" means a person licensed by the state liquor control board to sell useable marijuana and marijuana-infused products in a retail outlet.

(z) "Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium, opium derivative, and any derivative of opium or opium derivative, including their salts, isomers, and salts of isomers, whenever the existence of the salts, isomers, and salts of isomers is possible within the specific chemical designation. The term does not include the isoquinoline alkaloids of opium.

(2) Synthetic opiate and any derivative of synthetic opiate, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of the isomers, esters, ethers, and salts is possible within the specific chemical designation.

(3) Poppy straw and concentrate of poppy straw.

(4) Coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives or ecgonine or their salts have been removed.

(5) Cocaine, or any salt, isomer, or salt of isomer thereof.

(6) Cocaine base.

(7) Ecgonine, or any derivative, salt, isomer, or salt of isomer thereof.

(8) Any compound, mixture, or preparation containing any quantity of any substance referred to in subparagraphs (1) through (7).

(aa) "Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability. The term includes opium, substances derived from opium (opium derivatives), and synthetic opiates. The term does not include, unless specifically designated as controlled under RCW 69.50.201, the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). The term includes the racemic and levorotatory forms of dextromethorphan.

(bb) "Opium poppy" means the plant of the species Papaver somniferum L., except its seeds.

(cc) "Person" means individual, corporation, business trust, estate, trust, partnership, association, joint venture, government, governmental subdivision or agency, or any other legal or commercial entity.

(dd) "Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

(ee) "Practitioner" means:

(1) A physician under chapter 18.71 RCW; a physician assistant under chapter 18.71A RCW; an osteopathic physician and surgeon under chapter 18.57 RCW; a naturopathic physician under chapter 18.36A RCW; an osteopathic physician assistant under chapter 18.57A RCW who is licensed under RCW 18.57A.020 subject to any limitations in RCW 18.57A.040; an optometrist licensed under chapter 18.53 RCW who is certified by the optometry board under RCW 18.53.010 subject to any limitations in RCW 18.53.010; a dentist under chapter 18.32 RCW; a podiatric physician and surgeon under chapter 18.22 RCW; a veterinarian under chapter 18.92 RCW; a registered nurse, advanced registered nurse practitioner, or licensed practical nurse under chapter 18.79 RCW; ((~~a naturopathic physician under chapter 18.36A RCW who is licensed under RCW 18.36A.030 subject to any limitations in RCW 18.36A.040;~~)) a pharmacist under chapter 18.64 RCW or a scientific investigator under this chapter, licensed, registered or otherwise permitted insofar as is consistent with those licensing laws to distribute, dispense, conduct research with respect to or administer a controlled substance in the course of their professional practice or research in this state.

(2) A pharmacy, hospital or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in this state.

(3) A physician licensed to practice medicine and surgery, a physician licensed to practice osteopathic medicine and surgery, a dentist licensed to practice dentistry, a podiatric physician and surgeon licensed to practice podiatric medicine and surgery, a licensed physician assistant or a licensed osteopathic physician assistant specifically approved to prescribe controlled substances by his or her state's medical quality assurance commission or equivalent and his or

her supervising physician, an advanced registered nurse practitioner licensed to prescribe controlled substances, a naturopathic physician licensed to prescribe controlled substances, or a veterinarian licensed to practice veterinary medicine in any state of the United States.

(ff) "Prescription" means an order for controlled substances issued by a practitioner duly authorized by law or rule in the state of Washington to prescribe controlled substances within the scope of his or her professional practice for a legitimate medical purpose.

(gg) "Production" includes the manufacturing, planting, cultivating, growing, or harvesting of a controlled substance.

(hh) "Retail outlet" means a location licensed by the state liquor control board for the retail sale of useable marijuana and marijuana-infused products.

(ii) "Secretary" means the secretary of health or the secretary's designee.

(jj) "State," unless the context otherwise requires, means a state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, or a territory or insular possession subject to the jurisdiction of the United States.

(kk) "THC concentration" means percent of delta-9 tetrahydrocannabinol content per dry weight of any part of the plant ***Cannabis***, or per volume or weight of marijuana product, or the combined percent of delta-9 tetrahydrocannabinol and tetrahydrocannabinolic acid in any part of the plant ***Cannabis*** regardless of moisture content.

(ll) "Ultimate user" means an individual who lawfully possesses a controlled substance for the individual's own use or for the use of a member of the individual's household or for administering to an animal owned by the individual or by a member of the individual's household.

(mm) "Useable marijuana" means dried marijuana flowers. The term "useable marijuana" does not include either marijuana-infused products or marijuana concentrates.

--- END ---

Appendix B

Applicant Report and Follow Up

Applicant Report Cover Sheet and Outline

Washington State Department of Health Sunrise Review

COVER SHEET

- **Legislative proposal being reviewed under the sunrise process (include bill number if available):**

  Bill #: H 4573.4 Concerning prescriptive authority of naturopaths.

Summary: A naturopath may prescribe and administer controlled substances contained in Schedules II through V of the uniform controlled substances act, chapter 69.50 RCW, necessary in the practice of naturopathy.

Proposed Amendments: WANP recommends the Final Sunrise Review Report and Recommendations to the Legislature include a pain management section that conforms with HB 2876 (2010) *Concerning pain management* (Moeller); plus the following two **bolded** amendments that will require authorization by the Board of Naturopathy because H 4573.4 fails to require such authorization:

Sec. 3. RCW 69.41.030 and 2013 c 71 s 1 and 2013 c 12 s 1 are each reenacted and amended to read as follows: (1) It shall be unlawful for any person to sell, deliver, or possess any legend drug except upon the order or prescription of "….a naturopathic physician under chapter 18.36A RCW **when authorized by the board of naturopathy, ….”**

Sec. 5. RCW 69.45.010 and 2013 c 19 s 81 are each reenacted and amended to read as follows: …. (12) "Practitioner" means … a naturopathic physician under chapter 18.36A RCW **when authorized to prescribe by the board of naturopathy ….**

- **Name and title of profession the applicant seeks to credential/institute change in scope of practice:**

  Naturopathy (Naturopathic Physicians) RCW 18.36A

- **Applicant's organization:** Washington Association of Naturopathic Physicians (WANP)

  Contact person: Robert May, ND – Executive Director

  Address: 9500 Roosevelt Way NE, Ste 306, Seattle, WA 98115

  Telephone number: 206-547-2130 **Email address**: executive@wanp.org

- **Number of members in the organization:** Approximately 350

  Approximate number of individuals practicing in Washington: 850

  Name(s) and address(es) of national organization(s) with which the state organization is affiliated:
  The American Association of Naturopathic Physicians
  818 18th Street, NW, Suite 250
  Washington, DC 20006 www.naturopathic.org

- **Name(s) of other state organizations representing the profession:** None

OUTLINE OF FACTORS TO BE ADDRESSED

Please refer to RCW 18.120.030 (attached) for more detail. Concise, narrative answers are encouraged. Please explain the following:

(1) Define the problem and why regulation is necessary:

In Washington State, Naturopathic physicians (NDs) are licensed and regulated by the State Board of Naturopathy and have primary care scope of practice, including prescriptive authority for legend drugs, and the controlled substances testosterone and codeine. NDs are not currently authorized to prescribe other controlled substances commonly used in primary care practice.

As of January 2014, NDs are eligible to enroll as primary care providers in Apple Health (Medicaid) and are covered in the Exchange Medicaid Insurance plans, including Coordinated Care Corp., Community Health Plan of Washington, and Molina Healthcare of Washington. This expanded demographic includes many patients with medical conditions that require controlled substances in the primary care setting.

Due to the limitations on ND prescriptive authority, NDs now must refer patients to other primary care providers when controlled substances are necessary. This results in "dual-utilization" of medical providers, and increased costs to patients, insurers, and the State. It also interferes with optimal patient care by disrupting continuity and coordination of care.

In addition, the well-known and increasing shortage of primary care providers due to the expansion of Medicaid and increased coverage under the Affordable Care Act is making such referrals more challenging.

(2) The efforts made to address the problem:

H 4573.4, as submitted by Representative Cody, is the specific effort to update the naturopathic practice act (RCW 18.36A) to address the problem described above.

(3) The alternatives considered:

NDs are licensed and regulated by the State Board of Naturopathy. However, the Board cannot provide for such expansion of scope. Legislation, with rulemaking by the Board of Naturopathy, is required to make this change in prescriptive authority.

(4) The benefit to the public if regulation is granted:

Benefits to the public, insurance carriers and the State, include lower costs, improved quality of care and increased access to primary care providers. Regulation and supervision by the Board of Naturopathy will assure proper qualifications, education, training, examinations, and maintenance of competency.

(5) The extent to which regulation might harm the public:

The need for regulation of controlled substances to protect the public from harm is well documented and was further identified in the passage of HB 2876 (2010) *Concerning pain management* (Moeller), which required health care provider boards and commissions to adopt new and extensive rules regarding chronic, non-cancer pain management.

(6) The maintenance of standards:

The Washington State Board of Naturopathy regulates the naturopathic profession. This body is responsible for and subject to all of the oversight provisions and requirements for effective quality assurance standards to exist in the health profession as defined in the following:

- RCW 18.130 Regulation of Health Professions - Uniform Disciplinary Act
- WAC 246-12 Administrative Procedure and Requirements for Credentialed health Care Providers
- WAC 246-16 Standard of Professional Conduct

Ultimate oversight is already in place under the Washington State Secretary of Health.

(7) A description of the group proposed for regulation, including a list of associations, organizations, and other groups representing the practitioners in this state, an estimate of the number of practitioners in each group, and whether the groups represent different levels of practice.

Naturopathic physicians are the group proposed for regulation and are already licensed under RCW 18.36A and regulated by the State Board of Naturopathy under WAC 246-836. The Washington Association of Naturopathic Physicians (WANP) is the only group in the state representing naturopathic physicians, and has done so since 1934. WANP does not represent groups with different levels of practice. According to the Department of Health, there are currently 1177 NDs licensed in Washington State (as reported at the May 16, 2014, State Board of Naturopathy public meeting.)

(8) The expected costs of regulation:

NDs are already eligible to obtain DEA numbers at a cost of approximately $750 every 3 years. We anticipate additional requirements and costs for continuing education and training for those NDs who choose to prescribe the controlled substances listed under Bill #: H 4573.4.

We do not foresee any additional costs to the State from this legislation.

(9) List and describe major functions and procedures performed by members of the profession (refer to titles listed above.) Indicate percentage of time typical individual spends performing each function or procedure:

Naturopathic physicians are recognized in statute and in practice as primary care providers in the State of Washington. See attached reference.

As primary care providers, NDs supervise, coordinate, and provide initial care or continuing care to patients, and initiate a referral for specialty care and maintain supervision of health care services rendered to the covered person. WAC 284-43-130(26)

Attachment

NATUROPATHIC PHYSICIANS (NDs) ARE PRIMARY CARE PROVIDERS (PCPs)

Health Care Authority, Labor and Industries, and Public Assistance cover NDs as PCPs.

Exchange Regence Innova small group plan includes NDs as physicians performing primary care services.

Exchange Non-PPO Private Insurance plans cover NDs as PCP Physicians: Bridge Span Health Co. (Cambia's Regence individual Exchange Plan); Lifewise Health Plan of WA (subsidiary of Premera Blue Cross); Premera.

Exchange Medicaid Insurance plans cover ND PCP services: Coordinated Care Corp.; Community Health Plan of Washington; Molina Healthcare of Washington.

ND COVERED AS PCPs UNDER EXCHANGE CARRIER PLANS

WAC 284-43-865 OFFICE OF INSURANCE COMMISSIONER. Essential health benefits package benchmark reference plan.

A not grandfathered individual or small group health benefit plan offered, issued, amended or renewed on or after January 1, 2014, must, at a minimum, include coverage for essential health benefits. **"Essential health benefits"** means all of the following:

(1) The benefits and services covered by health care service contractor **Regence Blue Shield as the Innova small group plan** policy form, policy form number WW0711CCONMS, and certificate form number WW0112BINNS, offered during the first quarter of 2012. The SERFF filing number is RGWA-127372701.

NOTE: Regence Innova is the small group plan that was selected as the state's benchmark reference plan for the Exchange. **Naturopathic Physicians (NDs) are included as primary care Physicians (PCPs)** under Regence Innova: **Physician means** an individual who is duly licensed as a doctor of medicine (M.D.), doctor of osteopathy (D.O.) or **doctor of naturopathic medicine (N.D.)** who is a Provider covered under the Contract.

NDs COVERED AS PCPS UNDER HEALTH CARE AUTHORITY

SB 5034 - Making 2013-2015 operating appropriations. (Hill, Hargrove; By Request: Governor Gregoire)

18 NEW SECTION. Sec. 213. FOR THE STATE HEALTH CARE AUTHORITY

33 The appropriations in this section are subject to the following
34 conditions and limitations:
10 (40) Within the amounts appropriated in this section, the authority
11 shall **reimburse for primary care services provided by naturopathic**
12 physicians.

WSR 13-20-031 HEALTH CARE AUTHORITY [Filed September 23, 2013, 3:09 p.m.]
NOTICE

Title or Subject: Medicaid State Plan Amendment (SPA) 13-28. Effective Date: January 1, 2013.

Description: The agency intends to submit medicaid SPA 13-28 to:
• Comply with the state budget approved by the legislature in ESSB 5034, which recognizes **naturopathic physicians as physicians** who can enroll with medicaid and bill medicaid for **physician-related primary care services** provided to medicaid clients…. The agency anticipates no increase in annual aggregate expenditures associated with recognizing **naturopathic physicians** as medicaid providers….

WAC 182-500-0085 Health Care Authority, Medical assistance. definitions—P.
"Physician" means a doctor of medicine, osteopathy, **naturopathy,** or podiatry who is legally authorized to perform the functions of the profession by the state in which the services are performed.

WAC 182-502-0002 HEALTH CARE AUTHORITY. ADMINISTRATION OF MEDICAL PROGRAMS—PROVIDERS
Eligible provider types. The following health care professionals, health care entities, suppliers or contractors of service may request enrollment with the Washington state health care authority (medicaid agency) to provide covered health care services to eligible clients. For the purposes of this chapter, health care services include((s)) treatment, equipment, related supplies, and drugs.
(1) Professionals: …. (p) **Naturopathic physicians;**

NDs COVERED AS PCPS UNDER LABOR AND INDUSTRIES PLANS

WAC 296-20-01010 DEPARTMENT OF LABOR AND INDUSTRIES. Medical Aid Rules. Scope of health care provider network.
…. (2) As of January 1, 2013, the **following types of health care providers** (hereafter providers) must be **enrolled in the network** with an approved provider agreement **to provide and be reimbursed for care to injured workers in Washington state beyond the initial office or emergency room visi**t:
(a) Medical physicians and surgeons;
(b) Osteopathic physicians and surgeons;
(c) Chiropractic physicians;
(d) Naturopathic physicians;
…
(h) Advanced registered nurse practitioners; and
(i) Physician assistants.
… (4) The department may phase implementation of the network to ensure access within all geographic areas. The director of the department shall determine, at his/her discretion, whether to establish or expand the network, after consideration of at least the following:
• The percent of injured workers statewide who have access to at least five **primary care providers** within fifteen miles, compared to a baseline established within the previous twelve months;

WAC 296-20-01002 DEPARTMENT OF LABOR AND INDUSTRIES. Medical aid rules. Definitions.
… **Attending provider:** For these rules, means a person licensed to independently practice one or more of the following professions: Medicine and surgery; osteopathic medicine and surgery; chiropractic; **naturopathic physician**; podiatry; dentistry; optometry; and advanced registered nurse practitioner. An attending provider actively treats an injured or ill worker.

… Doctor or attending doctor: For these rules, means a person licensed to independently practice one or more of the following professions: Medicine and surgery; osteopathic medicine and surgery; chiropractic; **naturopathic physician**; podiatry; dentistry; optometry. An attending doctor is a treating doctor.
… Health services provider or provider: For these rules means any person, firm, corporation, partnership, association, agency, institution, or other legal entity providing any kind of services related to the treatment of an industrially injured worker. It includes, but is not limited to, hospitals, medical doctors, dentists, … osteopathic physicians, … **naturopathic physicians,** and durable medical equipment dealers.

WAC 296-23 DEPARTMENT OF LABOR AND INDUSTRIES. Radiology, radiation therapy, nuclear medicine, pathology, hospital, chiropractic, physical therapy, drugless therapeutics and nursing -- Drugless therapeutics, etc.
NATUROPATHIC PHYSICIANS
296-23-205 General instructions -- **Naturopathic physicians**.
296-23-215 Office visits and special services—**Naturopathic physicians.**

WAC 296-17A-6109 DEPARTMENT OF LABOR AND INDUSTRIES. Classification 6109. 6109-00 Physicians, surgeons, and medical clinics, N.O.C.
6109-04 Naturopaths, N.O.C. Applies to establishments of health practitioners not covered by another classification (N.O.C.) who diagnose, treat, and care for patients, using a system of practice that bases treatment of physiological functions and abnormal conditions on natural laws governing the human body, relying on natural remedies such as, but not limited to, acupuncture, sunlight supplemented with diet, and naturopathic corrections and manipulations to treat the sick. This classification includes clerical office and sales personnel, as well as other employees engaged in service in the naturopath's office.

NDs INCLUDED AS PCPS UNDER DSHS/DOH/DOL

RCW 74.09.010 Public Assistance. Medical care. Definitions
The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.
(1) "Children's health program" ….
(8) "Health home" or **"primary care health home**" means coordinated health care provided by a licensed **primary care provider** coordinating all medical care services, and a multidisciplinary health care team comprised of clinical and nonclinical staff. The term "coordinating all medical care services" shall not be construed to require prior authorization by a **primary care provider** in order for a patient to receive treatment for covered services by an optometrist licensed under chapter 18.53RCW. Primary care health home services shall include those services defined as health home services in 42 U.S.C. Sec. 1396w-4 and, in addition, may include, but are not limited to:
(16) **"Primary care provider"** means a general practice physician, family practitioner, internist, pediatrician, osteopath, **naturopath**, physician assistant, osteopathic physician assistant, and advanced registered nurse practitioner licensed under Title 18 RCW.

RCW 74.09.470 Public assistance. Children's affordable health coverage -- Department duties.
(6) The authority …. shall collaborate with the department of social and health services, department of health, local public health jurisdictions, the office of the superintendent of

public instruction, the department of early learning, health educators, health care providers, health carriers, community-based organizations, and parents in the design and development of this effort. The outreach and education effort shall include the following components:
(e) Development and dissemination of materials to engage and inform parents and families statewide on issues such as: The benefits of health insurance coverage; the appropriate use of health services, including **primary care provided** by health care practitioners licensed under chapters 18.71, 18.57, **18.36A (naturopathic physician),** and 18.79 RCW, and emergency services; the value of a medical home, well-child services and immunization, and other preventive health services with linkages to department of health child profile efforts; identifying and managing chronic conditions such as asthma and diabetes; and the value of good nutrition and physical activity;

WAC 246-338-020 DEPARTMENT OF HEALTH. Licensure—Types of medical test site licenses.
After July 1, 1990, any person advertising, operating, managing, owning, conducting, opening, or maintaining a medical test site must first obtain a license from the department. License types are described in Table 020-1.
(2) Provider performed microscopic procedures (PPMP) ….
(a) PPMP may be performed only by one of the following licensed professionals: … (v) **Naturopath licensed under chapter 18.36A RCW, Naturopathy ….**

WAC 246-803-010 DEPARTMENT OF HEALTH. East Asian Medicine Practitioner Definitions.
The definitions in this section apply throughout this chapter unless the context clearly requires otherwise:
(10) "**Primary health care provider"** is an individual licensed under:
(a) **Chapter 18.36A RCW, Naturopathy;**
(b) Chapter 18.57 RCW, Osteopathy—Osteopathic medicine and surgery;
(c) Chapter 18.57A RCW, Osteopathic physicians' assistants;
(d) Chapter 18.71 RCW, Physicians;
(e) Chapter 18.71A RCW, Physician assistants; or
(f) RCW 18.79.050, "Advanced registered nursing practice" defined—Exceptions

RCW 18.06.140 BUSINESSES AND PROFESSIONS. East Asian medicine practitioners. Consultation and referral to other health care practitioners.
(2) When a person licensed under this chapter sees patients with potentially serious disorders such as cardiac conditions, acute abdominal symptoms, and such other conditions, the practitioner shall immediately request a consultation or recent written diagnosis from a **primary health care provider** licensed under chapter 18.71, 18.57, 18.57A, **18.36A,** or 18.71A RCW or RCW 18.79.050.

WAC 308-96B-010 DEPARTMENT OF LICENSING; Definitions—Individual with disabilities special parking privileges.
For the purposes of determining eligibility under RCW 46.16.381, for individual with disabilities special parking placards and license plates, the following definitions apply:
(1) "Application for individual" means the form provided by the department that must be completed by the individual and **physician.**
(4) **"Licensed physician"** is a health care provider to include: … **naturopath (ND)** ….

HB 2549 (2008) Establishing a patient-centered primary care collaborative program (Seaquist).

NEW SECTION. Sec. 1. The legislature finds that our primary care system is severely faltering and the number of people choosing primary care as a profession is decreasing dramatically. **Primary care providers** include family medicine and general internal medicine physicians, pediatricians, **naturopathic physicians**, advanced registered nurse practitioners, and physician assistants.

Naturopathic Scope of Practice Sunrise
Follow Up Questions to Applicant

Responses from Washington Association of Naturopathic Physicians
Contact: Robert May, ND executive@wanp.org 206-547-2130

July 9, 2014

1. Please explain generally how prescription of controlled substances fits within the traditional philosophy and practice of naturopathy.

The scope of naturopathic medicine has evolved since its inception to include primary care practice. As the profession has grown and become more integrated within the larger healthcare system, the patient demographics have changed as well. NDs now participate in Medicaid, as well as all private insurance plans in Washington. To meet the needs of this larger patient population NDs need prescriptive authority for controlled substances Schedule II - V.

Traditional naturopathic philosophy emphasizes the importance of supporting the patient's innate healing capacity and thus includes a wide array of 'natural' therapeutics, such as diet, lifestyle and nutritional medicine. However, this philosophy does not preclude the use of treatments that are in the best interest of the patient and meet the current standard of care.

NDs are currently trained and licensed to utilize prescription drugs, including testosterone and codeine products in Schedules III, IV and V. Such prescriptions are most commonly used when non-pharmaceutical treatments are not appropriate to address a patient's condition at a particular time.

2. Schedules II through V of the Uniform Controlled Substances Act (UCSA) broadly includes opium/opiates, stimulants, depressants, narcotics, and anabolic steroids, with specific substances and drugs fully set forth in Chapter 69.50 RCW.

   (A) From among the listed drugs and substances in these schedules, which are those that would be commonly used in primary care practice of naturopathic physicians, for what specific purpose, and with what frequency?

ND education and scope of practice focuses on primary care services. Therefore, the ND use of controlled substances will be limited to those medications appropriate for primary care services. In addition, NDs have a wide array of non-pharmacologic treatments and have many options for treatment that do not involve use of controlled substances.

See the attached list of 'top twenty' most commonly prescribed controlled substances from the Prescription Review Program of the Washington Department of Health.

We anticipate, and recommend, that with the addition of prescriptive authority for controlled substances, NDs will be subject to all provisions of the Pain Management Rules, RCW 18.32.785, as applied to ARNPs, MDs, and DOs.

(B) Similarly, which of the listed drugs and substances would be rarely or never used in a naturopathic setting?

NDs would rarely or never use those controlled medications not recognized or appropriate for primary care practice.

Please see the 'top twenty' most commonly prescribed controlled substances list referenced above. We expect NDs prescription patterns will parallel the frequency of use reflected in this data and that additional controlled substances will rarely be used.

3. Is it your intent to include all Schedule II – V controlled substances, or do you intend for the board of naturopathy to have authority to limit the medications in rule?

Yes, it is our intent to include all Schedule II – V controlled substances, consistent with the ND primary care scope of practice. However, the WANP has also requested in our Applicant Report that the legislature includes the following three amendments to H-4573.4/14 4th in the final Sunrise Review Report and Recommendations to the Legislature. These Amendments will require the Board of Naturopathy to (1) adopt new rules on chronic, non-cancer pain management under HB 2876 (2010) *Concerning pain management* (Moeller); and (2) to authorize a naturopathic physician to prescribe controlled substances, as follows:

(1) Include a pain management section that conforms with HB 2876 (2010) *Concerning pain management* (Moeller); plus the following two underlined amendments that will require the Board of Naturopathy to <u>authorize a naturopathic physician to prescribe controlled substances</u> because H 4573.4 fails to require such authorization:

(2) Sec. 3. RCW 69.41.030 and 2013 c 71 s 1 and 2013 c 12 s 1 are each reenacted and amended to read as follows: (1) It shall be unlawful for any person to sell, deliver, or possess any legend drug except upon the order or prescription of "….<u>a naturopathic physician under chapter 18.36A RCW</u> <u>when authorized by the board of naturopathy, ….</u>"

(3) Sec. 5. RCW 69.45.010 and 2013 c 19 s 81 are each reenacted and amended to read as follows: …. (12) "Practitioner" means … <u>a naturopathic physician under chapter 18.36A RCW when authorized to prescribe by the board of naturopathy ….</u>

These amendments will conform naturopathic laws to those of the ARNP, DO, and MD boards and commissions regarding pain management. They will also require the Board of Naturopathy to promulgate new rules covering new education and training requirements for these new controlled substances as further discussed below.

4. Do you have specific data to support the reference to the "well-known and increasing shortage of primary care providers due to the expansion of Medicaid and increased coverage under the Affordable Care Act?"

Yes. Please see the attached document entitled, 'SHORTAGE OF PRIMARY CARE PROVIDERS REFERENCES.'

5. RCW 18.120.030(4)(c) asks the extent to which the public can be confident that qualified practitioners are competent.
   - (A) What education and training qualifies naturopaths to prescribe controlled substances?
   - (B) Please include initial education and training, as well as continuing education currently available to ensure ongoing competency.
   - (C) Please be specific on course content and credits/length and how this compares to the level of preparation offered to other licensed professions with full prescriptive authority.
   - (D) Please also be specific regarding curricula both in Washington and for out-of-state schools offering naturopathy training.
   - (E) Please describe both the current curricula and the training received by practitioners who graduated within the prior thirty years.
   - (F) The draft bill expands the scope of practice for all naturopathic physicians. How can the public be confident all currently licensed naturopaths have sufficient training?

According to Bastyr University, the largest naturopathic medical institution in the country, ND curriculum requires satisfactory completion of a total of 4383.5 hours of instruction. Of these hours, 3173.5 are didactic and 1210 are clinical with 60.5 hours dedicated to pharmacology. In addition, medication management is included in many of the clinical science courses in third and fourth year, though it is very difficult to provide an exact number of hours for these.

The State of Vermont, which is in the process of finalizing full prescriptive authority for NDs, surveyed a number of naturopathic medical institutions in the US and Canada and report those hours of pharmacology instruction are as follows:

- **Canadian College of Naturopathic Medicine, Toronto, ON – 70 hours**
- **National University of Health Sciences, Lombard, IL – 90 hours**
- **National College of Natural Medicine, Portland, OR – 72 hours**
- **Southwest College of Naturopathic Medicine, Scottsdale, AZ – 96 hours**

In Washington State, naturopathic physicians have had prescriptive authority for all legend drugs, including testosterone and codeine products in Schedules III, IV and V, since 2007 (WAC 246-836-210 and 246.836.211.) The WANP understands, according to DOH data, that there have not been any complaints against NDs for prescribing substances that are in the current authorized scope (i.e. legend drugs; codeine and testosterone products.)

Public confidence in ND competence is enhanced by the requirements that all naturopathic graduates must currently take and pass national board licensing exams (NPLEX) that include pharmaco-therapeutic agents in schedules II-V. In addition to the national examinations, the Department of Health, in November 2007, implemented WAC 246.836.210 and 246.836.211 requiring all NDs to complete additional educational hours for prescriptive authority for legend substances and the controlled substances testosterone and codeine products.

Continuing education requirements for NDs in Washington State are defined in WAC 246.836.080. The WANP will recommend to the legislature the inclusion of a requirement for the Board of Naturopathy to promulgate rules covering education and training requirements for this expanded prescriptive authority.

The WANP recommends the DOH and other professions directly provide information about 'the level of preparation offered to other licensed professions with full prescriptive authority.'

Since 2005, all NDs, including those who graduated within the prior thirty years, have been required to meet the education requirements specified in WAC 246.836.211. Similarly, to qualify for expanded prescriptive authority, NDs will have to meet appropriate and clearly defined educational requirements promulgated by the Board of Naturopathy following passage of this legislation, including the amendments recommended above.

Evidence of public confidence in NDs is demonstrated by a finding in the 2013–2014 Puget Sound Health Alliance report that rated Bastyr Center for Natural Health the fourth highest score for 'Overall Rating of the Provider', a measure of the patient's overall satisfaction. This was out of 46 medical groups with clinics in 185 locations across the Puget Sound region. The Center includes the Doctor of Naturopathic Medicine program.

6. RCW 18.120.030(3) asks what alternatives were considered to the proposal.
    - (A) Did you consider options other than granting full prescriptive authority to address the problem you identified with treating an expanded demographic?
    - (B) Is full prescriptive authority, including all Schedule II-V controlled substances, the only option?

Yes, full prescriptive authority, including all Schedule II-V controlled substances, is the only option available for treating the expanded demographic of patients in Washington. RCW 18.36A.020 (10) of the Naturopathy Practice Act, specifically prohibits the prescribing of controlled substances other than codeine and testosterone products that are contained in Schedules III, IV, and V in chapter 69.50 RCW. Therefore, only an amendment to this law will extend the authority to prescribe controlled substances to NDs.

Naturopathic prescriptive authority will be the same as that of ARNPs in a primary care setting. Full authority is necessary to address the full range of primary care clinical situations and also to maintain the ability for NDs to access new drugs that will surely be developed for use in primary care over time. Expanded prescriptive authority is also necessary to maintain access to changes in classification of medications. This recently occurred with Tramadol, previously a legend medication. It will soon be reclassified as a Schedule IV drug and NDs will no longer have authority to prescribe it.

Top 20 Controlled Substances

	01/01/2012-12/31/2012			01/01/2013-12/31/2013	
	Controlled Substance Generic Name	**# of RXs**	**# of Recipients**	**Controlled Substance Generic Name**	**# of RXs**	**# of Recipients**
1	HYDROCODONE /ACETAMINOPHEN	3,007,054	1,153,732	HYDROCODONE /ACETAMINOPHEN	2,814,288	1,109,338
2	OXYCODONE HCL	927,899	252,365	OXYCODONE HCL	962,909	271,387
3	OXYCODONE HCL/ACETAMINOPHEN	922,408	399,757	OXYCODONE HCL/ACETAMINOPHEN	854,344	375,630
4	ZOLPIDEM	916,823	225,108	ZOLPIDEM	834,515	204,446
5	ALPRAZOLAM	657,064	182,898	ALPRAZOLAM	638,556	180,613
6	LORAZEPAM	644,306	203,996	AMPHETAMINE	518,964	92,703
7	CLONAZEPAM	529,671	106,499	CLONAZEPAM	518,349	106,605
8	AMPHETAMINE	475,749	85,865	LORAZEPAM	457,689	158,821
9	METHYLPHENIDATE HCL	412,848	75,145	METHYLPHENIDATE HCL	414,548	76,226
10	MORPHINE SULFATE	333,717	65,950	MORPHINE SULFATE	328,015	66,173
11	DIAZEPAM	292,312	124,106	DIAZEPAM	278,931	119,725
12	ACETAMINOPHEN WITH CODEINE	243,795	139,650	ACETAMINOPHEN WITH CODEINE	211,735	119,994
13	~ METHADONE HCL	211,155	27,862	~ METHADONE HCL	191,545	25,486
14	GUAIFENESIN/CODEINE PHOSPHATE	180,170	148,100	GUAIFENESIN/CODEINE PHOSPHATE	186,139	153,634
15	TESTOSTERONE	144,088	41,884	TESTOSTERONE	156,896	45,000
16	BUPRENORPHINE HCL/NALOXONE HCL	138,928	14,671	HYDROMORPHONE HCL	138,165	49,107
17	HYDROMORPHONE HCL	132,190	48,272	BUPRENORPHINE HCL/NALOXONE HCL	137,558	15,548
18	LISDEXAMFETAMINE DIMESYLATE	125,911	25,104	LISDEXAMFETAMINE DIMESYLATE	129,295	25,691
19	CARISOPRODOL	125,095	26,943	PREGABALIN	120,854	25,560
20	PREGABALIN	118,266	24,108	CARISOPRODOL	110,555	23,584

** The recipient count for each drug is unduplicated but a recipient may have received more than one top 20 drug*

~ Methadone data in the PMP does not include Methadone dispensed for treatment at Opioid Treatment Programs

DOH SUNRISE REVIEW QUESTION ON PCP SHORTAGE

Submitted by WANP Robert May,ND, Executive Director

DOH: Do you have specific data to support the reference to the "well-known and increasing shortage of primary care providers due to the expansion of Medicaid and increased coverage under the Affordable Care Act?"

FEDERAL AND WA STATE LAWS RELATED TO SHORTAGE OF PRIMARY CARE PROVIDERS

DHHS Rule: We continue to encourage Exchanges to consider a broader definition of the types of providers who may furnish primary care services, because this should improve access to such services for consumers, particularly those in medically underserved or rural areas.

DHHS, 45 CFR Parts 155, 156, and 157. e. Network Adequacy Standards (§ 156.230) 03/27/2012.

Response: **We continue to encourage Exchanges to consider a broader definition of the types of providers who may furnish primary care services, because this should improve access to such services for consumers, particularly those in medically underserved or rural areas.** We also recognize that the definition of a "primary care provider" should be consistent across health insurance programs to the extent possible, and we encourage Exchanges to be mindful of existing definitions and approaches in other health insurance programs when outlining corresponding standards for QHP issuers participating in the Exchange. All provider contracts executed by QHP issuers participating in the Exchange must be fully compliant with State scope of practice laws.

https://www.federalregister.gov/articles/2012/03/27/2012-6125/patient-protection-and-affordable-care-act-establishment-of-exchanges-and-qualified-health-plans

WASHINGTON LAWS, 2011 Ch. 150 [1109] CHAPTER 150 [Engrossed Substitute House Bill 1183] PRIMARY CARE PROVIDERS—INCREASE—CLINICAL ROTATION

http://www.leg.wa.gov/CodeReviser/documents/sessionlaw/2011pam2.pdf

150 AN ACT Relating to increasing the number of primary health care providers in Washington; adding new sections to chapter 28B.115 RCW; and creating a new section.

Be it enacted by the Legislature of the State of Washington:

NEW SECTION. Sec. 1**. The legislature finds that a severe shortage of primary health care providers exists in Washington, particularly in rural and underserved areas of the state.** The legislature further finds that an over reliance on specialty health care at the expense of primary care results in a health care system that is less efficient. The legislature further finds that institutions of higher education must produce more primary care providers. The legislature further finds that the efficient use of clinical sites for rotations will expand the supply of primary care providers. The legislature further finds that expanding residency programs in community health centers will increase residents' exposure to primary care practice.

(16) **"Primary care provider" means a** general practice physician, family practitioner, internist, pediatrician, osteopath, **naturopath**, physician assistant, osteopathic physician assistant, and advanced registered nurse practitioner licensed under Title 18 RCW.

WASHINGTON LAWS, 2011 Ch. 150 [1109]
CHAPTER 150 [Engrossed Substitute House Bill 1183]

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REFERENCES TO WA STATE PCP SHORTAGES MEDICAID PLANS

Washington State Office of the Insurance Commissioner

FOR IMMEDIATE RELEASE – June 12, 2014

Media contact: Public Affairs (360) 725-7055

Individual health insurance market expands more than 30 percent – enrollment now at 327,000

OLYMPIA, Wash. – **The individual health insurance market grew 30 percent in one year to more than 327,000 people in Washington state**, according to new information reported by health insurers to the Office of the Insurance Commissioner… The latest enrollment numbers and other insurance market data also indicate that Washington state has succeeded in **reducing the number of uninsured by more than 370,000….** "The enrollment numbers from the insurers continue to show sustained growth in our individual health insurance market," said Insurance Commissioner Mike Kreidler…. **The Insurance Commissioner's Office estimated earlier this year that 113,000 of those who received notices would qualify for subsidies and 30,000 would qualify for the state's newly expanded Medicaid program, Apple Health.**

Key findings include: …. "People looking to buy their own health insurance or switch plans next year will likely have more choices," said Kreidler. "This, along with today's enrollment numbers, are more evidence that health reform is working." Release No. 14-29 The full report on Washington state's individual health plan enrollment.

Seattle Times

County survey: For Medicaid patients, access to primary-care may not be as advertised

May 13, 2014 at 11:04 PM

Posted by Carol M. Ostrom

http://blogs.seattletimes.com/healthcarecheckup/2014/05/13/county-survey-for-medicaid-patients-access-to-primary-care-may-not-be-as-advertised/

"Using 'mystery shoppers' looking for access to health care, Public Health – Seattle & King County has found troubling indications that access to primary-care providers may not be as advertised. **About three-quarters of the time, primary-care providers listed as accepting new patients on Medicaid managed-care organization websites in fact told the "shoppers" they were not accepting new Medicaid patients…. King County added about 80,000 new adult Medicaid clients over the past six months, surpassing the state's 2018 enrollment target….** Among states that expanded Medicaid and created a state-based exchange, Hutchinson calculated that **Washington's enrollment, as a percentage of those potentially eligible, was bested only by Massachusetts, Rhode Island and Vermont.**

An editorial in the Seattle Times from March 10, 2013 "Solving Washington's Primary-Care Workforce Shortage" (in support of SB 5615), points out that **"The likely expansion of Medicaid means about 300,000 more Washingtonians will be added to the rolls.** They will need access to care, despite a shortage of providers in every single county."
http://seattletimes.com/html/editorials/2020518472_editphysicianloanrepaymentxml.html?fb_action_ids=10101432101493955&fb_action_types=og.recommends&fb_source=aggregation&fb_aggregation_id=288381481237582

Inslee pleases docs with focus on access to primary care
February 13, 2014 at 4:35 PM Posted by Carol M. Ostrom
http://blogs.seattletimes.com/healthcarecheckup/2014/02/13/inslee-pleases-docs-with-focus-on-access-to-care/
Among them were **potential shortages of physicians and other health-care providers and how to continue increased reimbursements for primary-care doctors who see Medicaid patients — a group that has grown rapidly with the expansion of Medicaid under the Affordable Care Act.**

The Joint Select Committee on Health Reform Implementation
Workforce Advisory Group Final Report November 22, 2010 (attached)
The Workforce Advisory Group (WAG) was convened by the Joint Task Force on Health Reform Implementation (the Joint Task Force). The purpose of the WAG was to advise the Joint Task Force on ways to address the current workforce shortage, which is expected to increase due to federal health care reform and is already problematic due to demographic changes and projections in Washington….
Ideas Presented to the Workforce Advisory Group1
Short-Term Long-Term I. Efficient Use of Existing Primary Care Workforce
Allow naturopaths to be primary care practitioners for purposes of Medicaid.
Add naturopaths to the list of provider types covered by Medicaid.
Modernize the scope of practice of naturopaths to allow all minor office procedures and increased prescriptive authority (to include schedule II-V controlled substances).

REFERENCES TO WA STATE PCP SHORTAGES
ALL PLANS
The Health Resources and Services Administration (HRSA), an agency of the U.S. Department of Health and Human Services - Health Professional Shortage Areas
6/16/2014
HPSAs may be designated as having a shortage of primary medical care, dental or mental health providers. They may be urban or rural areas, population groups or medical or other public facilities.
NHSC Jobs Center Exported Search Results

Find Shortage Areas: HPSA by State & County
NOTE: The following information was obtained from the HRSA site when entering WASHINGTON STATE for All Counties for Primary Care Medical.
Data as of: 6/16/2014
STATE: WASHINGTON
County: All Counties
Discipline: Primary Medical Care
Open Positions = 63 PCP positions available in WA State As of January 1, 2014:
USA: There are currently approximately 6,000 designated Primary Care HPSAs. Primary Care HPSAs are based on a physician to population ratio of 1:3,500. In other words, when there are 3,500 or more people per primary care physician, an area is eligible to be designated as a primary care HPSA. Applying this formula, **it would take approximately 8,000 additional primary care physicians to eliminate the current primary care HPSA designations.** Additionally, the formula used to designate primary care HPSAs does not take into account the availability of additional primary care services provided by Nurse Practitioners and Physician Assistants in an area. **Other sources describing primary care supply use other ratios; for example, a ratio of 1 physician to 2,000 population. To meet this ratio, approximately 16,000 more primary care physicians would need to be added to the current supply in HPSAs.**
http://www.hrsa.gov/shortage/
http://hpsafind.hrsa.gov/HPSASearch.aspx
http://nhscjobs.hrsa.gov/external/search/export.seam?type=html&query=%7B%22fq%22:%22IsPrimaryCareFacility:true%22,%22q%22:%22%20GeoLocation:%5B46.63126233691654,-125.29397160781252%20TO%2048.84729856693493,-116.18630559218752%5D%22,%22sort%22:%22PositionsOpen_PC%20desc%22,%22rows%22:%22200%22%7D

Kaiser Family Foundation (reporting on HRSA's findings for Shortage Areas Statistics, as of April 28, 2014, for Primary Care Health Professional Shortage Areas)

http://kff.org/other/state-indicator/primary-care-health-professional-shortage-areas-hpsas/
Sources: Bureau of Clinician Recruitment and Service, Health Resources and Services Administration (HRSA), U.S. Department of Health & Human Services, HRSA Data Warehouse: Designated Health Professional **Shortage Areas Statistics, as of April 28, 2014**
Primary Care Health Professional Shortage Areas (HPSAs)

Location	Total Primary Care HPSA Designations	Percent of Need Met	Practitioners Needed to Remove HPSA Designation
United States	**6,0871**	**60.41%**	**8,073**
Washington	**147**	**46.71%**	**228**

NOTES: For primary medical care, the population to provider ratio must be at least 3,500 to 1 (3,000 to 1 if there are unusually high needs in the community). The number of primary care HPSA designations includes HPSAs that are proposed for withdrawal and HPSAs that have no data. By statute, designations are not withdrawn until a Federal Register Notice is published, generally once a year on or around July 1. The percent of need met is computed by dividing the number of physicians available to serve the population of the area, group, or facility by the number of physicians that would be necessary to eliminate the primary care HPSA (based on a ratio of 3,500 to 1 (3,000 to 1 where high needs are indicated)).The number of additional primary care physicians needed to achieve a population-to-primary care physician ratio of 3,500 to 1 (3,000 to 1 where high needs are indicated) in all designated primary care HPSAs, resulting in their removal from designation. The formula used to designate primary care HPSAs does not take into account the availability of additional primary care services provided by nurse practitioners and physician assistants in an area.

The National Conference of State Legislators
The ACA May Aggravate the Doc Shortage. What's the ACA Going To Do About It?
by Anthony Wilson, California Healthline Contributing Editor
Wednesday, June 11, 2014
http://www.californiahealthline.org/road-to-reform/2014/the-aca-may-aggravate-the-doc-shortage-whats-the-aca-going-to-do-about-it
The Obama administration and other ACA supporters crowed about the large enrollment figures, offering them as evidence that the law is working as intended. However, to paraphrase a common axiom, no good news comes without consequence. **While many agree it is good news that more U.S. residents have access to coverage, the influx of insured residents also means that the focus might need to be redoubled on a pre-existing problem: a shortage of primary care providers**. Scope of the Situation: Concerning, or Dire? Most observers predict that the ACA will further aggravate anticipated primary care physician shortages, but the question is by how much.

Primary Care Workforce *November 2011*
http://www.ncsl.org/research/health/primary-care-workforce.aspx
According to the information on this site, **in 2011 19-33% of the population in Washington State lived in a "Designated Health Professional Shortage Area".** From the same site, in the section entitled *Primary Care Workforce: Resources for State Policymakers*: "In 2009, the national primary care physician shortage was estimated to reach 21,000 by 2015. Fewer medical graduates are selecting primary care as a specialty and existing primary care physicians are retiring or leaving for opportunities in other fields. With passage of the Affordable Care Act,[1] it is estimated that an additional 32 million Americans will have insurance coverage by 2019. Starting in 2014, millions of the newly insured will seek medical care in a primary care setting, placing an even greater strain on the primary care workforce.

The Washington Policy Center
The Looming Doctor Shortage
By Dr. Roger Stark, MD, FACS, November, 2011
http://www.washingtonpolicy.org/publications/notes/looming-doctor-shortage
"**The United States in general and Washington State in particular are facing a severe doctor shortage in the next 10 to 15 years.** Not only is the population growing, but the baby boomer generation is aging and will require more medical services in the near future. **Also, the new federal health care law, the Patient Protection and Affordable Care Act, will give health insurance to 30 million previously uninsured people over the next few years.** These millions of newly insured patients will further burden our stretched provider network."

REFERENCES TO U.S. PCP SHORTAGES
Projecting the Supply and Demand for Primary Care Practitioners Through 2020
http://bhpr.hrsa.gov/healthworkforce/supplydemand/usworkforce/primarycare/
Published November 2013
HRSA: If the system for delivering primary care in 2020 were to remain fundamentally the same as today, **there will be a projected shortage of 20,400 primary care physicians**…. Demand for primary care services is projected to increase through 2020, **largely because of aging and population growth and, to a much lesser extent, from expanded insurance coverage as the Affordable Care Act is fully implemented.**

Doctor Shortage Not Impacting Just Veterans

Written by Raven Clabough

Tuesday, 03 June 2014 15:40

http://www.thenewamerican.com/usnews/health-care/item/18400-doctor-shortage-not-impacting-just-veterans

An investigative report released last week helped to shed some light on an issue that is plaguing America's veterans. According to the report, 1,700 veterans waiting to see a doctor at a Phoenix Veterans Affairs hospital were in fact missing from an official waiting last. The report also revealed that the Veterans Affairs Department is short of 400 doctors. **And the National Journal reported that the shortage of doctors is not merely limited to the VA. "**America is running out of doctors," wrote the National Journal. "The country will be 91,500 physicians short of what it needs to treat patients by 2020, according to the Association of American Medical Colleges. By 2025, it will be short 130,600." **The highest demand for the Veterans Affairs Department, as well as nationwide, is for primary care physicians, such as general internists, family doctors, and pediatricians** — the types of doctors many people go to first for non-emergency medical attention before seeing specialists. **In 2012, an Annals of Family Medicine study predicted the country will need 52,000 more primary-care physicians by 2025**

Additional Summary Comments Supporting the Naturopathic Scope of Practice Sunrise Review

Submitted by the Washington Association of Naturopathic Physicians
Contact: Robert May, ND executive@wanp.org 206-547-2130

Benefits of ND Prescriptive Authority for Controlled Substances, Schedules II - V

By granting full prescriptive authority for naturopathic physicians (NDs), the state and its patients will benefit because health care costs are expected to decrease, access is expected to increase, and a greater mix of health care providers will all benefit primary care patients. Specifically, duplicative, fragmented, and delayed services will be minimized or eliminated; as well as emergency room referrals for filling Schedule II-V prescriptions and double billing.

All health care practitioners recognize the potential harm to the public if appropriate medication therapy is delayed. Restricting availability of Schedule II-V drugs to ND patients represents a serious risk to public life, health, and safety.

Benefits of ND Prescriptive Authority for Controlled Substances, Schedules II – V, also include the following:

a) The public will benefit by the availability of additional qualified providers, already functioning in their primary care practice capacity, to prescribe prescription drugs, which may be more appropriate and less costly for the patient.
b) The State benefits because ND licensing fees cover all the costs of regulating ND education, training, and enforcement.
c) Patients will benefit in the reduction in time off work and transportation costs.
d) Patients are also protected by existing Drug Enforcement Agency requirements that apply equally to NDs and other health care providers who prescribe controlled substances. The Board of Pharmacy also provides sanctions for misuse of controlled substances.
e) Patients will benefit from ND treatment of the whole person as primary care providers, assuring continuity in patient treatment and greater accountability of the provider. Patients will feel more assured when they have one provider to go to regarding their care and treatment.
f) Patient care is also assured because NDs are already trained as PCPs to use independent judgment, consult with other health care providers, know their scope limits, and refer patients to more specialized providers when necessary.
g) And, NDs are traditionally very conservative in prescribing medications and typically utilize more natural, educational, lifestyle approaches, unless otherwise indicated for specific patient needs.

Washington State Health Care Innovation Plan, The Washington Way JANUARY 2014

http://www.hca.wa.gov/shcip/Documents/SHCIP_InnovationPlan.pdf

Page 40: "Leverage Washington State's Progressive Scope of Practice Laws to Improve Patient Management and Mitigate the Shortage of Primary Care Providers."

"Washington has led in scope of practice innovation in several disciplines, providing additional opportunity for meeting the needs of a growing and changing population. For example, Washington is one of 18 states that grant independent practice and full prescriptive authority to ARNPs. …. Roadmap focus areas will include:

□ Enhancing the supply of ARNPs as well as other primary care providers, including physician assistants….

□ Deploying registered nurses to their full potential…"

WANP Recommendation: NDs also need to be deployed to their full potential with full prescriptive authority.

Page A13: "Primary Care Workforce"

"Washington's current health workforce must continue to build capacity and make the shift to more collaborative and team-based care across the gamut of rural and urban areas and in support of a population diverse in age, disability, race, and ethnicity. As is the case in many parts of the country, the primary care workforce is facing significant challenges, and must both expand in number, work to full scope, and find new ways of extending services. Data also demonstrate issues with mal-distribution of the primary care workforce in many rural areas of the state, particularly post-Medicaid expansion."

WANP Recommendation: As is the case in many parts of the country, including Washington State, the primary care workforce is facing significant challenges and must both expand in number, work to full scope, and find new ways of extending services by allowing NDs to 'work to full scope' with full prescriptive authority.

Responses from Washington Association of Naturopathic Physicians
Contact: Robert May, ND executive@wanp.org 206-547-2130

July 27, 2014

Overview

In comments submitted to the Department of Health and offered in testimony at the public hearing on July 17, 2014, it is evident that there are two primary concerns of opponents to this Sunrise Review:

1) Public safety in relation to prescription of opiate-based medications, and
2) Naturopathic education and training

The WANP recognizes and agrees that both of these issues need to be addressed in order for the proposed legislation to serve the public good and improve the quality of naturopathic medical care in our State. We recognize the wide spread public health issues in our state and across the country related to the abuse and addiction from opiate medications, as well as the potential for overdose and serious adverse reactions with these drugs. We recognize that expanded prescriptive authority carries with it a significantly increased burden of responsibility for NDs and that such expanded authority also raises issues of drug-seeking behavior and diversion of medications.

To address these increased risks to public safety, we advocate for inclusion in the proposed legislation of, and will promote to the naturopathic profession, awareness and use of, all of the State's systems, monitoring, and reporting programs related to controlled substance prescribing, including:

Pain Management statutory language (http://apps.leg.wa.gov/WAC/default.aspx?cite=246-853-673),

Prescription Monitoring Program (http://www.doh.wa.gov/ForPublicHealthandHealthcareProviders/HealthcareProfessionsandFacilities/PrescriptionMonitoringProgramPMP.aspx),

DOH Pain Management Resources (http://www.doh.wa.gov/LicensesPermitsandCertificates/MedicalCommission/MedicalResources/PainManagement.aspx).

These established programs, in addition to the increased requirements for education and training that are detailed below, will ensure public safety by providing NDs with resources to safely and competently utilize medications from Schedules II – V in their primary care practices.

We also want to highlight the safe and successful prescriptive practices of naturopathic physicians at their current level of prescriptive authority. Since 2007 NDs in Washington have had authority for ALL legend drugs, and the controlled substances testosterone and codeine products. In addition to the aforementioned and widely recognized issues of abuse and addiction with opiate medications, it should be noted that many legend drugs have significant potential for drug interactions, (e.g. MAO inhibitors, anti-fungal azole medications, Coumadin), require more knowledge and monitoring to prescribe with safe parameters (e.g. Coumadin, lithium, insulin) and have serious potential side effects and complications (e.g. insulin, NSAIDs, diuretics, SSRIs).

The fact that NDs have incorporated legend drugs into their primary care practices successfully and without complaint or disciplinary action from the DOH since 2007 demonstrates that our doctors have a significant and working awareness and competence in medication therapy and management – and that with the supplemental education requirements proposed below – will be able to incorporate expanded prescriptive authority for Schedule II – V medications successfully and to the public's benefit.

We also offer the perspective that one of the primary factors impacting patient safety with regard to prescription medications is a strong doctor / patient relationship. Both naturopathic medical education and philosophy emphasize a comprehensive understanding of multiple health factors in patient assessment, including psycho-social parameters that give the doctor more insight into the core issues impacting a patient's health. NDs also emphasize patient education and self-responsibility for health positive behaviors. This is the reason that naturopathic office visits tend to take

more time, with 60-minute initial visits and 30-minute return visits quite common among the profession.

These naturopathic practice patterns and emphasis on the doctor – patient relationship, in combination with the wide array of other traditional non-drug naturopathic modalities, such as clinical nutrition, lifestyle counseling, body work techniques, and stress management practices create a foundation in which the use of controlled substance prescriptions can be used in lower dosages and for shorter periods of time, thus limiting the inherent abuse and addiction potential of these substances.

The proposals offered below for increasing both supplemental and continuing competency education will ensure that NDs safely and competently prescribe medications from Schedules II – V. We believe these additional educational requirements address the issues raised in the public hearing and the written comments submitted to the DOH.

DOH Public Hearing Panel Questions from 7/7/14

1. **Much of the information you've submitted emphasizes the naturopath's relationship to primary care, but I don't have a good sense of the range of what is considered "primary care." Could you please describe common conditions or medical issues that are likely to present among patients seeking primary care from naturopaths?**

   Primary care has the same meaning for naturopathic physicians that it does for other primary care providers, such ARNPs, MDs, DOs and PAs. Please see the attached document including a description of 'primary care' from the American Academy of Family Physicians. NDs manage and treat the same spectrum of acute and chronic conditions. ("AAFP primary care definition.")

   In naturopathic practice, common conditions include, but are not limited to, infections, abdominal pain and digestive disorders, chest pain, sprains and strains, fatigue, headaches, fevers, skin conditions, as well as chronic conditions such as high blood pressure, high cholesterol, asthma, anxiety, depression, hormone issues, diabetes, skin conditions, and women's health

issues. Like other primary care providers, NDs also perform physical exams, PAP smears and well-child visits. They order laboratory tests, provide immunizations and refer for specialist services whenever appropriate.

NDs have been providing primary care services for nearly 20 years in Washington and are recognized for contracting and reimbursement by all major health plans, including the Medicaid and Labor and Industries systems. Claims for naturopathic services utilize the same AMA CPT codes for office visits and primary care procedures as other primary care providers. Diagnoses are recorded with the same ICD-9 coding system used throughout the health care system. In addition, the WANP has already presented continuing education programs for naturopathic physicians in the new ICD-10 diagnostic coding system set to take effect in October 2015.

2. **Your submittals state that "the ND use of controlled substances will be limited to those medications appropriate for primary care services" and that "NDs would rarely or never use those controlled medications not recognized or appropriate for primary care practice." Could you please talk about which of the Schedule II-V substances would be appropriate for the primary care services you've described?**

   Examples of common controlled substances that could be used in naturopathic primary care practice include, but are not limited to the following:

   Schedule V:
   Codeine products – *Cough suppressant (authorized currently)*
   Pregabalin – *Anti-convulsant, Analgesic in neuropathic pain*
   Lomatil / Preparations w/small amts of opium – *Anti-diarrheal (Very rarely prescribed)*

   Schedule IV:
   Xanax – *Anxiolytic, sedative*
   Librium – *Anxiolytic, sedative*
   Klonopin – *Anxiolytic, sedative*
   Valium – *Anxiolytic, sedative*
   Zolpidem – *Hypnotic for insomnia*
   Tramadol – *Analgesic*
   Soma – *Anti-spasmodic (Very rarely prescribed)*

Schedule III:
Vicodin – *Analgesic*
Marinol – *Anti-nausea (Very rarely prescribed)*
Tylenol 3 – Analgesic (authorized currently)
Testosterone – Anabolic steroid (authorized currently)

Schedule II:
Ritalin – *Stimulant for ADHD*
Adderall - *Stimulant for ADHD and Narcolepsy*
Oxycodone – *Analgesic for severe pain*
Desoxyn – *Stimulant for ADHD and Obesity*
Codeine – *Analgesic for acute pain, NSAID allergy*
Morphine – *Analgesic for severe chronic pain (as an alternative to Oxycodone, rarely)*

As with all other professions with prescriptive authority, NDs must practice within the limits of their training and licensed scope of practice.

3. **Can you give us a general estimate of the percentage of primary care cases that would require Schedule II-V substances?**

   Specific data is not available to assess the actual percentage of controlled substance prescriptions by naturopathic physicians. We expect that ND prescriptive patterns will follow similar trends as other primary care providers with the caveat that NDs may prescribe controlled substances less frequently as their patients are often seeking alternatives to drug therapies.

4. **Some additional material you submitted draws a parallel between naturopaths and ARNP prescriptive authority. Have you read the ARNP rules relative to that group's prescriptive authority, and are naturopaths seeking the same conditions and requirements as those applied to ARNPs?**

   The WANP has reviewed the ARNP rules for prescriptive authority:

   WAC 246-840-410 "Application requirements for ARNP prescriptive authority"
   WAC 246-840-420 "Authorized prescriptions with prescriptive authority"
   WAC 246-840-450 "Renewal of ARNP prescriptive authority"

We assume these Rules provide an assurance of public safety and regulation and we have identified numerous parallels in the scope of practice and need for controlled substances in Schedules II – V between the ARNP primary care providers and naturopathic primary care providers. In terms of naturopathic primary care services, we do advocate for comparable conditions and requirements as those applied to ARNP primary care providers with regard to prescriptive authority for Schedules II - V.

5. You have asserted that naturopaths will help to fill a shortage in primary care practitioners and provided numerous references to such a shortage in other documents, several of which specify shortages in rural or underserved areas. You also included data from the federal Health Professions Shortage Areas database, which shows the distribution of shortage areas and underserved populations by county. Could you please talk about the geographic distribution of naturopaths in relation to the underserved areas and specific populations identified in the HRSA database?

Attached are geographic maps ("Maps ND by county 7-18-14") from the Department of Health identifying the location of NDs throughout Washington State. While the majority of NDs are currently located in King County, we anticipate continuing expansion into all areas of Washington. This is supported by a study conducted at Bastyr University that identified a strong interest from naturopathic medical students in practicing in both rural and underserved areas of our state. The study is attached. ("Survey - ND student interest rural or underserved areas.")

We anticipate increasing numbers of NDs serving rural and underserved areas resulting from inclusion of NDs in Medicaid. However, as was noted in the ARNP Sunrise Review report of 1992, some providers "are unwilling to move to rural locations because under current law they know that they cannot provide the full range of indicated medication therapy their patients might require." NDs face similar challenges in primary care rural practices due to this limitation in prescriptive authority.

6. The proposed bill would give naturopaths prescriptive authority only for those Schedule II-V substances that are "necessary in the practice of

naturopathy." In your submittals, you've stated that you expect "ND prescribing patterns will parallel the frequency of use" shown in the Prescription Monitoring Program table you submitted. There are 20 items on that list, compared with considerably more than 20 substances and all manner of derivatives listed in Schedule II alone. At the same time, your submittals indicate your intent to include all Schedule II-V substances. Given what you've said about limitations of use to primary care and probable use paralleling the PMP list, could you please explain why everything on Schedules II-V is "necessary in the practice of naturopathy"?

The WANP would like to be very clear that we do not consider "everything on Schedules II –V is 'necessary to the practice of naturopathy'" and most controlled substances are rarely, if ever used by any of the primary care professions**,** as evidenced in data from the Prescription Monitoring Program. This data shows that the twenty most common controlled substances, which account for less than 10% of all controlled substances and derivatives listed in Schedules II – V, constitute approximately 90% of controlled substance prescriptions. We also note that none of the professions with full prescriptive authority likely use ALL of the controlled substances available to them. However, the administrative model in use by all other prescribing professions will be applicable to NDs as well. Full access to Schedules II – V also allows for development and change in medication technology and classification of drugs, as has been seen recently with the reclassification of Tramadol from legend to Schedule IV status.

Dentists, podiatrists and nurse practitioners have full access to Schedules II – V, but only use those controlled substances as indicated and appropriate for their scope and patient populations. These same limitations will be in effect for NDs. As a result the WANP feels strongly that naturopathic physicians need access to the full range of Schedule II – V controlled substances.

The primary reason that NDs need prescriptive authority for Schedules II – V controlled substances is to provide optimal care. As primary care providers, NDs see the full range of patients and practice throughout the

state, often as independent practitioners. In acute clinical situations, such as in a severe migraine headache, low back strain/sprain, or in an uncomplicated kidney stone, current prescriptive authority is insufficient and can prevent patients from receiving the most effective treatment. Similarly, in cases of episodic anxiety, current ND prescriptive authority does not include anti-anxiety medications that can adequately address a patient's needs. Patients in any of the above situations must currently incur the cost of time and expense to schedule with another type of provider for these otherwise very manageable situations. Also, in an urgent situation, lack of access to a medication from Schedule II – V could create a hazard for our patients by delaying medically necessary and appropriate therapy and contribute to excessive use of emergency department services.

An additional reason for granting full scope prescriptive authority is that it allows the naturopathic profession to grow and evolve with changes in the health care and pharmaceutical industries. The recent re-classification of the drug Tramadol from legend status to Schedule IV is a good example of the type of problem that can occur when NDs have a limited or partial list of controlled substances.

All providers with full prescriptive authority, including dentists, podiatrists, and nurse practitioners, are required to practice within the limits of their training. Naturopathic physicians will be limited to the use of controlled substances appropriate to their scope of practice and within the context of naturopathic philosophy and training.

Medications commonly used in primary care run the full spectrum of Scheduled drugs to unscheduled Legend drugs. Limiting a primary care provider's prescriptive authority to legend drugs, plus testosterone and codeine products only, as the current naturopathic statute does, significantly compromises the doctor's ability to prescribe appropriate medications.

For example, common medications used for treating ADHD and narcolepsy such as Ritalin and Concerta (methylphenidate) and Adderall (dextroamphetamine/amphetamine) are Schedule II, but another common ADHD medication Stattera (atomoxetine) is a legend drug. While some ADHD patients may benefit from Straterra, if either of the other two most

commonly used ADHD medications (Ritalin and Concerta) are needed, the patient would have to access a different provider.

Common medications used to treat fibromyalgia and neuropathic pain, such as Cymbalta (duloxetine) and Neurontin (gabapentin) are legend drugs, but Lyrica (pregabalin) is a schedule V medication. Again, one particular drug is not appropriate for all patients and primary care providers need the ability to choose the medication that will be the safest and most effective.

In some cases, primary care providers must provide a short-term "bridge" prescription of a medication (such as a benzodiazepine) until the patient can access his or her original prescribing provider or specialist. Primary care providers also often help wean their patients off chronic benzodiazepines when the original prescriber or a specialist is not accessible. This is especially common in low-income underserved clinic settings. And, since benzodiazepines are not included in the current ND prescriptive scope, ND patients must either risk potentially severe withdrawal side effects from abrupt cessation of their medication, or they must access a different provider promptly.

Currently, NDs have very limited medication options in cases of acute and chronic pain. These options include NSAIDs, Tylenol and Codeine products.

NSAIDS such as naproxen and indomethacin are commonly used for mild to moderate acute pain and arthritis. However, in many cases, NSAIDs are inappropriate and potentially dangerous. For example, in patients using blood thinners like warfarin, patients with renal insufficiency, and patients with gastric ulcers these legend drugs are contraindicated.

Tylenol (acetominophen) may help with mild to moderate pain but rarely helps alone in cases of more severe pain, and it may be inappropriate in patients with liver disease. Schedule III Tylenol #3 (acetaminophen/codeine) is in current ND prescriptive scope, but it is indicated for mild to moderate pain.

Other common pain medications used by primary care providers for moderate to moderately-severe pain, such as Schedule III Vicodin (hydrocodone/acetaminophen) and schedule II Percocet

(oxycodone/acetaminophen) can avoid some of the above mentioned problems, but are outside the current scope of NDs.

Ultram (tramadol), a legend drug indicated for moderate to moderately severe acute pain, was a useful legend drug until just recently, when it was reclassified to a Schedule IV (and is now no longer within naturopathic prescriptive authority.)

NDs use many non-drug therapies (such as physical medicine and manual techniques) to relieve pain and often are able to help patients avoid drug therapy completely. However, in cases where those treatments are not effective, or are not medically appropriate, conventional pain medications may be needed, including the commonly prescribed Scheduled medications.

These are just a few examples of how patient care, and in some cases patient safety, can be compromised by the current limitations in prescriptive authority – and they provide a strong rationale for expansion of ND authority to include medications in Schedules II – V.

Response to Issues Raised at the Public Hearing

"Convenience"

The issue of 'patient convenience' was raised as insufficient reason to justify this expansion in prescriptive authority. The WANP fully agrees that convenience alone does not justify this legislative change. However, we also note that expanded prescriptive authority for NDs would decrease the need for patients to schedule additional office visits with additional providers solely for the prescription of a controlled substance. Such decreased utilization protects the doctor patient relationship and contributes to better case management, patient compliance, and quality of care and can save time and cost for additional medical visits, as well as unnecessary trips to the emergency department.

The fact that NDs were not included in the chronic pain management bill in 2010 was also raised. When this bill was passed, NDs only had access to controlled substances testosterone and codeine products, as is currently the case. These controlled substances are not typically relevant to chronic

pain management as defined in the bill and so inclusion of NDs was not warranted.

An MD attendee at the public hearing who supports expansion of ND prescriptive authority offered the perspective that the doctor – patient relationship is of primary importance in prescription safety and effectiveness. The WANP agrees with this perspective and recognizes the nature and average length of time of naturopathic office visits is consistent with this perspective. Extended face-to-face time strengthens the doctor patient relationship and allows the doctor to both gather information and also educate patients about their condition and care.

Education and Training

It is evident from comments to the Department of Health prior to the public hearing that the primary concern about expanding naturopathic prescriptive authority is whether NDs have sufficient education and training to safely incorporate medications from Schedules II – V in their primary care practices. The WANP appreciates these concerns and is committed to advocating for high quality supplemental education for NDs as well as expanded continuing education requirements to ensure ongoing competency and public safety.

Similar concerns were raised in 2005 when the legislature revised the naturopathic practice act RCW 18.36A to expand naturopathic prescriptive authority to include all legend drugs and the controlled substances testosterone and codeine products. Following that legislative action, the Department of Health implemented WAC 246-836-211 that requires the following in order for NDs to be eligible to apply for DEA certification (a pre-requisite to prescribing controlled substances):

WAC 246-836-211
Authorization regarding controlled substances.

(1) Upon approval by the board, naturopathic physicians may obtain a current Federal Drug Enforcement Administration registration. The board may approve naturopathic physicians who have:

(a) Provided documentation of a current Federal Drug Enforcement Administration registration from another state; or

(b) Submitted an attestation of at least ~~four~~ **twelve** hours of instruction. Instruction must be part of a graduate level course from a school approved under chapter 18.36A, 18.71, 18.57, or 18.79 RCW. Instruction must include the following:

(i) Principles of medication selection;

(ii) Patient selection and therapeutics education;

(iii) Problem identification and assessment;

(iv) Knowledge of interactions, if any;

(v) Evaluation of outcome;

(vi) Recognition and management of complications and untoward reactions; and

(vii) Education in pain management and drug seeking behaviors.

(2) The naturopathic physician must retain training documentation at least five years from attestation date.

Since implementation of WAC 246-836-211 in 2007, NDs have had expanded prescriptive authority and according to the Department of Health, there have been no formal charges made against an ND for prescribing within current authorized scope of practice.

Such lack of formal charges against NDs also shows that a residency program, on top of WANP's proposed education requirements, is not needed as ND education and training has been sufficient without residency ever since the passage of the ND's last scope bill mentioned above. Also, the WANP proposed education requirements will be greater than that of ARNPs and ARNPs have also shown that a residency program has not been needed as ARNPs obtained full prescriptive authority without a requirement for a residency program as well.

In this Sunrise process, the WANP proposes to modify WAC 246-836-211 to require an additional **12 hours** of supplemental education (currently 4 hours; ARNPs do not have a supplemental requirement) and training focused on controlled substances in Schedules II – V.

In addition, the WANP proposes changes to continuing competency requirements for NDs, currently defined as follows:

WAC 246-836-080
Continuing competency program.

(1) Licensed naturopathic physicians must demonstrate completion of ~~twenty~~ **thirty** hours of continuing education as provided in chapter 246-12 WAC, Part 7. Only courses in diagnosis and therapeutics as listed in RCW 18.36A.040 shall be eligible for credit.

(2) In emergency situations, such as personal or family illness, the board may in its discretion, for good cause shown, waive all or part of the continuing education requirement for a particular one-year period for an individual licensee. The board may require such verification of the emergency as is necessary to prove its existence.

We propose increasing the annual requirement for ongoing naturopathic continuing education to **30 hours** per year (versus the current 20 hours; ARNPs require 22.5 hours per year.) We also recommend **10 hours**, of the total 30 hours, be required in the area of pharmacology (not currently required; ARNPs require 7.5 hours per year of pharmacology.) This requirement for ongoing annual education in pharmacology is consistent with Oregon's requirement where NDs have had full scope prescriptive authority since 2007. It is also comparable to current continuing competency requirements in Washington for ARNPs who are required to have 15 hours of pharmacology credits every two years.

Please note that the WANP plans to request the legislature to modify H4573.4 to include the amendments specified in our Applicant Report requiring the Board of Naturopathy to promulgate formal rulemaking that requires additional education and training for NDs. The WANP believes the aforementioned recommendations will ensure public safety and ongoing competency of naturopathic physicians in providing optimal primary care services to the citizens of Washington. (See attached "Added Legal References.")

Washington State Health Innovation Plan

The Washington State Health Innovation Plan, published in January 2014, "….is built to achieve three ultimate aims: better health, better care, and lower costs." Page iii.

Approval of this Sunrise Review legislation is fully compatible with the intent and process outlined in the Plan as seen in the following excerpts:

*Page 40: *"Leverage Washington State's Progressive Scope of Practice Laws to Improve Patient Management and Mitigate the Shortage of Primary Care Providers."*

"Washington has led in scope of practice innovation in several disciplines, providing additional opportunity for meeting the needs of a growing and changing population. For example, Washington is one of 18 states that grant independent practice and full prescriptive authority to ARNPs. …. Roadmap focus areas will include:

- *Enhancing the supply of ARNPs as well as other primary care providers, including physician assistants….*
- *Deploying registered nurses to their full potential…"*

WANP Recommendation: NDs also need to be deployed to their full potential with full prescriptive authority.

*Page A13: *"Primary Care Workforce"*

"Washington's current health workforce must continue to build capacity and make the shift to more collaborative and team-based care across the gamut of rural and urban areas and in support of a population diverse in age, disability, race, and ethnicity. As is the case in many parts of the country, the primary care workforce is facing significant challenges, and must both expand in number, work to full scope, and find new ways of extending services. Data also demonstrate issues with mal-distribution of the primary care workforce in many rural areas of the state, particularly post-Medicaid expansion."

WANP Recommendation: As is the case in many parts of the country, including Washington State, the primary care workforce is facing significant challenges and must both expand in number, work to full scope, and find new ways of extending services by allowing NDs to 'work to full scope' with full prescriptive authority.

Report to the Legislature

In its report to the State legislature, the Health Care Authority has identified that lack of access to primary care results in unnecessary use of emergency departments. Approval of this Sunrise Review and passage of the proposed legislation can give NDs tools to more effectively help prevent such unnecessary use of emergency departments.

Emergency Department Utilization: Assumed Savings from Best Practices Implementation
Third Engrossed Substitute House Bill 2127, Chapter 7, Laws of 2012, 2nd Special Session (Partial Veto) January 15, 2013
Washington State Health Care Authority Office of the Chief Medical Officer
http://www.hca.wa.gov/documents/legreports/report-3eshb2127emergencydeptutilization.pdf

"Next Steps:
The seven best practices adopted by hospitals represent just the first step in reducing unnecessary use of the emergency room. To address the demand side of emergency department care, our state must address the larger, systemic reasons why Medicaid clients go to the emergency room for their care. ….. In some cases, ***a lack of adequate or timely access to primary care may contribute to unnecessary use of the emergency department. If a client does not have a primary care physician, or cannot be seen in a reasonable amount of time for a low-acuity need, he or she may turn to the emergency department.*** *….."*

Conclusion

In 1992, the Department of Health conducted a Sunrise Review entitled "Expansion of ARNP Prescriptive Authority." The conclusion of that process was a recommendation from the DOH to approve expansion of prescriptive authority for ARNPs.

The WANP notes numerous parallels throughout that report to the current Sunrise and the proposal to expand prescriptive authority for naturopathic physicians. These include:

- In 1992, ARNPs had "been legally prescribing legend drugs and Class V controlled substances in Washington for 13 years." NDs have been prescribing legend drugs and controlled substances limited to testosterone and codeine products in Schedules III – V for seven years.

- "Their prescribing patterns have proven effective and safe. This is evidenced by: (1) an increased demand for ARNP services, particularly in areas of the health care system underserved by their physician counterparts; (2) high levels of patient satisfaction; and (3) minimal complaints about ARNP prescribers before the boards of

nursing and pharmacy."

- ND licenses in Washington have steadily increased and are now comparable to the number of osteopathic physicians at near 1200.
- Evidence of public confidence in NDs is demonstrated by a finding in the 2013-2014 Puget Sound Health Alliance report that rated Bastyr Center for Natural Health – the teaching clinic for the naturopathic medical program – the fourth highest score for 'Overall Rating of the Provider', a measure of the patient's overall satisfaction. This was out of 46 medical groups with clinics in 185 locations across the Puget Sound region.
- According to the DOH, there have been no complaints and no disciplinary actions against NDs for prescribing within their current scope of practice.

The concluding statements and DOH recommendation in support of the ARNP Sunrise Review of the 1992 identify risks and benefits to the public, including:

"Information provided indicates that restricting availability of Schedule II – IV drugs to certain segments of the population creates a lack of access to care and represents a serious risk to the public life, health, and safety."

- WANP Recommendation: With NDs already serving in primary care roles throughout Washington, the WANP believes that failure to expand prescriptive authority for NDs creates the same risk for lack of access to appropriate care for the public as was noted in 1992.

And,

"The public would benefit by the availability of qualified providers, already functioning in an expanded practice capacity, to prescribe prescription drugs which may be more appropriate and less costly. ARNPs use independent judgment, deal with many of the same maladies as do

physicians, consult with other health care providers, know their limits and know when to refer."

- WANP Recommendation: In light of the documented increased need for primary care providers and increased access to care in Washington, the WANP believes that NDs are very well positioned to offer these same benefits to the public and that this statement is equally true for NDs with the inclusion of expanded prescriptive authority for Schedule II – V controlled substances.

We have identified numerous additional parallels in the 1992 ARNP Sunrise Review report and we have attached a copy for your review.

Given that:

- the circumstances in effect when the ARNPs gained expanded authority are very similar to those at present, in terms of a need for increased access in many areas of Washington,
- that NDs have a demonstrated record of understanding drug therapy and incorporating it in their practices effectively since 2007,
- that there have been minimal complaints and disciplinary action against NDs related to prescriptive authority,
- that the WANP is committed to inclusion of all pertinent controlled substance statutes, as applicable to other prescribing professions,
- that the WANP is committed to inclusion of an amendment to H4573.4 requiring the Board of Naturopathy to promulgate rules requiring additional education and training,
- that the WANP is recommending supplemental education of 12 hours in controlled substances from recognized experts in the field,
- that the WANP is recommending increasing annual continuing competency requirements for NDs to 30 hours per year with 10 specifically in pharmacology, (beyond the current ARNP requirements),

- that NDs in Oregon have been successfully prescribing Schedules II – V since 2007,
- and that this scope expansion will benefit the public, the state, insurers and individual patients,

the WANP encourages the Department of Health to recommend approval of expansion of naturopathic prescriptive authority to include Schedule II – V controlled substances.

WANP REFERENCES

1. **Much of the information you've submitted emphasizes the naturopath's relationship to primary care, but I don't have a good sense of the range of what is considered "primary care." Could you please describe common conditions or medical issues that are likely to present among patients seeking primary care from naturopaths?**

Primary Care

http://www.aafp.org/about/policies/all/primary-care.html

Primary Care

In defining primary care, it is necessary to describe the nature of services provided to patients, as well as to identify who are the primary care providers. The domain of primary care includes the primary care physician, other physicians who include some primary care services in their practices, and some non-physician providers. However, central to the concept of primary care is the patient. Therefore, such definitions are incomplete without including a description of the primary care practice.

The following five definitions relating to primary care should be taken together. They describe the care provided to the patient, the system of providing such care, the types of physicians whose role in the system is to provide primary care, and the role of other physicians, and non-physicians, in providing such care. Taken together they form a framework within which patients will have access to efficient and effective primary care services of the highest quality.

Definition #1 - Primary Care

Primary care is that care provided by physicians specifically trained for and skilled in comprehensive first contact and continuing care for persons with any undiagnosed sign, symptom, or health concern (the "undifferentiated" patient) not limited by problem origin (biological, behavioral, or social), organ system, or diagnosis.

Primary care includes health promotion, disease prevention, health maintenance, counseling, patient education, diagnosis and treatment of acute and chronic illnesses in a variety of health care settings (e.g., office, inpatient, critical care, long-term care, home care, day care, etc.). Primary care is performed and managed by a personal physician often collaborating with other health professionals, and utilizing consultation or referral as appropriate.Primary care provides patient advocacy in the health care system to

accomplish cost-effective care by coordination of health care services. Primary care promotes effective communication with patients and encourages the role of the patient as a partner in health care.

Definition #2 - Primary Care Practice

A primary care practice serves as the patient's first point of entry into the health care system and as the continuing focal point for all needed health care services. Primary care practices provide patients with ready access to their own personal physician, or to an established back-up physician when the primary physician is not available.

Primary care practices provide health promotion, disease prevention, health maintenance, counseling, patient education, diagnosis and treatment of acute and chronic illnesses in a variety of health care settings (e.g., office, inpatient, critical care, long-term care, home care, day care, etc.).

Primary care practices are organized to meet the needs of patients with undifferentiated problems, with the vast majority of patient concerns and needs being cared for in the primary care practice itself. Primary care practices are generally located in the community of the patients, thereby facilitating access to health care while maintaining a wide variety of specialty and institutional consultative and referral relationships for specific care needs. The structure of the primary care practice may include a team of physicians and non-physician health professionals.

Definition #3 - Primary Care Physician

A primary care physician is a generalist physician who provides definitive care to the undifferentiated patient at the point of first contact and takes continuing responsibility for providing the patient's care. Such a physician must be specifically trained to provide primary care services.

Primary care physicians devote the majority of their practice to providing primary care services to a defined population of patients. The style of primary care practice is such that the personal primary care physician serves as the entry point for substantially all of the patient's medical and health care needs - not limited by problem origin, organ system, or diagnosis. Primary care physicians are advocates for the patient in coordinating the use of the entire health care system to benefit the patient.

Definition #4 - Non-Primary Care Physicians Providing Primary Care Services

Physicians who are not trained in the primary care specialties of family medicine, general internal medicine, or general pediatrics may sometimes provide patient care services that are usually delivered by primary care physicians. These physicians may focus on specific patient care needs related to prevention, health maintenance, acute care, chronic care or rehabilitation. These physicians, however, do not offer these services within the context of comprehensive, first contact and continuing care.

The contributions of physicians who deliver some services usually found within the scope of primary care practice may be important to specific patient needs. However, the absence of a full scope of training in primary care requires that these individuals work in close consultation with fully-trained, primary care physicians. An effective system of primary care may utilize these physicians as members of the health care team with a primary care physician maintaining responsibility for the function of the health care team and the comprehensive, ongoing health care of the patient.

Definition #5 - Non-Physician Primary Care Providers

There are providers of health care other than physicians who render some primary care services. Such providers may include nurse practitioners, physician assistants and some other health care providers.

These providers of primary care may meet the needs of specific patients. They should provide these services in collaborative teams in which the ultimate responsibility for the patient resides with the primary care physician. (1975) (2006)

*In this document, the term physician refers only to doctors of medicine (M.D.) and osteopathy (D.O.).

Use of Term

The AAFP recognizes the term "primary care" and that family physicians provide services commonly recognized as primary care. However, the terms, "primary care" and "family medicine" are not interchangeable. "Primary care" does not fully describe the activities of family physicians nor the practice of family medicine. Similarly, primary care departments do not replace the form or function of family medicine departments. (1977) (2011 COD)

WANP Proposed WAC Amendments

Prescriptive Authority for Schedule II – V Controlled Substances

Annual Continuing Education

WANP proposes increasing the annual requirement for ongoing naturopathic education to **30 hours** of continuing education **per year (versus current 20 hours; ARNPs require 22.5 hours per year)** with **10 hours,** of the total 30 hours, required to be in the area of pharmacology **(not currently required; ARNPs require 7.5 hours)**. This requirement for ongoing annual education in pharmacology is consistent with Oregon's requirement where NDs have had full scope prescriptive authority since 2007. It is also comparable to current continuing competency requirements in Washington for ARNPs who are required to have 15 hours of pharmacology credits every two years.

WAC 246-836-080
Continuing competency program.

(1) Licensed naturopathic physicians must demonstrate completion of ~~**twenty**~~ **thirty** hours of continuing education **with ten hours in 'pharmacology'** as provided in chapter 246-12 WAC, Part 7. Only courses in diagnosis and therapeutics as listed in RCW 18.36A.040 shall be eligible for credit.

(2) In emergency situations, such as personal or family illness, the board may in its discretion, for good cause shown, waive all or part of the continuing education requirement for a particular one-year period for an individual licensee. The board may require such verification of the emergency as is necessary to prove its existence.

Supplemental Education for NDs

Supplemental Education and Training for DEA certification

WANP proposes to modify **WAC 246-836-211** to require an additional **12 hours of education (currently 4 hours; ARNPs do not have a**

supplemental requirement) in graduate level instruction by recognized experts in the use of controlled substances in the primary care setting. This is a one-time requirement for NDs to be eligible for DEA certification.

WAC 246-836-211

Authorization regarding controlled substances.

(1) Upon approval by the board, naturopathic physicians may obtain a current Federal Drug Enforcement Administration registration. The board may approve naturopathic physicians who have:

(a) Provided documentation of a current Federal Drug Enforcement Administration registration from another state; or

(b) Submitted an attestation of at **least ~~four~~ 12 hours** of instruction. Instruction must be part of a graduate level course from a school approved under chapter 18.36A, 18.71, 18.57, or 18.79 RCW. Instruction must include the following:

(i) Principles of medication selection;

(ii) Patient selection and therapeutics education;

(iii) Problem identification and assessment;

(iv) Knowledge of interactions, if any;

(v) Evaluation of outcome;

(vi) Recognition and management of complications and untoward reactions; and

(vii) Education in pain management and drug seeking behaviors.

(2) The naturopathic physician must retain training documentation at least five years from attestation date.

WANP Proposed RCW Amendments

a. **Proposed Amendments to H 4573.4:** WANP recommends the Final Sunrise Review Report and Recommendations to the Legislature include a pain management section that conforms with HB2876 (2010) *Concerning pain management* (Moeller)(see below); plus the following two **bolded** amendments that will require authorization by the Board of Naturopathy because H 4573.4 fails to require such authorization, as follows:

Sec. 3. RCW 69.41.030 and 2013 c 71 s 1 and 2013 c 12 s 1 are each reenacted and amended to read as follows: (1) It shall be unlawful for any person to sell, deliver, or possess any legend drug except upon

the order or prescription of "….a naturopathic physician under chapter 18.36A RCW **when authorized by the board of naturopathy, ….**"

Sec. 5. RCW 69.45.010 and 2013 c 19 s 81 are each reenacted and amended to read as follows:

…. (12) "Practitioner" means … a naturopathic physician under chapter 18.36A RCW **when authorized to prescribe by the board of naturopathy ….**

Proposed New Pain Management RCW (bolded words are changes from those in the current MD/DO/ARNP RCWs)

RCW 18.36A.__

Pain management rules — Criteria for new rules.

(1) By June 30, 2016, the board shall adopt new rules on chronic, noncancer pain management that contain the following elements:

(a)(i) Dosing criteria, including:

(A) A dosage amount that must not be exceeded unless a naturopath first consults with a practitioner specializing in pain management; and

(B) Exigent or special circumstances under which the dosage amount may be exceeded without consultation with a practitioner specializing in pain management.

(ii) The rules regarding consultation with a practitioner specializing in pain management must, to the extent practicable, take into account:

(A) Circumstances under which repeated consultations would not be necessary or appropriate for a patient undergoing a stable, ongoing course of treatment for pain management;

(B) Minimum training and experience that is sufficient to exempt a naturopath from the specialty consultation requirement;

(C) Methods for enhancing the availability of consultations;

(D) Allowing the efficient use of resources; and

(E) Minimizing the burden on practitioners and patients;

(b) Guidance on when to seek specialty consultation and ways in which electronic specialty consultations may be sought;

(c) Guidance on tracking clinical progress by using assessment tools focusing on pain interference, physical function, and overall risk for poor outcome; and

(d) Guidance on tracking the use of opioids, particularly in the emergency department.

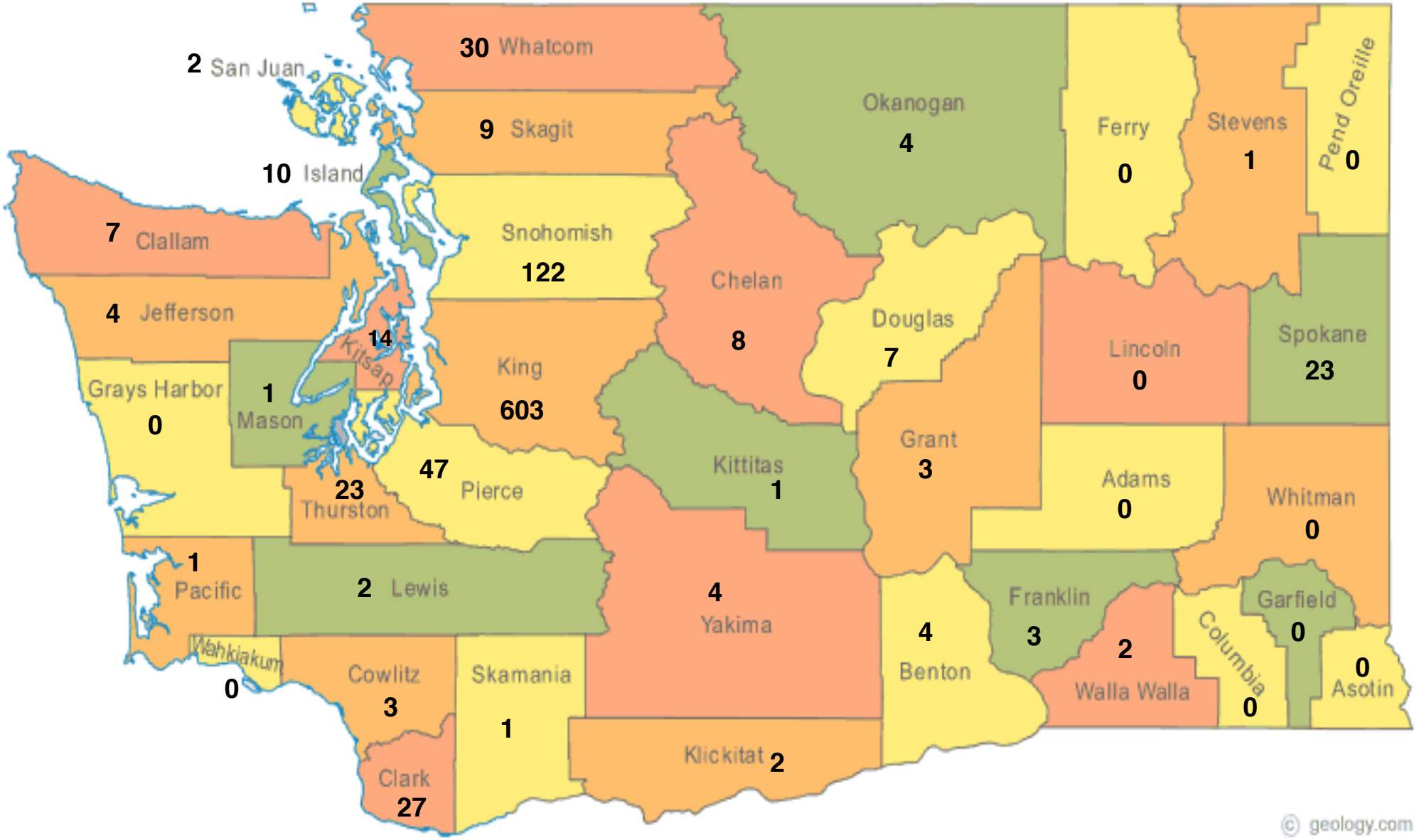
(2) The board shall consult with the agency medical directors' group, the department of health, the University of Washington, and the largest professional associations for naturopaths.

(3) The rules adopted under this section do not apply:

(a) To the provision of palliative, hospice, or other end-of-life care; or

(b) To the management of acute pain caused by an injury or a surgical procedure. [2010 c 209 § 7.]

NDs by County
1,010 Licensees in Washington State
(45 licensees whose county is unknown)



07/18/2014

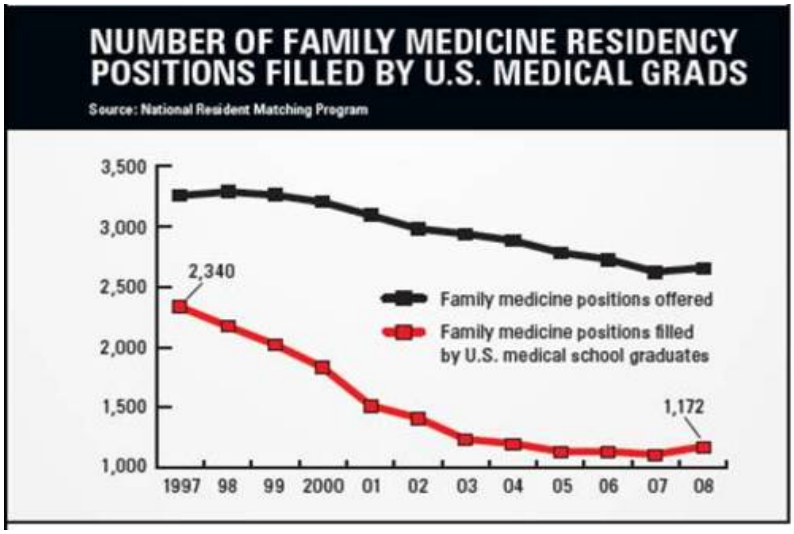
ND student interest in practicing medicine in rural and/or underserved medical settings

Michelle A. Simon, PhD, ND, Pamela Snider, ND
Seattle, Washington.

Introduction

Shortages in the primary care physician workforce are expected to worsen as the decade advances. Declining numbers of conventionally trained medical doctors (MDs) are in part due to little interest among students at medical schools in internal medicine as a career. **A 2008 JAMA study** found that only 23.2% of students surveyed responded that they were planning a career in internal medicine; **only 2% of those were planning to become general practice or primary care physicians**. These deficits impact rural and underserved communities hardest. **In a longitudinal study by Rabinowitz et al that evaluated the Physician Shortage Area Program, the single most important variable associated with rural practice was rural origin.** The objective of this survey was to ascertain the rural living experience level among naturopathic medical students, their level of interest in serving as primary care providers in rural and/or urban underserved community settings, and their willingness to relocate to these areas in exchange for medical school loan repayment.

Figure 1.



Design, Setting, and Participants

The survey was a web based cross-sectional survey of all medical students enrolled at one US naturopathic medical school, Bastyr University. All students received an invitation to complete the survey in the Fall quarter of 2010.

The main outcome measures were student demographics, career interests, rural life experience level as measured by number of years lived in a rural area, willingness to relocate in exchange for medical school loan repayment and year of medical school education.

Results and Discussion

There were 130 respondents to the online survey which was circulated among 407 active naturopathic students at Bastyr University. This represented a response rate of 33%.

Among students that have lived in a rural area, those with a level 4 or 5 interest in practicing naturopathic medicine rurally was 59% with 77 of the 130 respondents. (Fig 2, below) There was a correlation with the most experience in rural areas and a level 5 desire to practice there with over half of those with 10 or more years of rural experience desiring to practice rurally.

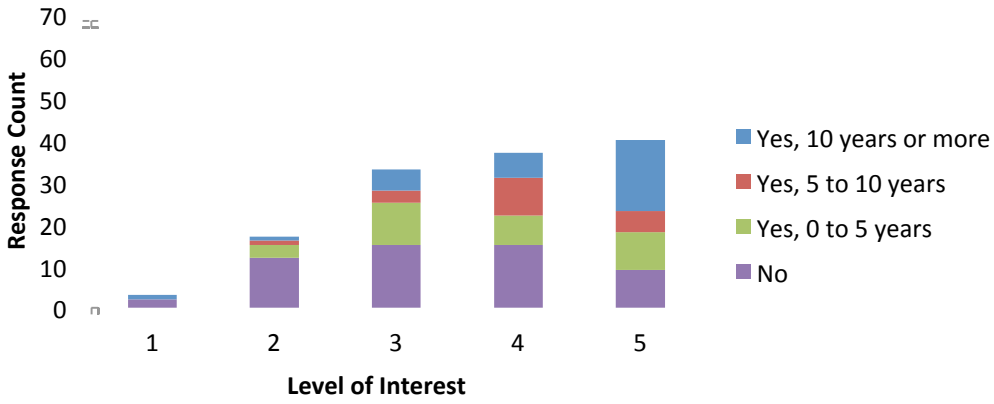


Figure 2: Level of interest in practicing naturopathic medicine in a rural area. (A rural community is defined as a city, town, or village of 2,500 citizens or less.) Rural living experience: 10 years or more, 5-10 years, 0-5 years or none.

There is a high level of interest among survey responders to practice naturopathic medicine in an underserved area. Those with a level 4 and 5 interest, 43 and 59 students respectively, represented 78% of all responders. (Fig 3, below) There seems to be a slight correlation between rural living experience and level of interest in practicing in underserved areas, but fully 33% of those with no rural experience expressed a level 5 interest level in practicing in an underserved area.

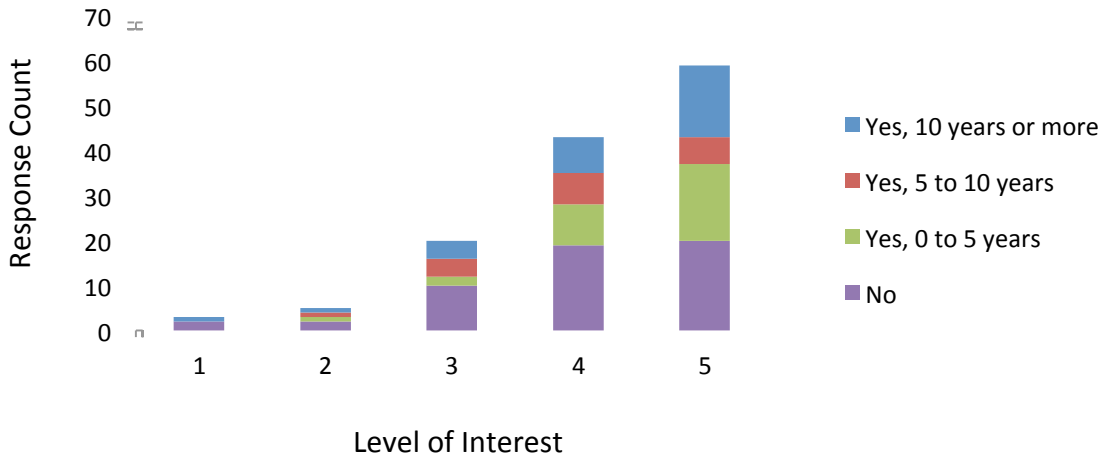


Figure 3: Level of interest in practicing naturopathic medicine in an underserved area. (Underserved refers to low income individuals, uninsured persons, immigrants, ethnic and racial minorities, and the elderly.) Rural living experience: 10 years or more, 5-10 years, 0-5 years or none.

The percentage of students with some rural living experience is 59% with 77 of the 130 respondents. Twenty three percent of the total has 10 or more years of rural experience.

Interest in working with special populations among the naturopathic students surveyed was robust. The highest interest levels were for work with Native American/Tribal communities and the elderly. (Fig. 4, below). For these populations the interest was equivalent with 65% of the respondents answering 4 or 5.

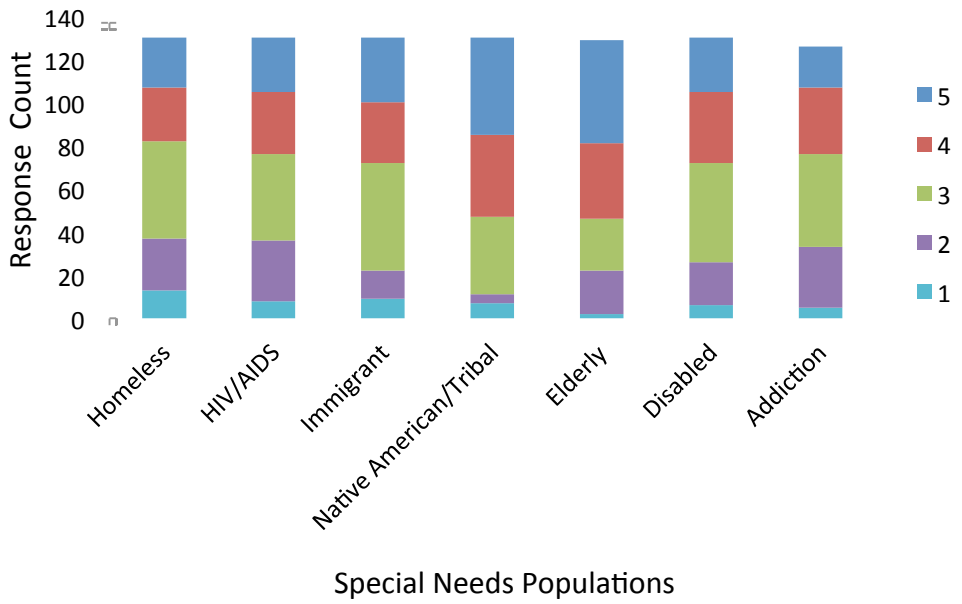


Figure 4: Level of interest in working with special needs populations: 1= no interest, 5= high interest.

The willingness of survey responders to relocate to a rural and/or underserved community to practice naturopathic medicine in exchange for medical school loan repayment is overwhelmingly positive with 94.6% of respondents expressing this willingness. (Fig. 5, below).

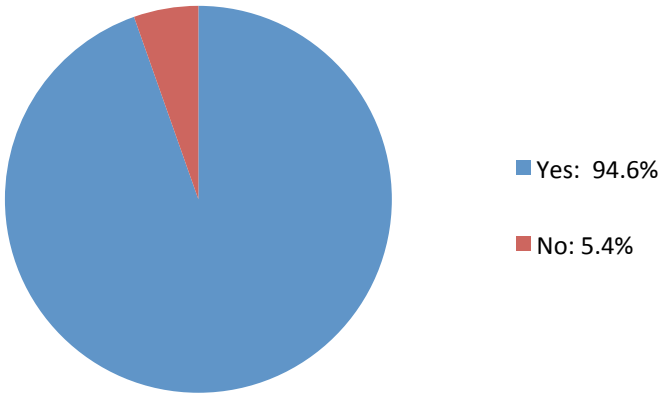


Figure 5: Willingness to relocate to a rural and/or underserved community to practice naturopathic medicine in exchange for medical school loan repayment.

Conclusions

Naturopathic medical students surveyed at one naturopathic medical school expressed significant interest in practicing primary care naturopathic medicine in rural and/or urban underserved community settings. Rural experience is not necessarily correlated with this interest, however, the high percentage of students who are from rural areas (59%) and expressed an interest in rural and underserved health care may provide answers to retention issues faced by state and federal loan forgiveness programs. **As has been demonstrated, rural origin is the single most important variable associated with rural practice. The vast majority of students, with or without expressed interest in this type of practice, were also willing to relocate to rural or urban underserved communities in exchange for medical school loan repayment. This represents a ready, willing, and able work force to help alleviate the current and projected workforce shortage in primary care medicine.**

Future Plans

The authors would first like to expand this survey to other naturopathic medical schools . A collaboration is under development with Jon Wardle, ND, MPH, PhD a Trans-Pacific Fellow at the University of Washington and at the University of Queensland in Australia to perhaps then expand the survey to allopathic medical schools.

Literature cited

Hauer, K.H., et al. 2008. Factors associated with medical students' career choices regarding internal medicine. *JAMA*. **300**(10): 1154-1164.

Rabinowitz HK, Diamond JJ, Hojat M, Hazelwood CE. Demographic, educational and economic factors and retention of physicians in rural Pennsylvania. *Journal of Rural Health* 1999; **15:** 212-218.

Acknowledgments

Thanks to the Washington Association of Naturopathic Physicians (WANP) who was a co-sponsor of this effort. Also thanks to Eric Jones ND and Deborah Brammer ND for their help in administering the survey to Bastyr students.

For further information

Please contact Michelle Simon, ND, PhD at *dr.michelle@earthlink.net*.

Expansion of ARNP Prescriptive Authority

Report to the Legislature

December 22, 1992

Licensing and Certification

EXPANSION OF AUTHORITY OF ADVANCED REGISTERED NURSE PRACTITIONERS TO PRESCRIBE CERTAIN CONTROLLED SUBSTANCES

INFORMATION SUMMARY

BACKGROUND

Senate Bill 5635 introduced in the 1991 session of the Legislature, proposed expanding the authority of advanced registered nurse practitioners (ARNPs) to prescribe certain controlled substances. On August 13, 1992, Representative Dennis Braddock, Chair of the House Committee on Health Care, requested that the Department of Health conduct a review of this proposal under the "Sunrise" law. The Department conducted a review according to the criteria in the "Sunrise" law (RCW 18.120.110) and the Department's Guidelines for Credentialing Health Professions in Washington State. The Department reported its findings and recommendations to the Legislature by December 31, 1992.

The purpose of the Sunrise Act is to avoid regulation wherever possible. The concern of the legislature in this case is that an increase in the ARNPs' scope of practice does not prevent other qualified individuals from practicing within the same scope. If a proposed increase in the scope of practice does not prevent other currently licensed or non-licensed groups from practicing within the proposed scope, then the review would focus on whether the applicant group can practice safely. The review would not consider whether an increase in scope is necessary from a health profession supply perspective.

OVERVIEW OF SUNRISE PROCEEDINGS

The Department of Health began discussions with interested parties on the proposed increase in the prescriptive authority of advanced registered nurse practitioners in September 1992.

Regulatory agencies in other states were requested to provide sunrise reviews, regulatory standards, existing laws and administrative rules, or other information which would be useful in evaluating the proposal. In addition, a literature search was conducted seeking professional journal and other articles regarding the current level of prescriptive authority of ARNPs in other states.

Various agencies, associations, organizations and individuals both proponents and opponents were invited to provide information and feedback on the proposal.

The Department of Health, Licensing and Certification, Office of Health Services Development convened a diverse committee og DOH staff to review material and provide input and serve as the hearings panel on the proposal. Staff from the medical, osteopathic, pharmacy and nursing boards were invited to participate as liaisons to their respective boards. A public hearing was held in Seattle on November 9, 1992 at which attendees were given the opportunity to express opposition to or support and receive answers to questions regarding the proposal. Interested parties were given an additional ten days to submit final comments and to provide additional clarifying information requested by the panel.

Final recommendations were prepared for presentation to the Secretary of the Department of Health. The Department's summary and analysis of the proposal is outlined below, along with the Department's recommendations.

I. SUMMARY OF THE APPLICANT GROUP PROPOSAL

The lettered sections below are from Section VI. of the Guidelines for Credentialing Health Professions in Washington State. The summary of the Applicant Group's responses to each section is in bold.

A. Whether there is a serious risk to the public's life, health, or safety if the scope of practice remains as it is.

ARNPs have been legally prescribing legend drugs and Class V controlled substances in Washington for 13 years. Their prescribing practices have proven effective and safe. This is evidenced by: (1) an increased demand for ARNP services, particularly in areas of the health care system underserved by their physician counterparts; (2) high levels of patient satisfaction; and (3) minimal complaints about ARNP prescribers before the boards of nursing and pharmacy. The proposed legislation relates specifically to extending existing ARNP prescriptive authority to include additional classes of drugs rather than expanding the current scope of practice into areas in which ARNPs are not educated or experienced.

An ARNP's ability to adequately practice to his or her full potential has been weakened by the prohibition on prescribing schedules II-IV drugs. This results in fragmented, delayed and duplicative care being provided to patients. Delays in receiving necessary medications can lead to increased health risks and additional costs postponing needed treatment.

ARNPs, collaborating physicians, and pharmacists recognize the potential harm to the public if appropriate medication therapy is delayed. Innovative approaches have been developed over the past 13 years which allow an ARNP to make the decisions about controlled substance selection and dosage for their patients. This enables them to "prescribe" while technically complying with current law. These innovative approaches include the use of presigned physician prescription pads, telephone orders to pharmacists by physicians at the request and specifications of an ARNP, or physician countersignature of an ARNP's drug orders in facilities, usually long after the medication has been administered to the patient.

Where practiced, these tactics have allowed patients timely access to needed care. As widespread as they are, unfortunately, they are not available in all areas of the state. This points to the need to put into statute currently accepted, if not legal, prescriptive practices. If these mechanisms of "gaming" the system were to be eliminated, and controlled substance prescriptions originated solely from physicians and dentists in strict compliance with existing law, the public health, safety, and welfare of the people of Washington would take a serious step backward.

B. Whether alternatives to legislation are available to solve the problem and, if so, why they were rejected.

The 1973 amendments to the Nurse Practice Act (Chapter 18.88.280 (16) RCW) specifically prohibit "permitting the prescribing of controlled substances as defined in schedules I through IV of the Uniform Controlled Substances Act, chapter 69.50." Therefore, a legislative mandate to remove the restriction on schedules II through IV is necessary.

A specific issue in this area which needs to be resolved relates to Certified Registered Nurse Anesthetists (CRNAs), one of the ARNP specializations. The boards of nursing and pharmacy currently take opposing views on whether the utilization of controlled substances by CRNA's constitutes prescribing. Based upon the Board of Pharmacy interpretation, the practice of selecting, ordering and administering drugs during anesthesia care involves prescribing. Such prescribing may not be undertaken through a delegated prescriptive authority from physicians or dentists, regardless of the presence of guidelines or protocols which address such practice arrangements.

Theoretically, an expansion of the "gaming maneuvers" previously discussed could provide de facto expanded prescriptive authority to more ARNP practices, and serve as an alternative to legislative solutions. However, this only continues the misconception of who actually makes the drug decisions for the ARNP's patient, and potentially increases the liability of collaborating physicians, pharmacists and RNs. A legislative alternative is the only possibility for resolution of this issue.

C. Benefit to the public if the change in practice scope is granted.

The potential for increasing access to indicated drug therapy while minimizing duplicative services will be afforded by the proposed legislation. Specifically, the following benefits are anticipated:

1. **<u>Access to needed care.</u> There is ample evidence that ARNPs have helped to fill a void for primary care practitioners in the rural and urban underserved areas of Washington. Their role is most effective when they provide the full range of services for which they have been trained, including the prescribing of necessary medications. Patients benefit by having their needs met as quickly as possible through a delivery system that affords continuity of care. The record over the past 13 years of patient experiences with limited ARNP prescriptive authority attests to the beneficial role of ARNPs in access to care.**

2. **Reduction in delayed provision of health services.** **Patients who require schedule II-IV controlled substances can have their condition properly evaluated and diagnosed by an ARNP. Under strict interpretation of current law, they are unable to receive the indicated medication without the involvement of a second provider. If a second provider is readily available, care may not be excessively delayed. Unfortunately, utilizing the services of a physician to repeat an exam or to merely prescribe medications is an ineffective and costly way to deliver health care in Washington. It limits the availability of the second provider to treat other patients when the second provider is, in fact, duplicating what the first provider has already done. In fact, there is little evidence to suggest that this second intervention by a physician normally changes the decisions made by the ARNP.**

3. **Cost savings for health care provision.** **The proposed legislation will help contain costs to the health care system in several ways. First, as pointed out above, less duplication of services will save money and time. Additionally, the patient is saved undue expense, risk, suffering, and time by receiving prompt treatment at a single point of service. It makes little economic sense for a patient or third party payor to incur the extra expense of a hospital emergency room visit to receive a prescription which should have been written by the ARNP in the first place.**

Certain patients may choose not to seek additional services, especially from providers with whom they are unfamiliar. For example, it is well documented that patients who rely on controlled substances for the outpatient treatment of certain psychiatric disorders can enter prolonged in-patient treatment due to untimely drug management. Such patients are frequently under the care of ARNPs specializing in psychosocial problems.

There are some ARNPs who are unwilling to move to rural locations because under current law they know they cannot provide the full range of indicated medication therapy their patients might require. They are unsure if the "gaming maneuvers" necessary to provide appropriate medication to their patients would be in place in those areas. This lack of provider availability thus requires patients to endure added expense and time to travel to other areas to receive health care.

C. Accountability.

The public, as well as other health professionals with whom ARNPs collaborate, will be better served as a result of the proposed legislation legitimizing existing practice. Currently, a review of prescriptions which originate with an ARNP and are signed

by a collaborating physician make it appear that the physician prescribes controlled substances at a higher rate than the physician actually does. ARNPs are on record supporting audits of ARNP-originated prescriptions, and the boards of nursing and pharmacy could develop a model for such use. Without prescriptions signed by the originating and authorized ARNP, however, such an audit would prove misleading.

Additionally, patients have the right to know who is responsible for initiating the selection and ordering of the medications used in their care. The ARNP typically retains the responsibility of educating the patient about the use and effects of the prescribed controlled substance. Management of the patient's condition that originally warranted the controlled substance use is also carried out by the ARNP.

D. The adequacy of proposed changes in training/experience requirements to meet responsibilities of the proposed practice.

ARNPs currently must comply with rigorous education and experience requirements for initial and continued prescriptive authority. In part, ARNPs must stay current in the prescription and management of Schedule II-IV controlled substances.

The proposed legislation does not amend ARNP education and training standards specifically to cover the additional schedules of drugs. It is understood that the board of nursing, with the advice of the proposed ARNP advisory council, will monitor education and practice. The board of nursing will also update rules about initial and continuing standards for prescriptive licensure. Washington State currently has some of the most stringent requirements in the nation for the continuing education of ARNPs.

E. The extent to which the change may harm the public.

The proponents do not foresee increased public harm as a result of the proposed legislation. However, two theoretically negative impacts are addressed:

1. **More ARNPs with controlled substance prescribing authority could mean more potential for drug diversion to the public and for addiction by ARNPs. According to input from the boards of pharmacy and nursing, addiction and diversion by nursing groups are not unheard of, but they seem to be unrelated to the prescriptive authority for these drugs. Often addictions are of the street variety as opposed to drugs prescribed by the practitioner.**

   Additionally, most health care facilities recognize the potential for theft if medications are either overstocked, unaccounted for, or poorly protected. That risk would not increase because current facility drug stocking patterns are not likely to change as a result of the proposed legislation.

2. **Some third party payors argue that allowing ARNPs to prescribe Schedule II-IV substances will increase their costs because of the increased utilization of ARNP services and consequently of prescription drugs. Such a result seems highly unlikely for the following reasons:**

   a. **Nurse practitioners, like their physician counterparts, do not bill their patients (and their insurance companies) for the sole cost of writing a prescription. Third party billings are submitted for various evaluation and management services, regardless of whether a prescription, or prescriptions, are written. As previously stated, costs go up when the ARNP must refer their patient to a second provider or emergency room for needed medication. Obviously, the second provider will naturally expect payment for their services, commonly billed under a separate evaluation and management code. The proposed legislation should result in less duplication of service and, therefore, reduced cost to patients and to the third party payors.**

   b. **Medication costs are affected by prescribing practitioners through the specification of the drug selected, (e.g., generic vs. name brand) as well as through the volume of prescriptions written. ARNPs are well aware of the cost effects of their prescribing practices and tend to turn to medication therapy less frequently than their physician counterparts. Still, when medications are indicated, they should be available through the prescription of the qualified provider. There is no reason to expect that controlled substances prescribed by an ARNP will cost the patient or their insurer more than if a physician prescribed them.**

F. Impact of the proposed change on cost of services to the public.Impact on costs of administering the program.

It is anticipated that costs of indicated service will decrease when one practitioner is allowed to provide the same service that currently requires two practitioners, frequently in different locations. Additionally, it is likely that utilizing ARNPs to their full potential as prescribers will enhance competition. A common theme among health care reform proposals is that competition brings down costs, as in other market-driven sectors. Nothing in the proposed bill serves to eliminate or decrease collaborative interaction between health care practitioners where it is appropriately indicated. This proposal will reduce the cost of services to the public.

Information regarding costs to the Department of Health in implementing the proposed legislation was unavailable to the applicant group **at the time of proposal submission.**

II. ANALYSIS BY THE DEPARTMENT OF HEALTH REGARDING THE NEED FOR AN EXPANSION OF THE PRESCRIPTIVE AUTHORITY OF ADVANCED REGISTERED NURSE PRACTITIONERS TO PRESCRIBE CERTAIN CONTROLLED SUBSTANCES

Studies, information and staff findings

Many articles and documents were presented by proponents in response to issues and concerns raised regarding the expansion of prescriptive authority. Opponents did not provide articles or documents to substantiate the positions taken in their written information or oral testimony.

Serious Risk to the Public:

Oral and written testimony provided by the Office of Community and Rural Health and other proponents at the public hearing maintains that not expanding ARNP prescriptive authority would severely restrict access to primary and specialty care in rural areas. Testimony provided concluded that anesthesia services for surgery and trauma care in rural hospitals may not be accessible. Information regarding Washington's rural areas was provided which demonstrates the access problem and reliance upon mid-level providers (including ARNPs.)

Information provided in various articles, including "Comparative Analysis of Nurse Practitioners With and Without Prescriptive Authority" indicates that nurse practitioners with prescriptive authority had more experience and were more likely to practice in rural or suburban areas or in nongroup settings than ARNPs without prescriptive authority.

Staff concludes that restricting ARNPs from prescribing schedule II-IV substances contributes to a lack of access to care, thus representing a serious risk to the publics life, health or safety. This appears to creates a situation where ARNPs have the responsibility but not the authority for the prescribing of schedule drugs which is currently occurring.

Alternatives to Legislation:

As pointed out by the applicant group, Chapter 18.22.280(16) RCW of the Nurse Practice Act specifically prohibits the prescribing of controlled substances as defined in schedules I through IV of the Controlled Substances Act, only an amendment to this law will extend to ARNPs the authority to prescribe schedule drugs.

Opponents did not offer an alternative to legislation, but instead an alternative to legislative proposal. They presented as an option the recently passed California statute permitting prescribing based on variables such as site of care, type of care patient health status, type of supervision and the number of ARNPs supervised.

The Yale Journal of Regulation suggests that restrictive provisions relating to site-specific care are deterimental and have the effect of setting up a two-teir system of care. Under a California-type of arrangement, in some locations and under certain situations, ARNPs would have full prescriptive authority while under others they would not. Research information provided in various articles suggests that these provisions are needless and detrimental and legislative specifications of such professional norms is unnecessarily duplicative. ARNPs are trained to use independent professional judgement in providing care and are trained to know when to consult with and to refer to other health care providers, and that they have an ethical and a legal duty to do so when appropriate.

Staff concurs with this conclusion and recommends that the California example notwithstanding, the only alternative may be a legislative solution to expand prescriptive authority.

Benefit to the Public:

Information provided suggests that the public would benefit from the maintenance of access to the current level of anesthesia care. Prescriptive authority expansion will allow place the full range of drugs within the ARNP scope of practice. This would allow prescribing drugs which may be most appropriate, less costly, better tasting and may have less significant side effects. Staff concurs with this finding.

Additionally, staff recognizes the need for a mix of qualified health providers if quality health care is to be attained.

Adequacy of Training:

The "brevity" of an ARNP's education was raised as a concern by opponents. However, since this sunrise request was specific to the expansion of prescriptive authority, our review centered on the adequacy of an ARNP's pharmacology education. Information submitted by proponents and educators provided a comparison of pharmacology related education for various health professionals having prescriptive authority. This comparison indicated the following formal education in pharmacology:

	graduate education	continuing education
Medicine	74 contact hours	none required
ARNPs	70 contact hours	15 hours every 2 years
CRNAs	130 contact hours	15 hours every 2 years
Dentists	40 contact hours	none required

	14 hours to deliver nitrous oxide	7 hours every 5 years
	14 hours for conscious oral sedation	7 hours every 5 years
	1 year for general anesthesia	18 hours every 3 years
Podiatrists	55 contact hours	none specific to prescribing requirements

Physicians receive additional training and experience related to drug therapy in conjunction with their residency education. However, they are qualified to receive a prescriptive license at the end of their medical school training. None of the disciplines require undergraduate pharmacology preparations and the above hours represent the minimum requirement necessary to qualify for a prescriptive license upon graduation.

ARNPs currently prescribe legend drugs which are considered dangerous or life threatening. The pharmacology education ARNPs currently receive clearly prepares them to make appropriate decisions regarding drug therapy. Their pharmocology education exceeds that of both Dentists and Podiatrists (who have the authority to prescribe schedule drugs); and their continuing education requiremtns in pharmacology are more stringent than any other health profession.

Present ARNP pharmaceutical training is comprehensive and adequate to meet the responsibilities of expanded prescriptive authority. It is recommended however, that a member from the physician and pharmaceutical communities be included in the proposed Advisory Council.

Public Harm:

Various articles indicate there is no evidence suggesting harm to the public would occur if ARNPs were granted the authorituy to prescribe scheduled drugs. Existing Drug Enforcement Agency requirements apply equally to ARNPs and other health professionals who prescribe scheduled drugs. Board of Pharmacy can also apply appropriate sanctions for misuse of scheduled drugs. Board of Nursing has a disciplinary structure in place.

Although the issue of safe dispensing remains a concern, especially related to the criminal element and potential break-ins. The Nursing and Pharmacy professions are nearing agreement on the availability of drugs for dispensing. There is legitimate concern on both sides and staff recommends that this issue be carefully scrutinized.

Costs of Services:

Opponents also raised the issue of increased cost due to "ARNP parity with physicians."

No documented evidence was presented by opponents or proponents to support positions. However, based on oral testimony, staff concludes that even if some costs increased due to "parity", other costs would still be reduced by elimination of duplication and reduced emergency room visits. Additionally, staff concludes that overall costs would also be reduced due to the availability of a more cost effective mix of health care providers and strengthening of referral patterns.

Staff acknowledges that although ARNPs are traditionally very conservative in prescribing, passage of this bill would increase prescriptions and in an increase in health care expenditures for them. There would also be a cost for administering this regulation. However, the overall effect would be a net reduction in costs.

REGULATION IN OTHER STATES AND JURISDICTIONS

Inquiries were sent to professional licensing bodies in 49 states and the District of Columbia, requesting information on the regulation and prescriptive authority of ARNPs in those states. Responses from 27 states were received.

Information provided by responding states and proponents indicate that 13 states currently grant ARNPs independent legislative authority to prescribe. In eight of those states, ARNPs are authorized to prescribe controlled substances. Twenty-four states provide dependent ARNP prescriptive authority (i.e., authority in some way dependent on state-authorized physician or pharmacist approval). Within these twenty-four states, ARNPs in ten states are authorized to prescribe controlled substances. ARNPs in three other states have site-dependent, limited authority to prescribe. A summary of the various state provisions related to legal authority, prescriptive authority, and reimbursement status of ARNPs is attached.

ESTIMATED COST OF REGULATION

The cost of regulation is based on a fiscal note analysis of a 1991 House Bill related to expansion of prescriptive authority. The level of activity required by that bill, although not identical, will provide a very close estimate. Those costs are as follows:

	Estimated Cost 1st Year	Estimated Cost 2nd Year	Total
New:			
Volume (#)	600	200	800
Rate	98.19	98.19	98.19

Revenue	58,914	19,638	78,552
Renewals:			
Volume (#)	800	800	1600
Rate	24.19	24.19	24.19
Revenue	19,352	19,352	38,704
TOTAL REVENUES	78,266	38,990	117,256
1st BIENNIUM			

2ND BIENNIUM

New:	
Volume (#)	200
Rate	98.19
Revenue	19.19
Renewal:	
Volume (#)	1900
Rate	27.17
Revenue	51,630
TOTAL REVENUES	71,270
2nd BIENNIUM	

The statute requires the Secretary to recover the costs for management of health professions through professional fees.

III. STAFF RECOMMENDATIONS

The Department of Health recommends approval of the expansion of prescriptive authority for Advanced Registered Nurse Practitioners.

Information provided indicates that restricting availability of Schedule II-IV drugs to certain segments of the population creates a lack of access to care and represents a serious risk to the public life, health, and safety.

The alternatives presented by opponents do not appear to address the issues of ARNP training and capability of ARNPs to safely and effectively prescribe Schedule II-IV substances. These opponent alternatives seek to address the overall ability of ARNPs to function as independent providers, a topic which is not within the purview of this sunrise review.

The public would benefit by the availability of additional qualified providers, already functioning in an expanded practice capacity, to prescribe prescription drugs which may be more appropriate and less costly. ARNPs are trained to use independent judgement, deal with many of the same maladies as do physicians, consult with other health care providers, know their limits and know when to refer.

Pharmacology training requirements for ARNPs are comprehensive and adequate to meet the responsibilities of expanded prescriptive authority. However, it is recommended that the ARNP advisory committee include a licensed physician and licensed pharmacist in order to provide a broader perspective regarding specific training requirements.

Evidence provided demonstrates that expansion of prescriptive authority would not harm the public. Costs are expected to decrease, access is expected to increase, and the change will provide for the best mix of health care personnel.

A concern regarding public safety was raised due to the potential for theft or burglary of controlled substances at additional dispensing sites. There may be a need for dispensing of controlled substances when and where a pharmacy may not be accessible. It is the Department's recommendation that the nursing and pharmacy professions work to reach a resolution on this issue. The Department recommends that this issue continue to be carefully scrutinized.

No documented evidence was presented to support the position that expanded prescriptive authority would increase or decrease costs. However, it seems likely that overall cost of medical care would potentially be decreased by elimination of duplication, double billing and reduced emergency referrals for filling Schedule II-IV prescriptions.

Appendix C

Public Hearing Summary

Naturopathic Scope of Practice Sunrise
Public Hearing
July 17 2014

Kristi Weeks, director of legal services and legislative liaison at the Department of Health (department), called the hearing to order and gave instructions to participants. She introduced department staff assisting with the hearing, and introduced the hearing panel. The panel's role is to make sure we have all the information we need to make a sound recommendation, so they will ask a lot of questions. The panel members were:

- Alex Lee, staff attorney in our Office of Legal Services;
- Meghan Porter, communications and evaluations coordinator for the Washington Tracking Network from our Environmental Public Health division;
- Deborah Johnson, policy analyst in our Health Systems Quality Assurance division.

Ms. Weeks announced that after the hearing, there will be a 10-day written comment period before the department drafts the initial report. This is to allow interested parties to provide additional information on topics brought up at the hearing, and allow those who could not attend the hearing to submit information. Ms. Weeks reminded participants that the sunrise review process has statutorily mandated criteria that should be the focus of discussion at the hearing.

Next, Ms. Weeks welcomed the applicant panel to make their presentation on the proposal.

Applicant Presentation

Robert May, ND, Executive Director
Washington Association of Naturopathic Physicians (WANP)

Dr. May stated that the proposed legislation H 4573.4, would be changing the scope of naturopathic practice to expand prescriptive authority from the current status of all legend drugs and the controlled substances testosterone and codeine products, to all controlled substances within schedules II through V.

The draft legislation from Representative Cody does not include requirements for the promulgation of rules regarding education and training for naturopathic physicians who would be expanding their prescriptive scope. He asked to make it very clear that WANP recognizes this and intends to ask the legislature to amend the draft bill to specifically require the Board of Naturopathy (board) to do rulemaking to address the necessary education and training to ensure public safety and optimal care by naturopathic physicians (NDs) in the use of these new medications.

He added the intent to include two or three other amendments noted in the applicant report that would bring this legislation into conformity with the Controlled Substances Act. These are already in law for other prescribing professions. In addition, he added the need for specific language that was in HB 2876, referred to as concerning pain management by Representative Moeller, that set very specific and discreet guidelines and clinical requirements for the use of controlled substances in the management of pain for any provider types who have this prescriptive authority.

He stated he feels that naturopathic law and practice should be required to meet these standards. This is a primary addition that should be added to the applicant report and he stated WANP is not endorsing the language of the bill as it exists right now.

Since 2005, when the last prescriptive authority expansion for naturopathic physicians occurred (implemented in 2007 after rules were written), NDs have had the authority to prescribe all legend substances and the controlled substances testosterone and codeine products. Dr. May stated there has been no formal disciplinary actions against NDs for prescribing within that authorized scope of medications. There have been a number of what are referred to as stipulations- they're called STIDs, that are informal dispositions, minor corrective actions that do not qualify at a level of disciplinary actions.

Kristi Weeks corrected Dr. May that STIDs are informal discipline, but discipline nonetheless.

Dr. May stated thanks to Ms. Weeks for the correction, and indicated he thought there was such a distinction. In 2013, the Washington State Legislature included naturopathic physicians in funding for Medicaid primary care services. And since January of this year, 2014, NDs have been enrolling, participating and serving this new demographic of patients in Washington.

With the implementation of the Affordable Care Act and the expansion of Medicaid in Washington, he stated NDs have become aware that their ability and role as primary care providers is in more demand; and NDs are practicing in more and more areas of the state. As a result, NDs have also identified the need for additional tools to fully provide optimal primary care in all these settings. This is the basis for bringing forward this request to expand the prescriptive authority. In the current status, the system as it is supports a number of issues that add to cost and decrease to quality in care for patients who are seeing naturopathic doctors for their primary care services.

This includes dual-utilization which, in the event that a patient does need a particular controlled substance, requires a prescription from a second practitioner who has this license ability. This can delay appropriate treatment; can increase cost to the patient, to the state, and to insurers; and disrupts patient-doctor relationships, effective coordination of care, and optimal management for that patient. It can also increase issues of non-compliance if a patient has to take additional time off or travel to see another provider to get something that is needed.

Dr. May referred the hearing participants to WANP responses to supplemental questions from the department. He stated WANP has specifically tried to provide more information that creates the basis for the proposal, and demonstrates both the value, the safety to the public and the advantages to the state. Dr. May also referred to the written comments in opposition to the proposal that were shared at the hearing, and stated there appears to be some factual misunderstanding about the nature of naturopathic medical education. He introduced Dr. Jane Guiltinan from Bastyr University to present next and address ND education.

Jane Guiltinan, Dean of the Naturopathic Program at Bastyr University

Dr. Guiltinan introduced herself as a naturopathic physician since 1986 and Dean of the School of Naturopathic Medicine at Bastyr University. She stated her role on the panel is to provide information on the current education and training of naturopathic physicians at Bastyr University and, more broadly, the other four accredited naturopathic programs in the United States.

Bastyr University is a four year doctoral residential program. Students who come into the program must have a bachelor's degree and all their typical pre-med prerequisites before they begin the program. It is a four or sometimes five year program, 4,383.5 hours. Of those hours, there were some comments in the concerns of the comments that were posted that there was no anatomy or pathology, and that is inaccurate. The first two years of the program are essentially basic science years; where students take anatomy, including cadaver dissection, physiology, biochemistry, pathology, clinical laboratory diagnosis, etc. The curriculum is currently being revised (they are in the third year of revising) to go from a discipline-based basic science curriculum to a systems based curriculum. So what you see in the Bastyr University catalog might say "integrated structure and function" and "integrated musculoskeletal" but within those integrated modules, they are teaching anatomy, physiology, biochemistry, pathology, etc.

The third and fourth years are primarily the clinical years, a combination of both didactic (about 1,000 or 1,200 hours) and clinical sciences. Those are the "ology's"- rheumatology, pulmonology, dermatology etc. Within those courses, students learn principles of pharmacotherapy. They take a total of 60.5 hours in pharmacology. Half of those hours are in the second year of the program; the other half are clinical pharmacology in the third year of the program. Then, there are 1,210 clinical training hours where students train in outpatient settings; primarily in the teaching clinic in Wallingford, where they see about 40,000 patient visits a year. Also in external clinical sites, such as community health clinic systems, women's health shelters, senior centers, etc. In those clinical training hours they are supervised by licensed physicians, and they, again, do primary care medicine where they do appropriate evaluation, diagnosis and then come up with therapeutic treatment plans which may include non-pharmacologic approaches and also, oftentimes, medical pharmacotherapy approaches.

There were questions about whether the other colleges in the United States provide the same level of training and the answer to that is yes. All five accredited colleges of naturopathic medicine in the United States have approximately the same number of hours and approximately the same curriculum. They are all accredited regionally, Bastyr University by the Northwest Commission on Colleges and Universities, which is the same accrediting agency that accredits the University of Washington. They're also programmatically accredited by the Council on Naturopathic Medicinal Education, where there's much more information about the accreditation process and standards. This is an accrediting body that's recognized by the Department of Education and Bastyr has recently been reaffirmed for six additional years of accreditation.

There were some comments about residencies, and Dr. Guiltinan stated that the residencies, at this moment, in the naturopathic profession's maturation are optional. Bastyr University is by far the largest provider of residency opportunities for graduates, offering about 25 residency slots per year. The other schools are somewhat less than that. Residencies are subsidized by the colleges themselves; they receive no subsidies from the Graduate Medical Education Fund either by the state or the federal government.

That is the current level of education and training. There is also a requirement for 20 hours per year of continuing education requirements for naturopaths in the state. As Dr. May stated, they are firmly in support of rulemaking that would identify where additional education and training requirements would be appropriate for NDs if this legislation passes. She then introduced Dr. Krumm to speak from a clinical perspective.

Dr. Chris Krumm, ND, HealthPoint

Dr. Chris Krumm described his background, clinical work, patient population, and followed with a recent case example that to help illustrate the need for the proposed scope expansion.

He graduated with his doctorate degree in naturopathic medicine from Bastyr University in 2004, then completed two years of clinical residency, which included practicing at the main community health clinic of HealthPoint in Kent. Dr. Krumm was hired as a full-time naturopathic physician at HealthPoint after completing his residency, and has worked there for the last seven years. HealthPoint is a large, multi-center community health organization, serving primarily low-income and underserved King County patients. They are an important provider of Medicaid services in the state of Washington, and also serve many uninsured residents. Many of their patients struggle with additional physical, mental and psyco-social stressors that complicate their care. They were one of the first federally funded organizations in the country to employ naturopaths, as part of a multi-disciplinary care team, starting about 15 years ago. The NDs at HealthPoint practice alongside MDs, DOs, nurse practitioners, and PFPAs as part of the clinical care team. They carry their own patient load as primary care providers (PCPs) and frequently serve as consultants for their colleagues' patients. In addition, they manage acute walk-in patients when their PCPs are out or their schedules are full.

Since Medicaid coverage for naturopathic primary care services began in January of this year, demand for ND appointments has risen significantly. He is finding a lot of patients that have wanted to see him for years, but were not able to afford even the lowest sliding scale fee who are now starting to consult with him using their Medicaid coverage. The demand has grown so much that HealthPoint recently hired a fourth naturopathic physician to be on staff and help meet the increased patient needs in this area.

The relatively recent Medicaid inclusion of NDs in Washington did a lot to reduce barriers of access for a lot of Medicaid patients. The limitations of the current naturopathic prescriptive scope still presents challenges; and while he is able to address most issues without needing to write a controlled substances prescription, there are cases where a controlled substance is necessary and the most appropriate choice. He stated he wanted to share one very recent case example that occurred that seems particularly relevant in this matter.

He had a long-term patient who was very medically complicated. She presented with severe, acute, radiating back pain. He been working for a long time to help manage her diabetes, asthma, hypertension, sleep apnea, and, more recently, atrial defibrillation (for which she's now on Warfarin, blood-thinner). She revealed to Dr. Krumm that she'd been self-medicating with high dose ibuprofen. It's the combination which, you know, puts her at great risk of bleeding. They knew from past episodes of pain that Tylenol did not work. She had tried that again, and it did not touch her pain. She was intolerant of many typical narcotic pain medications, with the exception of Tramadol, that other people had provided for her.

Dr. Krumm knew this because about a year earlier, he had helped her through a similar episode, a severe pain episode, using physical medicine and a short course of Tramadol. However, Tramadol has just been reclassified from a legend substance to a schedule IV controlled medication that he can no longer prescribe according to many emails and warnings from the pharmacy board. He needed to find another option for her. She was unwilling to see any other provider that he could have referred her to in the clinic, so he asked several people if they could take a look. He found one provider who reviewed her case and agreed that it seemed the most appropriate prescription for her. She received a prescription, but unfortunately, by the time she got out of her appointment, the pharmacy had closed so she could not refill

the prescription that night. Dr. Krumm saw her back on follow-up the very next day, and she revealed she was once again taking her high dose ibuprofen against his strong warnings against it.

She eventually was able to stop, and filled the appropriate prescription without any serious effects to his knowledge. But he stated it is a good example of how this restriction on ND prescriptive authority can, in some cases, delay appropriate medical therapy and put patients at risk of serious side effects. In this case, they got away without a severely bad outcome.

Aside from the safety issues related to delaying appropriate therapy, any reduction in dual-utilization and time spent consulting unnecessarily within a busy primary care practice will help avoid wasting resources that cost patients and insurers and the state valuable time and money. Along with a long track record of NDs serving as PCPs in such a high-need environment for 15 or so years, this is the reason both the HealthPoint CEO, Don Trumpeter, and medical director, Evan Oakes (an MD) are supporting the sunrise review prescriptive scope expansion. All of the conventional medical colleagues he works with at HealthPoint have expressed support for this because they feel this is the right choice for their clinics, patients and for the state.

Panel Questions

Q. Deborah Johnson asked about the specific 60.5 hours in pharmacology. How many hours of that would be estimated to include schedules II-V controlled substances?

A. Dr. Guiltinan responded and clarified that. 60.5 hours of pharmacology is specifically pharmacology, or clinical pharmacology in integrated therapeutics modules; and then, additionally, in the "ology" modules, or the clinical science modules, there are other hours that would address medication management. At this moment, they would be covered in a very basic way, because they would be covered as a class of drugs. Mechanism of action would be covered, some particular drugs would be covered, and all naturopathic medical students must take a basic science and a clinical science national board examination. There are blueprints for those examinations, and there are required medications that the students are required to learn. In those requirements are scheduled drugs, because some other states who license naturopathic physicians have broader scopes and already have these scheduled substances in their scope; Oregon and Arizona are two examples. So yes, they would be covered in a basic way right now.

Q. If this authority were granted, would you be changing that up? Would you be increasing that, or increasing emphasis on that at all?

A. They would be hard-pressed to add any hours or credits to the curriculum, because it's already jam-packed. But she stated they would certainly "tweak" those hours and revise them to include any expanded scope that is a result of this process.

Q. The next question was directed to Dr. May. Much of the information WANP has submitted centers on NDs relationships to primary care. I do appreciate the case example that you gave as well, but beyond that case example, I don't really have a good sense of the range of what's considered primary care. Could you please describe common conditions and medical issues that are likely to present specifically among naturopaths and their patients coming for primary care?

A. Dr. May stated that he may ask Dr. Krumm to supplement with his clinical experience, but stated he is aware that naturopaths had have the role of serving as PCPs for some of the major insurers in our state for

over 15 years. And in that context, primary care is an interchangeable title among the type of provider offering those services. He stated he feels that would include everything from routine physicals, preventive services, acute care, and then the management of referrals. He said in the Regence Blue Shield system, naturopathic doctors have been in the role of gatekeeper in that capacity for many years. In that type of system, he's not sure how many of those particular benefit plans are still operating, but in those managed care plans NDs are responsible and have to authorize referrals to specialists that their patient might need. He suggested that the role of primary care offered by naturopathic physician is interchangeable with the role of primary care offered by a nurse practitioner, or a medical doctor, or osteopath or physician's assistant in a similar system.

Q. Your submittals also state that, "the ND use of controlled substances will be limited to medications appropriate for primary care services" and that, "NDs would rarely, or never, use those controlled medications not recognized or appropriate for primary care practice". Could you please talk about which of the Schedule II-V substances would be appropriate for the primary care services you've indicated?

A. Dr. May stated that they submitted a document from the prescription monitoring program (PMP) at the Department of Health that identifies about 20 controlled substance prescriptions in Washington. It is his understanding is that over 90% of the prescriptions of controlled substances are contained within those 20 medications. Without speculating into an area NDs have not yet had authority to prescribe, he felt that ND patterns of prescription will model those already documented in the PMP program.

Q. The proposed bill language as it currently stands would give naturopaths prescriptive authority only for the Schedule II-V substances that are, "necessary in the practice of naturopathy". You've stated that you expect that the prescribing patterns would generally follow that PMP list that you submitted. There are 20 items on that list, but in Schedule II alone, without counting any of the other schedules, there are considerably more than 20 substances, and then all their derivatives on top of that. At the same time, your submittals indicate the intent to include all of the Schedule II-V substances. Those two seem to me to be at sort of an odds with one another, so given what you've said about the limitations of use to primary care and then probable use paralleling the PMP list, could you explain why everything on those schedules is considered necessary in the practice of naturopathy?

A. On the one hand, there's the administrative issue and the example Dr. Krumm demonstrated by the limitation that has occurred when a drug is rescheduled, or reclassified. When looking at the prescriptive authority of professions like the nurse practitioners or physician assistants, even including dentists, podiatrists, and other groups; there don't seem to be discreet lists of medications. Rather, they have authority for classes of drugs within the appropriate scope of their profession. He stated he would encourage similar language, because it prevents the profession from having to come back each year as drug status changes, or new research is found, or a new medication is released, and have to go to the legislature to change a limited list that is out of date. In comparing this with the prescriptive authority with, say, nurse practitioners, they don't see any of those limitations, and so they have modeled their proposed legislation on that same model.

Q. Would you oppose language in the bill, "necessary in the practice of naturopathy"?

A. Dr. May stated that they would not. That is the qualifier that underlies all the professions. Any practitioner who has full scope is going to be constrained by their scope of practice or specialty or whatever their area is.

Q. Regarding the definition of the practice of naturopathy and the language in the draft bill. The statute currently talks about naturopathic medicine and defines the practice of naturopathic medicine. The draft language indicates that a naturopath can prescribe controlled substances necessary in the practice of naturopathy. Is the practice of naturopathy distinct from the practice of naturopathic medicine?

A. Dr. May stated he would view that as being synonymous. He believes all terms naturopathic were included in the bill; so in a sense, naturopathy, naturopathic physician, naturopathic doctor, naturopathic medicine, would be viewed as being essentially the same term.

Q. The practice of naturopathy would be equal to the practice of naturopathic medicine?

A. Yes.

Q. Can you just tell the panel what the basic foundation of naturopathic medicine is?

A. Dr. May responded that naturopathic medicine is a unique and historical perspective on healthcare that views the human body as having inherent or innate healing capacity. This practice and medicine is designed to always look as far as possible to support that inherent, natural process in the body to achieve health. Many treatments related to diet, lifestyle, and nutrition are to provide the body with the environment, the support to manifest healing or reverse disease. As they noted, with the expansion of the NDs role in the state, they are seeing patients who are much sicker than they have in the past or who are already on prescription medications. This includes those who have acute injuries or painful situations in which the best choice of medicine is likely a pharmaceutical agent. Their philosophy does not preclude any particular therapy. They would look towards what is the most gentle, least invasive manner of achieving health for an individual.

A. Do you think that that's going to confuse patients, when they come in expecting natural remedies and then an ND offers them pharmaceuticals? Do you think that's going to cause any problems with future patients or current ones who expect a certain theory, because you are naturopaths?

A. Dr. May responded that he thinks some patients may be surprised. His impression from talking with NDs is that far more patients will actually be relieved that when they know a medication is the right course of care, they are able to stay with their doctor who they have established a relationship with and take that medication in the context of an overall naturopathic approach to their health.

Q. Pharmaceuticals would be the last stop? You would try all other natural remedies and then go to pharmaceuticals, if necessary.

A. In a general way, that's one way of saying it. If someone comes in who has just sprained their ankle very badly or is in acute pain, it may not be appropriate to go through trying a lot of herbal remedies or compresses or other things that could be valuable in more minor situations. It's really a question of what is the patient need at a particular time that gives them the best care. Does that answer your question?

Q. It just seems confusing to mix the two. NDs claim to practice natural healing but then throw pharmaceuticals in just because they are considered primary care practitioners now. But NDs have always considered themselves as a primary care practitioners, so why now? That's kind of where I'm confused.

A. Dr. May responded that he guesses in the past, patients sometimes came in needing something beyond the ND scope of practice. It wasn't that the doctors didn't recognize that, or refer them where needed. It's just that it required an entire additional appointment, fee, and time for the patient. He asked whether Dr. Krumm had something to add.

Dr. Krumm added that a lot of this has to be put into perspective of the patient population, income, and desire to become better regardless of what it takes to do so. A lot of his patients have a great preference for natural medicines, however they're low income. The $20 they pay for a flat fee sliding scale charge for an appointment is all they have. If they are on Medicaid and learn that their plan does not cover natural supplements or herbal medicines, they have to pay out of pocket to get such an item. Then it becomes a choice of what is the most appropriate conventional medication that they can get that is covered. If they are on a $40 a month natural cholesterol supplement when they can get a prescription medication for free or a very low co-pay, that makes a difference. The NDs have to explain the pros and cons, and it's just a different patient population than I think people were seeing 20 or 30 years ago. Does that answer your question a little better?

Q. A question was asked about intramuscular injections and what Dr. May thinks about that.

A. Dr. May stated he believes they would view whatever the optimal route of a particular drug delivery that was needed at a particular time by a particular patient, is what they would do. But he stated he doesn't feel comfortable pulling out particulars or saying "yes we would- this would always be used intravenously" or "intramuscularly" or anything else. It would be dependent on the substance and on the clinical context.

Q. Dr. May was asked to give a general estimate of the percentage of primary care cases that would require schedule II-V substances.

A. Dr. May responded that he doesn't think he has that data, but would be happy to work with the department or try to find something like that.

Q. Dr. Krumm was asked to estimate, based off of his clinical experience, how many of his patient that he refers to get pharmaceuticals.

A. Dr. Krumm stated it's a relatively low percentage, but it does come up often enough where he's faced with having to refer patients to one of his colleagues. He stated that they often have no desire to see one of his colleagues because a lot of his patients are very adamant about going to see a naturopathic physician. They trust them in management of their care. But overall, he stated that the vast majority of cases don't need to be referred for pharmaceuticals, but when certain things come up, it is appropriate.

Dr. Guiltinan added that based on her observation in the teaching clinic in Wallingford, it likely be something less than 5% of the population that would potentially need to be referred for controlled substances.

Q. Dr. May was asked about a reference earlier to ARNP prescriptive authority, and some additional materials he had submitted that draw a parallel between naturopaths and ARNP prescriptive authority. She asked whether he had read the ARNP rules and WAC relative to their prescriptive authority, and if so, is that what naturopaths are seeking.

A. Dr. May responded that they are very aware that ARNPs have clinical specialties that the naturopathic profession does not; such as anesthesiology, pain management, psychiatric nursing. They have specific prescriptive authority requirements for the different specialties, and so they are not looking for anything to that extent. He stated they are limiting their comparison to the independent primary care nurse practitioners. He stated they have reviewed those rules, but he doesn't claim to know them well enough to speak to them specifically at the hearing.

Q. A follow up was asked, whether Dr. May is aware that with the ARNP construct, an individual has to have an endorsement and carry it along with their license, and renew it along with their license for prescriptive authority? It's not a blanket prescriptive authority for all ARNPs.

A. Dr. May responded that he does understand they ARNPs have to maintain a separate nursing license, a license as an ARNP, and then there are additional educational requirements for their prescriptive authority.

Q. Is that the type of scenario that you are seeking for naturopaths?

A. Dr. May responded that without committing to that exact format, they are looking at continuing education and training requirements that would ensure optimal practice and public safety, which will likely require additional continuing education for naturopathic physicians.

Q. You submitted information about the federal health personnel shortage areas for Washington State by county. You had asserted that naturopaths will help to fill shortage of primary care practitioners, and provided numerous references to a lot of different materials. Some of those focused on shortages in rural or underserved areas, and then you included data from this database by reference. It shows the distribution of shortage areas and underserved populations by county. Could you please talk about the geographic distribution of naturopaths in relation to the underserved areas and specific populations identified for Washington State in this document?

A. Dr. May responded that he can address that the vast majority of naturopaths are within the greater Puget Sound area at this time; and in fact, the majority are in the three most populous counties of King, Pierce and Snohomish County. He stated that they have doctors in many of the other counties, and they are in small numbers at this time. However, as the profession grows, and their ability to integrate with the medical system and participate in programs such as Medicaid, and options for reimbursement, they expectant that many graduates will want to serve in and practice rural and underserved areas. He added that they have study data conducted through Bastyr University students indicating a very high percentage are interested in practicing in rural and underserved areas. He stated he feels that as the barriers to their ability to practice there are reduced, we will see many more naturopaths move to those areas to offer primary care services.

Q. A follow up was asked. Beyond the rural areas, a lot of these are discreet to homeless, migrant health type populations. Do you have any data around serving specifically those populations?

A. Dr. May responded that he doesn't have specific data on that. NDs are new to the Medicaid system, and are growing. When, he last talked with the Health Care Authority, the data had not yet been available. He stated that Bastyr University's teaching program includes a number or rotations that Dr. Guiltinan can probably address that have to do with homeless programs, underserved areas and so it's all a regular part of the education.

Dr. Guiltinan added that yes, Bastyr has an external site program of approximately 23 external sites where a team of faculty and naturopathic medical students go into these settings and provide care, free of charge, to underserved communities. That includes seniors, homeless women's shelters, homeless youth high school, underserved high school, teen health center, and other such settings.

Public Testimony

Ms. Weeks asked for the first panel of public testimony to come up. This included Katie Kolan from Washington State Medical Association (WSMA) and Dr. Peter Dunbar from WSSA.

Dr. Peter Dunbar

Peter Dunbar began testimony. He introduced himself as professor of anesthesiology at the University of Washington and in practice at Harborview Medical Center for the past 20-and-something years. In addition to medical school and college, he did a pain fellowship in 1990; which is an additional year on top of his anesthesia training, and four years of anesthesia residency and medical school. He stated that he worked initially in pain service at Fred Hutchinson Cancer Research Center, and then was chief of the pain service at Harborview Medical Center. He stated that in his experience, with the advantage of time, much has changed in the prescribing of opiates in the last 30 years since he graduated medical school.

When he was a student, they never prescribed opiates for anything other than very short periods of time, following surgery or the like. They never prescribed opiates for chronic conditions, or for what they called non-malignant conditions, that were not involved with cancer. He described a battle over opening up opiate prescribing to the general public and general use by primary care providers, which Dr. Dunbar stated he fought. He stated this idea was championed by a group of anesthesiologists who thought that they could safely treat non-malignant pain with opiates.

He stated that experience led to the epidemic of opiate overdoses that now plague our society. He stated "the road to hell is paved with good intentions," because their intentions were that people without cancer are also hurting and suffering so they deserve to be treated with opiates too. However, taking the individual anecdotal case and expanding it to the general principle doesn't work when you start talking about issues with public health. By the time Dr. Dunbar was in charge of the pain service at Harborview, they were seeing the number of people dying of opiate overdoses in Washington doubling every 18 months. And as he said he predicted in 2005, by 2009 or 2010, the number of people who died in this state from opiate overdoses was greater than the number of people who died from automobile accidents.,

He stated they people in the United States consume over 80-90% of all the opiates that are consumed on the entire planet; despite our population being significantly less than 5% of the planet's population. And, unfortunately making it even worse, we've increased the use of opiates across the country, and the use of opiates is absolutely horrifying, as the document which was showing the top 20 uses. He added that he does not believe we've significantly reduced the problem of chronic pain in America, He said he doesn't have data on this, but there does not seem to be fewer people with less pain now, despite using 5-10 times as much opiates as our country did in the past.

Something Dr. Dunbar stated they never taught him in medical school about the permanent damage done by people being on long periods of opiates, like 90 days or longer, and that the chance of somebody who's taken opiates that long of getting off those opiates is very low. He thought about 5%. He said it has been his experience that long-term use of opiates has permanently changed people's response to pain. It also actually reduces life expectancy.

He said he appreciates the concern that the naturopathic physicians show for their patients to want to make it somewhat more convenient for their patients, but he feels that the last thing we need is to make it more convenient to get opiates. They are dangerous and people who are on them are incredibly persuasive. Nothing, nothing is more persuasive than somebody who wants their opiates. If people need opiates, then they really need to be working with somebody who's a specialist in that topic. He stated he's not necessarily saying that you have to be a board certified pain specialist like him, but at the very least it needs to be someone who's taken a great deal of interest pain management with adequate and extra training in it. He warned against opening the floodgates on yet another set of providers giving opiates and adding to an already existing problem.

Katie Kolan, WSMA

Ms. Kolan introduced herself as director of legislative and regulatory affairs at the Washington State Medical Association (WSMA). She stated that she wanted to specifically address the high-level points WSMA has reviewed in the applicants' proposal. She first addressed the designation as a primary care provider to justify support of expanding the scope to allow the prescribing of controlled substances scheduled II-V. That is an administrative designation in law, and the designation of a naturopathic doctor as a primary care practitioner is just that. It does not, specifically and inherently, come with the authority to prescribe or the need or reason to prescribe. The designation as a primary care provider does not, in and of itself, support the decision to allow for an expanded scope.

The proponents also brought up in their application that some of the patient population a naturopathic doctor sees may require the use of these medications. Her second point was that the provider shortages and dual-utilization that was called out in the application; those are two areas that the medical association is also very concerned about. She stated they don't want to see overuse or dual-utilization of practitioners either. But in the case where prescribing of these dangerous medications is necessary, referral is appropriate. And she stated that Dr. Dunbar said it earlier, convenience is not a reason to allow for an expanded scope; to allow access to these dangerous drugs through prescribing to a patient who is visiting with a naturopathic doctor.

Her third point was that WSMA was actually a little bit confused about the reference of HB 2876 that was passed a couple years back. It was passed to direct the boards and commissions to adopt rules regarding the management of chronic non-cancer pain. She stated that naturopathic doctors were notably omitted from that list of practitioners. It makes sense, based on the timeline that that legislation passed. But specifically, they were not considered as being one of those list of practitioners who should be granted additional scope, or should at least be educated to allow their patients who are on those medications to also become educated about that patient population that they're seeing.

There was reference in the applicant panel to additional education and additional training, and of course WSMA is open to seeing what those additional recommendations are. But they have not yet seen that; and so the relevance of that legislation to them has no specific nexus or meaning. Ms. Kolan also brought up a question of process and notice regarding the sunrise process. They have not been able to see the additional supplementary questions that were submitted to the applicant that they picked up a copy of on their way into the hearing. Those were not posted on the website prior to the hearing. So WSMA has not had an opportunity to reply to those additions to the applicant report. WSMA will be reviewing the supplemental information and providing comments on those during the comment period after the hearing.

Q. Ms. Weeks asked a question on whether WSMA's concerns would be different if the proposal did not include controlled substances in Schedule II.

A. Ms. Kolan stated she does not believe they would be different. She will need to run that through the executive committee, leadership, and clinical experts to determine that, but felt comfortable answering that it probably wouldn't change it.

Q. Ms. Weeks asked the same question to Dr. Dunbar

A. Dr. Dunbar responded that it's hard to say. Fundamentally, he sees the value of naturopathic physicians, may see himself referring patients to a naturopathic physician. He stated that he doesn't really know much about naturopathy, except don't eat too much fat. His knowledge about naturopathy really consisted of nutrition. He stated that what we know about opiate receptors, there are 26, 27, 30 opiate receptors, and we are always finding new ones, and there are various drugs that will affect those receptor, some in Schedule II, others in Schedule III. He deferred to the medical association.

Q. Ms. Kolan was asked whether she has ever heard stories about inconvenience with someone who was visited a naturopath and being referred on.

A. Ms. Kolan responded that none of WSMA's physicians have come to her with that particular complaint. She hasn't asked that specific question of them, but they represent across the board from primary care practitioners to specialty and sub-specialty practitioners, and it's a general theme that the issue of referral and re-referral, and over- dual-utilization seems to be a problem across the board for patients.

Q. Ms. Kolan was asked if there is a specific number of hours of pharmacology training for MDs.

A. She stated she we will follow up with the specific hours, but she think that, just very crudely, medical schools are 4 years; with an additional residency after medical school (3-7 years); and if you want to move into a sub-specialty it's an additional one to three years on top of that. She stated WSMA will follow up with thee specific hours of training, but since the proposal they reviewed had no reference to specific hours and training, they did not have an opportunity to respond yet.

Dr. Dunbar added that additional pharmacology training is great for teaching how drugs work, but there's a lot more to it. It's a question of systematically integrating how the drugs work from a psychological component, which you're not going to learn about in a pharmacology class. There is also how they will react to other drugs and other illnesses, and a whole lot of the systematic integration of the training across things. He stated he would not presume to know much about naturopathy if he did 60 hours of training. It would not be equivalent to going to Dr. Guiltinan's school. It would give him a narrow slice, but the trouble is, these drugs are complicated. They've been around for millions of years and our bodies have learned to become very attached to them, which makes them a very special and different class of drug.

Melissa Weakland, MD

Dr. Weakland introduced herself as a family physician medical provider, representing herself. She is an active member in the Washington Association of Family Practitioners and serves on the King County board. But she stated her organization represents a large panel of people, with diverse opinions. She stated she is in support of the naturopathic increase in scope; even though her broader organization has

submitted a statement in opposition to it. She stated she has been a primary care practicing physician for over 10 years, with a very vibrant practice. She wanted to address some of the comments that came up.

She said there are two issues that have been discussed. One from the naturopathic side is more about access to quality primary care. She stated the concerns that have been raised about it are about a different issue of safety in helping patients. She stated she thinks we need to recognize there's a very shift in the health care where what's considered alternative treatments can and has become part of mainstream medical care. In her world there are many MDs now practicing alternative treatments, and it's interesting that no one opposes or questions when she wants to do acupuncture or provide supplemental treatments. But somehow, when a naturopath wants to have a broader toolbox, then suddenly there's huge concern that their training is not adequate for it. Alternative care is part of mainstream now. Her patients come in seeking naturopathic care. She said often patients don't even think about whether she is an MD or an ND. Patients go to someone their friend said was a great doctor. Titles get more concerning in these types of situations.

She said that Dr. Krumm gave some examples from the clinical side and a question was raised whether it interrupts the primary care experience as an MD when patients come to them for prescriptions that naturopaths can't write. She stated that it does. She received referrals from patients in this way, not a lot of them, but some. She stated that it's about the patient-physician relationship, and she thinks in terms of safety, that is the most important thing in prescribing. She knows her patients. She has a patient who comes to her once a year because she does a lot of flying for her job and has fear of flying. She uses medication to help with that anxiety that her naturopathic primary care physician can't prescribe. She comes to Dr. Weakland once a year for 10 or 20 pills. This patient could really roll that visit into a normal primary care visit, but instead has to take time out of her schedule and pay for an extra visit.

She stated she also had a patient referred to her in acute back pain, who sees a regular naturopathic physician. He has about three episodes of back pain about every 20 years or so, and he came to her because his provider could not provide a narcotic for his back pain. It works very well for him. So she had to see him, and she did not have a relationship with him. It's not how she likes to practice medicine, and not what she considers safe medicine. She says it causes a dilemma because she wants to see patients who are seeing her because they want to see her, not because she can write them a script that the provider they want to see can't do.

Safety is the main concern. It's the main opposition that her organization put forth, as well as the WSMA. But she questions whether there is evidence that shows that the training she has makes her better prepared to prescribe these medications. She referred to Dr. Dunbar's testimony that some of the things he was talking about were not taught to him in medical school. She thinks the safety she has in prescribing is what she learned from working with patients from her clinical experience over the years. There are different rules in place depending on the dosage of opioid prescribed. If she has a patient who takes a certain dose of a certain amount of a narcotic, she either has to consult a pain specialist for that, or show that she has special training to do that. So there are different rules that already exist to protect patients from inappropriate prescribing.

She also stated that Dr. Dunbar made a great point that it's a problem that exists now with her and her colleagues. They are the ones prescribing these medications, and it's a big problem. She is curious where the evidence shows that she is so well trained in prescribing these better than what her naturopathic colleagues would be. She thinks her colleagues in the world of medicine are about evidence-based

medicine and hold themselves pretty high in that. So, she questions where the evidence is for all the concerns that are put forth about the naturopath and prescribing safety. They have proposed additional training. She feels there would be accountability after the fact. This presents an opportunity. There is a health care dilemma. There is a primary care provider shortage. This is a group of physicians who are very motivated to provide quality care, and there is a barrier to providing it. If we are look for solutions, instead of continuing to put up barriers, this is a potential solution to expand primary care for people who desire it and need it. If there is a problem in the future, it seems it can be addressed at that point.

Q. You started that you don't understand why we're concerned about expanding the naturopathic scope, because you can expand yours to prescribe or recommend herbs and minerals. I think there's a big difference between expanding scope for controlled substances and offering herbs and minerals to someone. So I'm confused by your statement. I think what we're supposed to do is exactly that; to find out what if best for the patients. Opening up prescriptive authority for controlled substances is much different than offering herbs or minerals or another natural approach to your patients. Can you clarify?

A. Dr. Weakland stated she thinks part of it was brought up earlier about patients potentially being confused if they came to see a naturopath who prescribed a pharmaceutical. She thinks that was partially to address that, but she doesn't think patients are confused at all in that setting. She thinks it is the way of the world, of health care today, that all of the modalities are being mixed together. She added that, in terms of safety, the patient-physician relationship is what improves safety more than anything, and in general, naturopathic clinics are set up to have stronger patient-physician relationships than what most of her clinical settings allow her to have. She agreed there is quite a difference between a supplement, but because of chemical properties, she cautioned they are not as benign as perhaps sometimes people think.

Hearing Wrap Up and Next Steps

Kristi Weeks then wrapped up the hearing and provided next steps which included:

- An additional 10 day written comment period through July 27th, at 5:00 pm for anything that has not been addressed or any rebuttals participants would like to make.
- The department will share an initial draft report with interested parties in September for rebuttal comments.
- Those participating in the sunrise will receive the draft as long as the department has contact information.
- We will incorporate rebuttal comments into the report and submit it to the Secretary of Health for approval in October.
- Once the Secretary approves the report, it is submitted to the Office of Financial Management for approval to be released to the legislature. OFM provides fiscal and policy support to the governor, legislature and state agencies.
- It will be released to the legislature prior to the legislative session, and will be posted to our website once the legislature receives it.

Hearing Attendees

Name	Representing	Position
Robert May	WANP	Pro
Chris Krumm	WANP	Pro

Jane Guiltinan	WANP	Pro
Terry Kohl	WANP	Pro
Adam Geiger	WANP	Pro
Mona Fahoum	WANP	Pro
Katie Kolan	WSMA	Con
Dr. Peter Dunbar	WSSA	Con
Nina Walsh	WANP	Pro
Melissa Weakland	Ballard Neighborhood Doctors Integrated Clinic	Pro

Appendix D

Written Comments

Naturopathic Scope of Practice Sunrise
Written Comments
July 15, 2014

I am in favor of this proposal to all naturopathic physicians to prescribe substances per 18.120 RCW.
Michael Theisen, MA, LMHC, Associate Professor/Program Director
Master of Arts in Counseling (MAC) Program

This is NUTS! What's a "naturiopath" gonna do?
Write for cannabis extracts & derivatives of course!
Maybe we should allow them to write for a smidgeon of codeine, hydrocodone & of course the historically widely abused agent of history, paregoric!
(unsigned email)

I support the opportunity for Naturopathic Physicians to have expanded prescriptive authority. Many of my midwifery patients see a Naturopathic Physician as they would a primary care provider, and the ability of the Naturopathic Physician to prescribe medications for the health and benefit of the patient is a critical component of general primary care. These Naturopaths are trained and qualified to render efficient, effective care to their patients. Permitting them to prescribe medications keeps the quality and continuity of care consistent. I support this revision in the sunrise review.

Nancy Spencer, LM CPM

I have worked in a collaborative primary care practice with NDs for 15 years. I support the proposed Sunrise Review prescriptive scope expansion for NDs. I believe that to fully participate as PCPs in most primary care settings, NDs need the authority to prescribe the full spectrum of medications used in such settings, including controlled substances when indicated. NDs have been safely managing full prescriptive authority with all legend drugs and the controlled substances testosterone and codeine preparations since 2007.

Karen Rongren ARNP, Family Practice, HealthPoint, Bothell, WA

I am writing in support of the proposal to confer to Naturopathic Doctors in the state of Washington full prescriptive authority for schedules II-V controlled substances.

I have been a medical doctor since 1981, and a naturopathic physician since 2002. I currently hold active Washington licenses for both, and am in full time private practice in Vancouver, WA. I have also had the privilege of serving as Chair of the Washington Naturopathic Board from 2011-2013.

The primary societal benefit of bestowing NDs full prescriptive authority is that it would allow them to more completely serve in their role as primary care physicians, without having to refer to other (frequently overburdened) primary care providers for otherwise redundant services. Especially in light of

the growing shortage of primary care providers, the economic and patient care access advantages of mitigating the current system's dual utilization of services are obvious.

The pivotal question is whether such expanded prescriptive authority would maintain adequate patient safety. My answer to this question is yes. Here's why:

Firstly, Washington would not be breaking new ground, since Naturopathic Doctors in Oregon already have such authority. I attended naturopathic medical college in Oregon, and have practiced for the past nine years across the border from Oregon. As such, not only do I know many naturopathic physicians who practice in Oregon, but a significant fraction of my patients reside there; many have seen NDs there. It is my experience that controlled substance prescribing by NDs is conducted as safely as that of my MD colleagues, and tends to be exercised with even greater caution.
Second, Naturopathic Doctors in Washington have been managing full legend drug prescriptive authority, along with the controlled substances testosterone and codeine, since 2007. Many of these drugs have great potential for harm if improperly used, yet they have been prescribed safely by NDs since their formulary was expanded.

It is therefore my conclusion that expanding the prescriptive authority of Washington Naturopathic Doctors to include schedule II-V controlled substances would be beneficial to both patients and doctors, have a positive economic benefit for all relevant parties, and could be exercised without compromising public safety.

Please feel to contact me for further comment or discussion if you would like.

Daniel I Newman, M.D., N.D., M.S.O.M.
Diplomate, American Board of Internal Medicine
Diplomate, American Board of Pain Medicine
Diplomate, North American Board of Naturopathic Examiners

As a practicing physician in a busy community health center, I support the proposed Sunrise Review prescriptive scope expansion for NDs.

To fully participate as PCPs in most primary care settings, NDs need the authority to prescribe the full spectrum of medications used in such settings, including controlled substances when indicated. The current limited prescriptive scope for NDs results in dual-utilization of providers, ultimately costing patients, insurers, and the State more, and potentially decreasing quality of care disrupting continuity and coordination of care. NDs have been safely managing full prescriptive authority with all legend drugs and the controlled substances testosterone and codeine preparations since 2007.

I currenlty practice with an ND who provides quality care and often is the primary care provider for many of our patients. It doesn't make sense for me to get involved with a patient that I don't know at all simply to be able to prescribe a controlled substance.
Xiomara Munoz, DO

I am writing this letter on behalf of our naturopaths here at HealthPoint and in support of the proposed Sunrise Review prescriptive scope expansion for Naturopathic Doctors (NDs) being considered by the Washington State Department of Health.

HealthPoint was one of the first federally funded organizations in the country to employ Naturopaths as part of our multi-disciplinary care teams. We have also been an important provider of primary care for many patients receiving Medicaid coverage in the State of Washington as well as many of the uninsured residents of our State. Operating primarily in King County, we serve a large proportion of underserved patients who struggle financially and suffer from many additional physical, mental, and psychosocial factors.

Over the years, we have found that our patients greatly benefit from having access to naturopathic services. Our naturopaths have served as consultants as well as primary care providers for a number of our patients. I, personally, have been impressed with their competence and compassion in how they interact with and serve our patients here at HealthPoint.

The proposed Sunrise Review prescriptive scope expansion for our NDs would help improve the service that they offer our patients. I agree with my colleagues here at HealthPoint that the current limitations on their prescriptive authority risks duplications of services between our NDs and MD/DO and other midlevel providers. While the coordination of care between our allopathic providers and naturopaths is quite good because we work side by side on a day to day basis, there is no doubt that any reduction in unnecessary visits or time spent consulting unnecessarily within busy primary care settings drains resources and costs patients, insurers, and the State valuable time and money.

In my opinion, expanding their prescriptive authority makes sense. NDs have been safely managing full prescriptive authority with all legend drugs and the controlled substances testosterone and codeine preparations since 2007. Our NDs are well trained and have been valuable members of our care teams for over 15 years. I recommend that the Department of Health adopt the proposed Sunrise Review prescriptive scope expansion for Naturopathic Doctors (NDs) in Washington State.
Evan M. Oakes, MD, MPH, Medical Director
HealthPoint

I'm contacting you to support the WA Association of Naturopathic Physicians' request for a proposed expansion of the naturopathic physician's prescriptive authority to include schedules II-V controlled substances. This letter is my submission to this 'sunrise review' being conducted by our Department of Health.

I am a practicing primary care family medicine MD. I have a thriving practice and have been in clinical medicine over 10 years. My patients relay many stories both negative and positive of their experiences in BOTH the ND and the MD world. I have an understanding that the quality of care provided in our community is provider and situation dependent as opposed to training and MD/ND/DO/ARNP/PA initial dependent.

Expanding the ND prescribing scope to include all necessary medications used in primary care is a potential positive step for patients and our healthcare system. NDs are currently limited to prescribing legend drugs, testosterone, and codeine. This limitation requires NDs to refer their patients to me and other primary care providers, resulting in "dual-utilization" of medical providers, interference in the patient provider relationship and added costs to the healthcare system.

We are told we are in a primary care shortage and this trend will continue. My patients are confident in the care they receive from naturopathic physicians and actively seek naturopathic care. I have seen no evidence of unsafe prescribing nor heard of frank negligence by care provided by NDs. I sometimes disagree with specifics in care provided by NDs but that is also my opinion of some care by MDs also. I

have found that the doubts my MD colleagues express of primary care NDs is based in opinion and speculation and not evidence based - something my world typically rallies against.

I believe expanding the ND prescribing scope is an opportunity to continue increasing access to quality primary care with better continuity and coordination of care. If at a later date evidence shows otherwise, then appropriate action can be taken. But given at this time there is much fact supporting the need for a larger pool of quality primary care and no clear evidence showing harm in ND prescribing or quality of care, I think our community has much to gain supporting this increase in the ND scope.

Dr Melissa Weakland MD,Ballard Neighborhood Doctors

I am writing in support of the Naturopathic Physicians of Washington State being given full prescriptive authority comparable to the Family Nurse Practitioners in this State.

For ND's to fully participate at PCP's in most primary care settings NDs need the authority to prescribe the full spectrum of medications used in such settings, including controlled substances.

I have been a Family Nurse Practitioner for 24 years and have had the privilege of working for over 5 years with ND's in an integrated medicine clinic in Seattle. In that timeframe, due their limited prescriptive scope, there were times that they approached me in a collaborative effort for various prescriptions. At no time were the requests unwarranted. In fact in every case their case presentation, consideration of other options and concern for individualized patient care took priority. Due to their limited scope I would see the patient briefly free of charge and write, in 100% of the cases, the requested medication.

As indicated above the current limited prescriptive scope for ND's results in dual-utilization of providers. I did not charge the patient or the ND for my time and the patient did not have to travel to another office. However, this is not always the case in underserved areas or in clinics without another healthcare provider with a broader scope. Ultimately without this option for patients it costs them, insurers, and the State more, and potentially decreases the quality of care by disrupting continuity and complicating coordination of care. And it puts a great burden on the patient. In short, my primary care provider is an ND but, she cannot provide me with the full spectrum of medications I might need if I had a migraine or a severe acute MSK injury and this leaves me very concerned. Due to my commitment to ND's practicing primary care I have not switched providers. However, for others this may be enough of an issue for them to seek care elsewhere.

Nurse Practitioners were in this same predicament in this state not too many years ago. And since our inclusion in our current prescriptive scope of practice the number of cases of abuse and misuse still falls short statistically of MD's in this state.
NDs have been safely managing many prescription drugs including testosterone and codeine preparations since 2007 and I firmly believe they are capable of expanding their scope to include Schedule II drugs. Consequently I contend and support that ND's are fully capable of having their scope expanded with continuing pharmacy education requirements attached.

Lise Anderheggen-Leif, ARNP,Evergreen Health: Hospice and Palliative Care

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I am writing on behalf of Association of Washington Healthcare Plan (AWHP) members regarding the Department of Health's (DOH) sunrise review of a Washington Association of Naturopathic Physicians (WANP) proposal that would expand the scope of practice of naturopathic physicians to allow them to

prescribe controlled substances contained in Schedules II through V of the Uniform Controlled Substance Act. On behalf of the consumers we serve, AWHP member healthcare plans are committed to maintaining patient safety and access to the highest quality of care at the best possible cost. Accordingly, we offer the following comments and recommendations for your consideration.

Patient Safety
Over the past few years, concern has continued to grow in Washington State regarding over-prescription of opioids and the related health consequences to its residents. The Washington State Office of the Attorney General (AGO) reports that "Prescription drug abuse is epidemic in Washington State. There are more deaths annually from prescription drug abuse than that from meth, cocaine and heroin *combined.*[1]" The Washington State Medical Association (WSMA), in conjunction with other leading Washington healthcare organizations established "Washington Emergency Department Opioid Prescribing Guidelines".

Included in this valuable resource document is the following information: "As the use of prescription opioids for chronic non-cancer pain has increased, so have unintended consequences related to opioids. In Washington, from 1995 – 2009, there was a 17 fold increase in unintentional poisoning deaths and a 7 fold increase in poisoning hospitalizations involving prescription opioids. There has been a 6 fold increase in state-funded substance abuse treatment admissions for prescription opioids in Washington from 2003 – 2010.[2]"

It is with this troubling situation in mind that we urge significant caution in extending to additional provider classifications the authorization to prescribe these powerful substances and strongly support the inclusion of appropriate training and education for such a scope of practice expansion.

Training & Certification
A key component of patient safety is comprehensive provider education and training. As part of its Sunrise Review, we recommend that information be provided regarding the educational curriculum and training requirements that naturopathic physicians must complete regarding the therapeutic use management of controlled substances, particularly opioids contained in Schedules II through V of the Uniform Controlled Substance Act. Prescribers of this class of medication must have the ability to assess and deal with addiction. We urge the inclusion of specific training for naturopaths on acute and long term chronic pain management and recommend starting with education that the Washington State Medical Association has developed on this topic. The legislation should be clear that training for effective delivery of such services be mandatory for licensure in naturopathy.

It also would be helpful to include information regarding how the proposed prescriptive authority interfaces with certification and other requirements of the U.S. Drug Enforcement Administration (DEA).

Costs
The applicant indicates in Section (4) *The benefit to the public if regulation is granted,* that the proposed scope of practice expansion will result in lower costs. We recommend that evidence be provided to support this cost savings claim, as well as how the proposed expansion will avoid an overall cost increase due to increased utilization.

Magnitude of Impact
In the third paragraph of the Sunrise Review Application Section (1) *Define the problem and why regulation is necessary*, the applicant states that "Due to the practice limitations on ND prescriptive authority, NDs now must refer patients to other primary care providers when controlled substances are necessary." As part of the Sunrise Review process, we also recommend that information be provided

regarding the frequency of such occurrences and the number of patients affected.

Thank you for the opportunity to provide these comments and recommendations. We hope you will find them of assistance. Please do not hesitate to contact me with any questions or to discuss.

Sydney Smith Zvara
Executive Director
Association of Washington Healthcare Plans

[1] http://washingtonacep.org/Postings/edopioidabuseguidelinesfinal.pdf
[2] http://www.atg.wa.gov/prescriptiondrug.aspx#.U8Rdv0Tn_IU

I am writing to respectfully provide written testimony in full support of extending the prescribing privileges for Naturopathic Doctors in the State of Washington. I feel that N.D.s in WA should be allowed to prescribe the full range of controlled substances that are currently allowed by other primary care providers. As increasing numbers of N.D.s become licensed and are thus more prevalent in primary care settings, the need for prescribing all the controlled substances that are typically prescribed in those settings is only logical. Restricting prescribing privileges for a particular group of primary care providers leads to duplication of services (when patients must see a second provider for the same problem), and consequently increases the cost of care to everyone involved. Also, when patients are unable to accomplish a second visit in a timely manner, morbidity persists and can be an additional source of increased health care costs. Since 2007, N.D.s have been safely prescribing all legend drugs, as well as codeine and testosterone (both controlled substances), and I am confident that the same will be true of other scheduled drugs.

I am a dually licensed physician in WA (M.D. and N.D.), and have been practicing in academic naturopathic settings for the past eight years. I would like to say that I have nothing but the highest regard for my naturopathic colleagues, who, in my opinion, match all other groups of medical professionals in terms of professional skill, dedication to excellence, integrity, empathy and commitment to healing in the gentlest but most effective way. I do hope that, in the future, the needs of their patients can be served equally when a controlled substance is the best therapeutic choice.

Katherine A. Raymer, M.D., N.D.

While I do not know the curriculum for naturopathic school, it is my understanding that naturopathy is a practice of nontraditional medicine that frowns upon the use of drugs. I am aware that naturopathic physicians are not required to do postgraduate training (medical and osteopathic physicians are) and many decry the non evidence based practices of naturopathy. Based on this, I don't understand why Washington State permits any prescribing by naturopathic doctors and I certainly would not recommend allowing them to prescribe controlled substances.
Leslie Burger, MD

After reading the laws that govern this proposal, I can find at least a dozen good reasons to deny prescriptive authority to Naturopaths, but the overwhelming reason is that the fundamental teaching of naturopathic physicians is a belief that this is an *alternative approach to medicine.*

I have worked with several graduates from Bastyr University. All expressed thinly covered disdain for traditional medicine like MD's, DO's, and NP's practice, and most strongly believing that they knew

better. I simply do not see any reason at all to grant these folks prescriptive authority to dispense C-II drugs to an already over prescribed population in the state of Washington.
I believe this would just open the door to the possibility that the problem of over prescribing of controlled drugs would just continue to grow. In fact, these are the same drugs that are the cause of overdose and death to people across the nation, not just here in Washington.

I would strongly suggest that the Naturopathic Physician stick to the areas of expertise that are stressed in their education, namely using nature's own ways to promote healing, and leave the prescribing of all controlled drugs limited to the professionals that are now licensed to do so. There is no reason to expand access for patients to habit forming and dangerous drugs, and there are dozens of reasons not too.
Denny Birk, RPh, Oncology Infusion Pharmacist

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WASHINGTON OSTEOPATHIC ASSOCIATION MEDICAL
WOMA

July 15, 2014

DEPARTMENT OF HEALTH

JUL 16 2014

HEALTH SYSTEMS
QUALITY ASSURANCE

Ms. Sherry Thomas
Washington State Department of Health
Health Systems Quality Assurance
PO Box 47850
Olympia, WA 98504-7850

Re: Sunrise review addressing ND prescriptive authority

Dear Ms. Thomas,

Although we have signed on to the WSMA joint comment letter, the Washington Osteopathic Medical Association wanted to include some additional information concerning the Naturopathic Sunrise Review.

According to the National Association of Naturopathic Medicine, *NDs practice a distinct method of primary health care - an art, science, philosophy and practice of diagnosis, treatment, and prevention of illness. Naturopathic physicians seek to restore and maintain optimum health in their patients by emphasizing nature's inherent self - healing process, the vis medicatrix naturae. This is accomplished through education and the rational use of natural therapeutics.*

Naturopathic medicine has its place in health care and its providers have been designated by Medicaid and other health plans as primary care providers to accommodate patients who have adopted this philosophy of medicine. If a client selects a Naturopath as their PCP, they should understand the limitations that go with that professions' scope of practice. Primary Care Provider designation is not a legitimate reason to expand prescriptive authority which requires significantly more training to ensure public safety. If naturopathic medicine is not working for a patient, treatment should be sought elsewhere with a provider that has the necessary training to safely prescribe other medications.

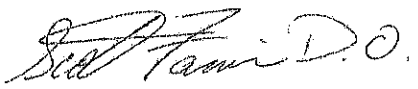
As an example, osteopathic medical students at the Pacific Northwest University of Health Sciences receive 163 contact hours in pharmacology in their first and second years, largely focused on mechanism of action, potential adverse effects and appropriate applications. The curriculum further integrates the basic sciences into system based learning and the lessons are reinforced in the context of each organ system. The next two years of school are clinical where the discussion of the diagnosis directing medication selection, dosing and even alternative therapies are a daily discussion. All of this training merely allows the osteopathic medical student the privilege to apply for a limited educational

license through the DOH so that they can spend the next three years, or more, honing their skills as residents while being overseen by an attending physician.

By comparison, the Bastyr University curriculum lists no pharmacology in years 1 and 2, and a total of 27.5 contact hours in year 3 of their four-year track (or year 4 of their five-year track). We have not been able to substantiate any comparable accredited residency training programs for NDs. The concern of expanding prescriptive authority in the ND community is not just about hours of class time. Even if they added a significant number of hours to their curriculum, they will still lack the extensive, time consuming and necessary training it requires to not be a danger to the public

Thank you for the opportunity to comment on this issue.

Sincerely,



Scott Fannin, DO
President

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Fax: 360-352-4303

July 15, 2014

Ms. Sherry Thomas
Washington State Department of Health
Health Systems Quality Assurance
PO Box 47850
Olympia, WA 98504-7850

Re: Sunrise review addressing ND prescriptive authority

Dear Ms. Thomas:

On behalf of the undersigned organizations representing physicians in various specialties of interest from across Washington State, we are submitting comments on the Sunrise Review to allow naturopaths (NDs) to prescribe controlled substances contained in Schedules II-V of the Uniform Controlled Substances Act. Thank you for the opportunity to share our comments. We look forward to working with you as the Department of Health (Department) moves forward with this proposal.

We are opposed to expanding the scope of practice for licensed NDs to include the authority to prescribe controlled substances contained in Schedules II-V of the Uniform Controlled Substances Act beyond those drugs NDs are currently authorized to prescribe, for the following reasons:

1. NDs lack sufficient substantive pharmacological and other training to enable them to safely prescribe Schedule II-V controlled substances.

2. While there is a need to increase access to adequately-trained medical providers, expanding the authority of insufficiently trained professionals poses risks to the public without increasing access to adequate care.

3. Given recent legislative efforts (such as HB 2876, 2009-10) to protect the public from unsafe prescribing practices, granting less trained providers the authority to prescribe these dangerous substances is not only unnecessary, it is also contrary to legislative intent. Importantly, doing so could pose risks to the public.

Please see the analysis below supporting our position.

(1) <u>Defining the problem and why regulation is necessary:</u>

We disagree with the fundamental premise of the Washington Association of Naturopathic Physicians (Applicant). Applicant argues that because NDs already have limited prescribing authority for legend drugs and some controlled substances (namely, testosterone and codeine products in Schedules II-V), and because they have been designated as primary care practitioners for populations requiring the use of controlled substances, that scope should be expanded to allow for the prescribing of controlled substances Schedule II-V.

The decision to limit who may prescribe these drugs, and specifically, to exclude NDs, is well founded and based on the fact that physicians, osteopathic physicians, physician assistants, and advance practice registered nurses complete training that covers a broader array of medical issues in greater depth than the training completed by NDs. This is discussed in detail below.

Designation as a primary care provider in law is insufficient evidence to support the expansion of an NDs scope of practice to include the ability to prescribe controlled substances Schedule II-V.

We disagree with Applicant's argument that they should be able to prescribe Schedule II-V controlled substances simply because they have been designated as primary care providers in various state insurance plans. Washington State allows the NDs to enroll as primary care providers in Apple Health and though various Exchange products that serve a patient population in the primary care setting. It is true that some of the patient population in that setting may require the use of controlled substances, but that is insufficient justification to allow NDs to prescribe medications for which NDs lack sufficient training to safely prescribe and monitor. The administrative designation as a primary care provider connotes nothing about the training and scope of practice of the provider. Chiropractors cannot prescribe medications, for example, and they do not have the same scope of practice as medical doctors, osteopathic physicians, physician assistants, and advance practice nurses, yet chiropractors are considered eligible to be an attending provider in the Labor & Industries provider network. **There is no inherent right to prescribe controlled substances based solely on an administrative designation as a primary care provider.**

The decision to allow NDs to enroll as primary care providers in the above identified programs was not based upon the state's need to allow NDs the ability prescribe controlled substances Schedule II-V or any other category of drug. In fact, the designation as a primary care provider and the ability to enroll as such was founded for purposes of establishing insurance carrier networks for both the Medicaid population as well the commercial population, and to allow the Department of Labor and Industries to establish a provider network, etc. None of the designations in law to allow NDs to enroll as primary care providers for the purpose of the billing and network establishments speak to the ability to expand NDs scope of practice to allow the prescribing of controlled substances Schedule II-V.

Patient benefit from appropriate prescribing of controlled substances Schedule II-V does not support an expansion of scope of practice for NDs to prescribe those substances.

Though patients who seek care in any of the above identified programs may legitimately require controlled substances to treat some conditions, this in no way indicates that NDs have the training to recognize when and how to safely prescribe these medications.

Provider shortages, referral patterns and "dual utilization" do not support expanding NDs scope of practice to include the ability to prescribe controlled substances Schedule II-V.

We agree with Applicant's statement that there is a "well-known and increasing shortage of primary care providers due to the expansion of Medicaid and increased coverage..." However, the fact that the public could benefit from increased access to primary care services does not support the claim that NDs should have an expanded scope of practice to allow for the prescribing of controlled substances Schedule II-V.

The "dual utilization" of medical providers, provider shortages, potential increase cost to the state and disruption in coordination of care because NDs are required to refer to a prescribing provider for controlled substances Schedule II-V does not support expanding the scope of practice to allow the prescribing of those drugs for NDs. There is no evidence to support the notion that patients who seek NDs as primary care providers suddenly need prescriptions for controlled substances. NDs have been practicing in Washington State for decades without the ability to prescribe most controlled substances and nothing in recent years has fundamentally altered the nature of an ND's practice to allow NDs to prescribe these controlled substances.

The Applicant surmises that NDs would be able to limit the referrals to prescribing physicians if they were allowed to prescribe these medications. There is no data to support that the granting of prescribing authority would change referral patterns. Also, referrals for the treatment of any issue beyond the scope of a primary care practitioner will also necessarily occur due to the nature of the practice (i.e., requiring a specialist for additional care). To that end, there are other - safer - ways of addressing provider shortages and referral patterns other than expanding ND's scope to include access to these very dangerous drugs.

(2) **The efforts made to address the problem.**

Applicant argues that H 4573.4 is the specific effort made to address the problem of lack of prescribing authority for controlled substances Schedule II-V. It would be worth noting that this draft piece of legislation included no other guiding materials to support legislative intent.[1] Specifically, the proposal is silent on the points Applicant was trying to make – that designation as a primary care practitioner, "dual utilization" of practitioners, disruption in coordination of care, etc. – would be addressed by a change in scope to allow for the prescribing of these medications. Moreover, this piece of legislation did not secure other sponsors, was not introduced in the legislature or discussed in a public committee, and generally does not speak to the intent behind the draft legislation. As a result, the legislative document adds nothing substantive in support of Applicant's request.

(3) **The alternatives considered.**

We have no comment for this section.

(4) **The benefit to the public if the regulation is granted.**

[1] See applicant report.

Applicant provides no evidence to support its claims that there will be benefit to the public if regulation is granted, or that insurance carriers and the State will see a benefit if this regulation is granted. Applicant's statement that the "public, insurance carriers and the State" will see lower costs, improve quality of care and increased access to primary care providers if NDs can prescribe controlled substances is conclusory and unsubstantiated.

Moreover, Applicant provides no evidence that regulation by the Board of Naturopathy will ensure proper qualifications, education, training, examinations, and maintenance of competency. Applicant offers no proposals for additional educational requirements equal to, or exceeding, those required in other professions to allow for prescribing of these medications. In the sections below, we will address our concerns regarding proper qualifications, education, training, examinations, and maintenance of competency.

(5) The extent to which regulation might harm the public.

We fail to see the connection between the HB 2876 and how granting prescribing authority to NDs to prescribe controlled substances Schedule II-V will avoid harm to the public. We agree that HB 2876 was passed to direct five boards and commissions to adopt rules concerning the management of chronic non-cancer pain; it was passed because of the concern over patient deaths from overdoses of opioid medications. Adding NDs to the list of health care providers who may prescribe controlled substances, especially with their lack of training in clinical pharmacology, has the potential to worsen the problem HB 2876 was intended to mitigate.

It should be noted that HB 2876 addressed the management of chronic non-cancer pain for the following professions, *excluding NDs*:

- Physicians
- Physician assistants
- Osteopathic physicians
- Osteopathic physician assistants
- Advanced registered nurse practitioners
- Dentists
- Podiatric physicians

The stated goal of the pain management rules is to "keep patients safe and give practitioners who prescribe opioids the best practices in pain management." While this legislation addresses the management of chronic non-cancer pain, NDs are notably omitted from the law's language. Rather than expanding prescribing authority, HB 2876 was intended to address safety concerns, stating, "the rules…encourage practitioners to become better educated in the safe and effective uses of these powerful drugs.[2]"

NDs training and education is inadequate to allow for safe and effective prescribing of these medications.

[2]http://www.doh.wa.gov/ForPublicHealthandHealthcareProviders/HealthcareProfessionsandFacilities/PainManagement.aspx

In order to prescribe medications safely and correctly, it is critical that the prescriber understand anatomy, physiology, pharmacology and the pathophysiology of diseases. NDs do not have those necessary skills, training and education. Applicant fails to address how that lack of training, education, and experience will not actually render harm to the public, especially with regard to the prescribing and use of controlled substances Schedule II-V. Physicians (MD/DO) not only complete didactic courses in pharmacology, but also learn the clinical application of pharmacology in their extensive training with relevant medical specialties such as cardiology, neurology, pulmonology, neurology, orthopedics, pharmacology and emergency medicine. NDs lack this level of extensive training, and are ill-prepared to safely prescribe Schedule II-V drugs or diagnose the conditions for which these powerful drugs may be appropriate.

We are also concerned that Applicant's report fails to describe the nature or amount of additional training it would find sufficient to prepare NDs to prescribe these controlled substances safely. Furthermore, we believe that even with a few hours of additional training, NDs would *still* lack the experience and knowledge to successfully diagnose and treat uncommon and serious conditions, especially those that require administration of controlled substances. Additionally, Applicant fails to indicate with any level of specificity how it intends to determine the competency of NDs to administer controlled substances, even after they complete additional training.

Other state notes regarding prescribing authority.

The vast majority of states either does not license NDs or do not allow them to prescribe Schedule II-V substances. In fact, only ten states allow for limited prescribing authority for NDs and none of those states allow NDs to independently prescribe these powerful drugs.

Conclusion.

The undersigned organizations recommend that the Department deny Applicant's request to expand ND scope of practice to include authority to prescribe controlled substance Schedule II – V, for the reasons detailed above. We disagree that the proposal will provide for safe and effective prescribing of controlled substances Schedule II-V. We also argue that the proposal has failed to demonstrate that the training and education of NDs (and any supplementary training contemplated) will be sufficient to perform a comprehensive exam and patient assessment for the appropriate prescribing of these drugs and thus the requested expansion places the public at unnecessary risk of harm.

Thank you for the opportunity to share our concerns. If you have any questions, please feel free to contact Kathryn Kolan at (360) 352-4848 or Denny Maher at (206) 956-3640.

Sincerely,

Dale Reisner, MD, President
Washington State Medical Association

Paul Abson, MD, President
Northwest Academy of Otolaryngology

David L. Beck MD, President
Washington Society of Addiction Medicine

Brett Coldiron, MD, FAAD, President
American Academy of Dermatology

Timothy Dewhurst, MD, FACC, President
Washington Chapter, American College of Cardiology

Enrique Enguidanos, MD, FACEP, President
Washington Chapter, American College of Emergency Physicians

Scott Fannin, DO, President
Washington Osteopathic Medical Association

Jeffrey Frankel, MD, Governmental Affairs Chair and Past President
Washington State Urology Society

Patrick J. Halpin, MD, President
Washington State Orthopedic Association

Margaret Hood MD, FAAP, President
Washington Chapter, American Academy of Pediatrics

David B. Hoyt, MD, FACS, Executive Director
American College of Surgeons

George J. Hruza, MD, President-Elect
American Society for Dermatologic Surgery Association

Scott Isenhath, MD, President
Washington State Dermatology Association

Judith Jacobsen, MD, Chair
Washington Chapter, American Congress of Obstetricians
and Gynecologists

Vicky Jones, MD, President
Washington State Medical Oncology Society

M. Sean Kincaid, MD, President
Washington State Society of Anesthesiologists

Kathryn Kolan, JD
Director of Legislative and Regulatory Affairs

Saul Levin, M.D., M.P.A.
C.E.O. and Medical Director
American Psychiatric Association

Denny Maher, MD, JD
Director of Legal Affairs

Jonathan Medverd, MD, President
Washington State Radiological Society

Ravi Moonka, MD, President
Washington Chapter, American College of Surgeons

Robert X. Murphy, Jr., MD, President
American Society of Plastic Surgeons

David W. Parke II, MD, Executive Vice President & CEO
American Academy of Ophthalmology

Rachel Reinhardt, MD, President
Washington Academy of Eye Physicians and Surgeons

Peter Roy-Byrne, MD, President
Washington State Psychiatric Association

Mike Urakawa, PA-C, President
Washington Academy of Physician Assistants

Norman E. Vinn, DO, MBA, FACOFP, President
American Osteopathic Association

cc: State and National Specialty Societies
AMA Staff
WSMA Senior Staff

WASHINGTON ACADEMY OF FAMILY PHYSICIANS

July 14, 2014

Sherry Thomas, Policy Coordinator
Washington State Department of Health
P.O. Box 47850
Olympia, WA 98504-7850

Dear Ms. Thomas:

The Washington Academy of Family Physicians (WAFP), on behalf of its over 3,100 members, opposes the sunrise review application proposing to allow naturopathic physicians to prescribe controlled substances contained in Schedules II through V of the Uniform Controlled Substances Act.

As the largest medical specialty organization in Washington State, WAFP has reviewed the application from the unique perspective of Family Medicine, and concurs strongly with the comments submitted by the Washington State Medical Association on behalf of physicians generally.

On the front lines of primary care, family physicians often come face-to-face with the devastating results of inappropriate use of controlled substances. Expanding the authority of those whose training is insufficient to assure they are prescribed safely will only increase the risks posed to the public by these dangerous drugs. And doing so under the guise of increasing access to primary care is a disservice to – and will only distract from – other legitimate means of addressing this important need.

Our opposition is also consistent with the position of the American Academy of Family Physicians, of which we are the Washington chapter. In those states that permit licensure of naturopaths, the AAFP opposes any expansion of naturopaths' scope of practice, including prescriptive authority, not supported by naturopathic education and training.

Sincerely,

Christopher Gaynor, MD, FAAFP
President

Karla Graue Pratt
Executive Vice President

1239 – 120th Avenue NE, Suite G, Bellevue, WA 98005
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STATE OF WASHINGTON
HEALTH CARE AUTHORITY
626 8th Avenue, SE • P.O. Box 45502 • Olympia, Washington 98504-5502

Memorandum

To: Sherry Thomas, Policy Coordinator, Health Systems Quality Assurance, Department of Health
From: Dennis Martin, Administrator, Office of Legislative Affairs and Analysis, Health Care Authority
Re: Sunrise Review – Naturopath Scope of Practice Change
Date: July 15, 2014

Thank you for providing notice of the Sunrise Review hearing regarding change to the scope of practice authority for naturopaths. After reviewing the applicant report and proposed legislation, the Washington State Health Care Authority (HCA) submits the following information regarding the health benefit plans administered by the HCA that could be affected by this proposed mandate, which would allow for Naturopaths to prescribe and administer controlled substances (Schedules II through V).

The Heath Care Authority strives to ensure patients have access to safe, effective treatment while reducing the number of people who misuse, abuse, or overdose from these powerful drugs. The Authority takes increasing the number of potential prescribers seriously, as it may increase the potential for inappropriate prescribing. However, the potential magnitude of an increase of controlled substance prescriptions affecting the benefit plans administered by the Authority is indeterminate.

The primary concern regarding this practice change is whether adequate pharmacology training will be required consistent with the change in scope of practice. The applicant report states, “Regulation and supervision by the Board of Naturopathy will assure proper qualifications, education, training, examinations, and maintenance of competency.” The vagueness of the language leaves room for ambiguity. A specific requirement, such as an additional year of residency which some naturopaths choose to complete, may be more comprehensive and appropriate for the proportional increase in scope.

Medicaid has identified no conflict with Federal rule. As long as the prescriber has legal authority to prescribe the medications in question (which this legislation provides), and the prescriber is enrolled with Medicaid, Medicaid can pay under the same rules as any other medication. Federal rule limits the products paid for, not the status of the prescriber. If naturopaths were allowed by law to prescribe Schedules II – V, Medicaid would be allowed to pay for those prescriptions.

The Authority 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.

System Office
1801 Lind Ave. S.W., #9016
Renton, WA 98057

July 16, 2014

Ms. Sherry Thomas
Washington State Department of Health
Health Systems Quality Assurance
PO Box 47850
Olympia, WA 98504-7850

Dear Ms. Thomas:

Re: **Re: Sunrise review addressing naturopath prescriptive authority**

On behalf of Providence Health & Services, thank you for the opportunity to provide commentary on expanding the scope of practice for licensed naturopathic physicians (NDs) to include the authority to prescribe controlled substances contained in Schedules II-V of the Uniform Controlled Substances Act.

Providence Health & Services is a not-for-profit Catholic health care ministry committed to providing for the needs of the communities it serves – especially for those who are poor and vulnerable. Providence and its affiliates employ more than 70,000 people across five states - Washington, Oregon, Alaska, California and Montana – with a system office located in Renton Washington.

In Washington state, Providence and its secular affiliate, Swedish Health Services, comprise 13 hospitals, 240 physician clinics, senior services, supportive housing, hospice and home health programs, care centers and diverse community services. The combined health system is the largest health care provider in Washington and employs 30,000 people statewide. In 2013, Providence and Swedish provided $413 million in community benefit, including $118 million in free and discounted care for Washingtonians who could not afford to pay. Together, we are working to improve quality, increase access and reduce the cost of care in the communities we serve.

Providence believes that the expansion of prescriptive authority beyond the current authorization that NDs hold is not in the best interest of the public and will not contribute to increased access to care in a meaningful way. Furthermore, we agree with the Washington State Medical Association in stating that an expansion of this kind would have negative, unintended consequences and would pose a threat to public safety. In short, the purported gains do not outweigh the significant risks.

NDs not only lack training in clinical pharmacology they do not have practical knowledge of drug effects, both good and bad. This is something that medical doctors seek to master throughout their careers, not an understanding that comes readily with a pharmacology continuing medical education. Therefore adding NDs to the list of providers who are allowed to prescribe controlled substances would represent a significant departure from recent efforts made by the legislature, the hospital association and participating providers to protect the public from unsafe prescribing practices. Substantial gains have been made in the last year toward this objective and this proposal will likely reverse that trend. We are particularly concerned with what appears to be a lack of understanding regarding safety issues by the applicant. This is evidenced by their omission of references to proposed additional education, training and examinations in their proposal. the applicant provided no data to support predictions of lower costs and improved quality of care.

Providence recommends that the Department deny this proposal to expand ND scope of practice. The applicant did not provide sufficient evidence regarding how this would benefit the public and improve access to quality care. And, and more importantly, we believe that if this expansion were approved, it would pose a significant threat to ongoing efforts aimed at promoting safer prescribing practices.

Thank you again for the opportunity to share our concerns. For more information, please contact Eileen Sullivan at (425) 525-3738 or via e-mail at eileen.sullivan@providence.org.

Sincerely,

Craig Wright MD

Craig Wright, MD
Senior Vice President
Physician Services

Naturopathic Scope of Practice Sunrise
Written Comments Recived After Hearing
July 27, 2014

Please limit prescriptive authority to homeopathic medications. Legend drugs and controlled substances are beyond the scope of their knowledge to provide safe therapy. What the public doesn't need is another profession who doesn't know how to use medications that can harm them.

I have personally seen patients who have been hospitalized from the inadequate use of medications by naturopaths.

Thank you.

Dr. James Bradley Knott, Pharm.D
Director of Pharmacy

Naturopathy favors a holistic approach with non-invasive treatment and generally avoids the use of surgery and drugs. It seems suspect that a doctor of Naturopathy would want to extend their privileges increasing their ability to dispense drugs.

The argument based on the notion of fewer Medical doctors available for naturopaths to partner with is a false premise.

It seems the request to expand scope of practice is based on revenue. The proposal resists the concept of referring patients when a practitioner is operating outside their scope of practice. Scope of practice is based on level of expertise. Naturopaths appear to have a ridiculously wide scope of practice already. A naturopath has the right to give patients mental health counseling, acupuncture, nutritional counseling, and massage to name a few. Can 4-5 years of schooling provide the level of expertise to be solely responsible for the health of a human being?

Practitioners of naturopathy often prefer methods of treatment that are not compatible with evidence-based medicine, and in doing so, reject the tenets of biomedicine. It seems paradoxical that such a group would want to extend their scope of practice to include more drugs.

Much of the ideology and methodological underpinnings of naturopathy are in conflict with the paradigm of evidence-based medicine. Many naturopaths have opposed vaccination for example. Why would practitioners of naturopathy want to expand their ability to prescribe drugs?

Amy Alpine PhD LMHC CCDC II

Hello,
It seems to me, that as Naturopathic Physicians are fully trained physicians, that they should have the same prescribing capacity as a other.
Patricia Dawson.

I agree that Naturopathic doctors should be allowed to prescribe controlled drugs as they have requested in their proposal in the Naturopathic Scope of Practice Sunrise Review application.

Linda L Wilcox, R. Ph

I have reviewed the material in this email regarding the WA Naturopathic Scope of Practice Sunrise Review. Expanding the WA Naturopathic Physicians Scope to include CII through CV scheduled medications comes with added responsibility, such as more Continuing Education Requirements in Pharmacology. Currently, I am registered as a Pharmacist in both WA and OR. Additionally, I am also licensed as Naturopathic Physician in OR and currently have DEA registration. In Oregon, Naturopathic Physicians can obtain DEA registration and write for controlled substances scheduled CII through CV. Obtaining DEA registration is completely up to each individual Naturopathic Physician. I vote YES to expanding the WA Naturopathic Physicians Scope to include CII through CV scheduled medications.--
Sincerely,
Paula S.

I am a graduate from SCMM in Tempe Arizona. I have practiced in both Arizona and Washington state, and currently have my own practice in Bellevue, Washington. I have had experience working with Medical Doctors and Doctors of Osteopathic Medicine, and have had experience prescribing scheduled medications. I believe that it is especially important in Washington state, where Naturopathic Physicians are recognized as primary care physicians, that ND's are able to prescribe along the same scope as other primary care physicians. We are trained in pharmacology just as MDs and DO's with the philosophy to first do no harm. I believe that with increased prescription rights, ND's will continue to practice smart, safe and responsible medicine. It will only give ND's the opportunity to become equals in the primary care world and allow us the ability to fully manage primary care issues that are already under our scope.
Amira Ahdut ND, LAc

We ardently oppose the proposal that would allow naturopathic physicians to prescribe Schedules II through V controlled substances of the Uniform Controlled Substances Act. As community pharmacists, we witness first hand the devastating effects of inappropriate over prescribing of opioids within our local community. We strongly believe that due to the lack of training in both pharmacology and pharmacotherapy, naturopathic physicians are not equipped with the training and experience needed to properly prescribe and monitor patients taking Schedules II through V controlled substances. By extending their prescriptive authority, we strongly believe there will be a greater danger to patient safety and further contribute to the prescription drug abuse epidemic in our community. Therefore, we strongly request that the Department of Health reject this proposal due to the overwhelming risks to the public.,

Duong Bell, PharmD
Kavita Nankani, PharmD
Anna Powell, PharmD
Faith Liikala, PharmD
Kate Atienza, PharmD

I am writing in support of Naturopathic Physicians having prescriptive authority. Naturopathic Physicians are among the most dedicated, ethical, caring and moral practitioners I have ever been acquainted with. It seems to me that since all physician/healing professions were at one time nature based the use of prescription medication is a natural extension of the Naturopathic profession. Healing comes in many immeasurable forms, not simply the research based ones; Naturopathic healers are educated, trusted and skilled at many healing forms that humanity has yet to find a way to measure. I wholeheartedly support the use of Naturopathic Doctors having Prescriptive Authority.

David Stanzak

From my personal and professional experience of working with Naturopathic physicians, I support the expansion sought for their prescriptive authority. I find them to be ethical, well trained and excellent at looking at the physical wellbeing of the whole person which can influence their choice of treatment. They have proven their responsibility to patient care and are certainly qualified to have their scope of practice expanded to include this expanded prescriptive authority.

Lynn Stedman, RDH, Director/Associate Professor
Dept. of Dental Hygiene
Columbia Basin College

As a registered pharmacist, I do not feel that Naturopathic Doctors have the training necessary to prescribe the full range of controlled substances accessible to MD, DO, ARNP, and PAs.

Jason Rusk, PharmD

The WA East Asian Medicine Association (WEAMA) would like to express concerns about a precedent being set in this Naturopathic Sunrise Review, asserting that acupuncture is considered within the scope of practice under the Department of Labor and Industries (L & I) classifications for naturopaths. The area of concern is underlined below:

> WAC 296-17A 6109-04 Naturopaths, N.O.C.
> Applies to establishments of health practitioners not covered by another classification (N.O.C.) who diagnose, treat, and care for patients, using a system of practice that bases treatment of physiological functions and abnormal conditions on natural laws governing the human body, relying on natural remedies such as, but not limited to, acupuncture, sunlight supplemented with diet, and naturopathic corrections and manipulations to treat the sick. This classification includes clerical office and sales personnel, as well as other employees engaged in service in the naturopath's office.

We understand that this specific rule, 296-17A 6109-04, describes the risk class for naturopaths to report work hours and premiums owed for their workers' compensation insurance coverage. However, we would like to clarify that naturopaths do not have acupuncture or dry needling in their scope of practice under their statute (Chapter 18.36A RCW) and have not met the requirements under state law for practicing acupuncture unless they are dual licensed ND and EAMP.

In 1999 the Department of Health did a Sunrise Review that specifically prohibited Dry Needling/Acupuncture to be done by naturopaths, and the Legislature declined to add it to their scope of practice. The legal requirements for performing acupuncture in Washington State can be found under RCW 18.06.050 Applications for examination — Qualifications.

Curtis Eschels, President, WA East Asian Medicine Association

July 24, 2014

Ms. Sherry Thomas
Washington State Department of Health
Health Systems Quality Assurance
PO Box 47850
Olympia, WA 98504-7850

Re: Sunrise review addressing ND prescriptive authority

Dear Ms. Thomas:

On behalf of the physician and physician assistant members of the Washington State Medical Association, the following is our response to staff questions from the July 17, 2014 public hearing concerning the Sunrise review of naturopathic prescriptive authority. We appreciate this second opportunity to comment, and look forward to working with you and the Department of Health should this proposal move forward.

As you'll recall, the WSMA testified in opposition to expanding the scope of practice for licensed NDs that would include the authority to prescribe controlled substances contained in Schedules II-V of the Uniform Controlled Substances Act. Further, we presented our comments in a letter dated July 15, 2014 which included a number of professional medical organizations.

Question: Would WSMA's comments be different if Schedule II was not included?
No. Opioid medications all carry with them the risk of habituation, addiction, overuse, abuse, and serious complications, including death. Other non-opioid scheduled medications have complex actions in the human body and can result in serious complications if prescribed for the wrong purpose or prescribed improperly. NDs do not have a background sufficiently based in scientific pathophysiology and pharmacology, or the necessary amount of clinical training in the use of such medications, to prescribe Schedule III-V. Allowing NDs to prescribe Schedule III-V medications would put patient safety at risk in Washington State.

Question: How many hours of pharmacology do MD/DOs receive compared to NDs?
MDs/DOs receive significantly more training in pharmacology than NDs. The Authorization Regarding Controlled Substances, WAC 246-836-211, requires NDs to complete four hours of graduate-level instruction in pharmacology.

For MD/DOs, the exact number of hours of pharmacology training completed varies by school. The University of Washington requires its medical students to take two quarters of specific pharmacology instruction, amounting to an estimated 180 hours of class time. In addition, pharmacology is covered as part of many other courses, so medical students learn about pharmacology during the remaining two years of medical school.

Equally important, MDs and DOs continue to augment their knowledge of clinical pharmacology, including the indications and contraindications for prescribing medications for diseases and conditions, during their residency training, which may last three to five years.

Exposure to training in basic pharmacology and clinical pharmacology is more limited for naturopathic students. Furthermore, naturopathic residencies are less common than those for MDs and DOs, are not required, and do not last as long as residencies for MDs and DOs.

Thank you for the opportunity to share our comments. If you have questions, please feel free to contact Kathryn Kolan at (360) 352-4848 or Denny Maher at (206) 956-3640.

Sincerely,

Dale Reisner, MD
President

cc: WSMA Executive Committee
WSMA Senior Staff

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION
PO Box 47866, Olympia, WA 98504-7866

July 24, 2014

Ms. Sherry Thomas
Washington State Department of Health
P.O. Box 47850
Olympia, Washington 98504-7850

Re: Sunrise review addressing naturopathic prescriptive authority

Dear Ms. Thomas:

I am the Chairman for the Medical Quality Assurance Commission. I have received comments from several members of the Medical Commission commenting on the sunrise review application to allow naturopathic physicians to prescribe controlled substances contained in Schedules II through V of the state's Uniform Controlled Substances Act. I oppose the proposal for the following reasons:

First, naturopaths do not have the necessary training and education to safely and effectively prescribe controlled substances. Medical and osteopathic physicians receive extensive training in pharmacology and in the clinical application of pharmacology in their medical specialty training. This training and clinical application is critical as many controlled substances are complicated to use and are highly addictive to patients. Naturopaths are trained to use naturopathic medicines, as defined in RCW 18.36A.020(9). Naturopaths do not have the training to diagnose serious conditions that may require the use of controlled substances, and then to prescribe controlled substances in a safe and effective manner.

Second, the proposal is inconsistent with legislation passed in 2010. The legislature passed HB 2876 to address a public health crisis: the rapid increase in overdose deaths from prescription opioids. The legislation directed five boards and commissions to develop rules governing the management of chronic non-cancer pain. The result was significant. Last year, the Department of Health announced that the overdose death rate dropped 23% between 2008 and 2011. Though this decrease in deaths is the result of a concerted state-wide effort to address this problem, the legislation played a key role in raising awareness of the issue, and in the Medical Commission's development of an educational program to educate providers on safe and effective use of opioids in managing chronic pain. Permitting naturopathic physicians, with their limited training in

pharmacology, to prescribe all controlled substances may very well negate the public safety gains from this important legislation.

For these reasons, I believe the proposal will not promote safe and effective prescribing of controlled substances. I recommend that the Department of Health inform the Legislature that expanding the scope of a naturopathic physician's practice to include prescribing all controlled substances places patients at risk and is not in the public interest.

Thank you for the opportunity to express the concerns on this proposal.

Sincerely,

Richard A. Brantner, MD
Chairman, Washington State Medical Quality Assurance Commission

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

August 15, 2014

Sherry Thomas
Washington State Department of Health
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PO Box 47850
Olympia, WA 98504-7850

Dear Ms. Thomas:

The Board of Osteopathic Medicine and Surgery (board) appreciates the opportunity to submit comments on the Sunrise Review to allow naturopaths (NDs) to prescribe controlled substances contained in Schedules II – V of the Uniform Controlled Substances Act. At our July 25, 2014 business meeting, the board reviewed the letters submitted by the Washington State Medical Association (WSMA) and the Washington Osteopathic Medical Association (WOMA).

As stated in the letter of concern from WOMA, the Bastyr University naturopath curriculum consists of a total of 27.5 contact hours directly related to pharmacology. The board recognizes that this is not enough training to safely and responsibly prescribe scheduled drugs. Compare that, as noted in the WOMA letter, with the 163 contact hours that osteopathic medical students at Pacific Northwest University of Health Sciences receive in their *first two* years.[1]

Certain allied health professions who have no prescriptive authority have greater than 27.5 hours of pharmaceutical training. For example, paramedics generally have about 50 hours of pharmacological training in the drugs that they are authorized to administer with *no* prescriptive authority.

The board also recognizes and would like to highlight several key points made in the letter of concern from WSMA:

- Recent legislative efforts to protect the public from unsafe prescribing practices indicate that granting authority to prescribe scheduled drugs to improperly trained providers is contrary to legislative intent[2];
- Allopathic and osteopathic physicians not only complete didactic courses in pharmacology, but also study the clinical application of pharmacology in their extensive training with relevant medical specialties[3]; and

[1] Letter from WOMA to Ms. Sherry Thomas, DOH dated July 15, 2014, page 1
[2] Letter from WSMA to Ms. Sherry Thomas, DOH dated July 15, 2014, page 1
[3] Letter from WSMA to Ms. Sherry Thomas, DOH dated July 15, 2014, page 5

- Only ten states allow for limited prescribing authority and none of those ten states allow naturopaths to independently prescribe schedule II – V drugs[4].

Again, the board shares the concerns previously communicated in letters submitted by WSMA and WOMA and recognizes that the training and education of naturopaths is insufficient to safely examine and assess patients who are prescribed schedule II-V medications. Allowing naturopaths to prescribe these scheduled drugs compromises patient safety. Thank you for the opportunity to comment.

Sincerely,

Catherine Hunter, DO, Chair
Chair, Washington State Board of Osteopathic Medicine and Surgery
State of Washington Department of Health
PO Box 47852
Olympia, WA 98504-7852

[4] Letter from WSMA to Ms. Sherry Thomas, DOH dated July 15, 2014, page 5

Appendix E

Other States

Other States with Prescriptive Authority for Naturopaths for Controlled Substances
(As identified through research by Department of Health staff)

State	Prescriptive Authority	Pharmacology Education / Continuing Education	Formulary / Other Requirements	Citation
Arizona	Requires board certification. **Authorized to prescribe:** - Legend drugs - Morphine - Schedule III, IV, and V controlled substances with below exceptions. **Exceptions:** - Intravenous medication - Cancer chemotherapeutics - Antipsychotics	**Pharmacology education:** 60-hour series of pharmacy courses and examination in pharmacotherapeutics. Southwest College in Tempe, AZ has made this additional training part of their required curriculum for NDs. **Continuing education:** 10 hours of the required 30 hours per year in pharmacology.	Arizona has a very broad formulary.	Chapter 32, Article 15, Arizona Revised Statutes (generally)
California	Requires a "Naturopathic Drug Furnishing Number" from the Naturopathic Medicine Committee. **Authorized to prescribe:** - Schedule III-V controlled substances limited to those drugs specified in a standardized protocol, under "physician and surgeon" supervision. - Schedule III controlled substances require a patient-specific protocol approved by treating or supervising physician.	**Pharmacology education:** 48 hours of Phamacoloty/cognosy **Continuing education:** At least 20 of the 60 hours required biennially shall be in pharmacotherapeutics.	Requires supervision by a "physician and surgeon." Standardized procedures/protocol must specify which drugs may be furnished or ordered, under what circumstances, the extent of physician and surgeon supervision, method of periodic review of the naturopathic doctor's competence, and review of the provisions of standardized procedure/protocol.	Chapter 8.2, Article 4
Oregon	All licensed naturopathic physicians have prescriptive authority. **Authorized to prescribe:** Legend drugs and controlled substances recommended by the Formulary Council and approved by the Oregon State Board of Naturopathic Medicine.	**Pharmacology education:** Must pass the Oregon Formulary Examination. One-time mandatory pain management education within 24 months of initial license renewal. **Continuing education:** Ten of the 50 hours required annually must be in pharmacology.	Large formulary that includes schedule II controlled substances.	ORS Chapter 685
Vermont	Special license endorsement for prescriptive authority. **Authorized to prescribe:** Schedule II-IV Controlled Substances on a formulary.	**Pharmacology education:** Must pass an examination created by the Office of Professoinal Regulation. This examination is now available. **Continuing education:** Ten hours biennially in the pharmacology of legend drugs.	Formulary of authorized substances that will sunset in 2015. Supervising physician must review and evaluate prescriptions for one year after receiving the special license endorsement and until the first 100 prescriptions are issued	Vermont administrative rules and information provided by naturopathic advisor to the Office of Professional Regulation

Appendix F

Rebuttals to Draft Recommendations

I support the department's position that there is no need to expand NDs prescriptive privileges.

Curtis Thompson

Their current scope is more than adequate and I have serious reservations as they are going against the tenants of the practice of Naturopathy. My boss is a past Bastry Grad and completed more post grad education at Harvard in Rheumatology and was a hospitalist at NW Hospital for nearly seven years. He shared that he is getting very concerned as he has many MD and DO friends and he does not feel that the ND's should be Rx'ing pain medication or anxiety meds for which their training is insufficient to accommodate. He also notes serious concerns that the ND community seems to be trying to include in their scope the practice of acupuncture and east asian medicine for which they are not formally trained and are materially and didactically less than the DOH requires in good faith.

Thank you kindly, Juliana Mason

Prescriptive authority as widely used by M.D.'s, D.O.'s, Physician Ass'ts. are more than adequate for good health care provision in Washington State.

N.D.'s should absolutely NOT be allowed to write for controlled substances including narcotic, tranquilizers & CNS stimulants. The N.D.'s should also be pre-empted from writing for hormonal agents such as estrogenic agents & male hormones including E.D. agents.

Let 'em use all the vitamins they want in "ORAL" form only. No injections please.

Kermit Sheker, M.S., R.Ph.

I would greatly appreciate my ND having an expanded scope in prescription writing. I trust my ND for my care, and that includes his prescription writing on my behalf.

Pia Marshall

Please allow ND's to prescribe medications in the same fashion as MD's. It is helpful to have this service for patients with their holistic view point.

Andrea Dahlman

My name is Chris Julien and I have been forced to go to other doctors to obtain prescriptions due to WA law not allowing my naturopath to prescribe me with medication I very much need. I think this is a bad law that needs to be changed. Please change the law to allow naturopaths to prescribe controlled substances (such as Alprazolam).

Chris Julien, CPA, Manager II, Berntson Porter & Company, PLLC

I am a practicing naturopathic physician who has had first hand experience with the limitations of the current prescriptive authority of ND's. I firmly believe patients are hurt by ND's inability to prescribe an equivalent pharmacy to MD's.

Below are the negative impacts on my patient's due to my limited prescriptive scope:

- Financial Impact: Increased costs for visits to another practitioner solely for a prescription
- Time Inefficiency: Loss of time from work or family or similar inconveniences
- Quality of Care: Delay of timely care or non-compliance
- Coordination of Care: Disruption of the doctor patient relationship

Please consider recommending expanding ND prescriptive authority. Thank you.

Justin Steurich, ND, The University Health Clinic

I would not support expansion of the naturopathic prescriptive authority, in fact I would support curtailing their authority back to the original basis. They simply do not have the education in pharmacology to adequately protect patient safety with the present protocol.
Dave Manning, RPh

I believe that if a naturapatic doctor wants to prescribe controled substances it should be in collaberation with a board certified M.D.. The purpose behind naturopathic medicine is not to use prescriptive pain meds but to cure with natural substances. If this is allowed I believe you will see patients seeking opiate increase with this approval.

I do not believe the naturopathic physician to be qualified to presribe anything but naturally occuring substances. Legend drugs and controlled substances should be left to the M.D. to allow better evaluation of the patient as well as better control of the prescribing of these medications.

If you choose to allow this process to continue 10 hours of CE is not enough. There should be a requirement of 10 hours of CE for each class of medication to help insure they are semi-qualified to prescribe. Short of that all prescriptions should be endorsed by a M.D. prior to being filled.

Thomas Kloepping D.Ph. R.Ph.

I (and my family) have been a patient of an ND (a few different doctors) for 17 years now. The fact that they cannot write certain types of prescriptions causes me much trouble in that I have to find another doctor to do that for me. This incurs more time and expenses for me and my family. I don't know about you, but extra time and money are pretty tight for us! Please expand ND's prescription writing privileges.

Mrs. Tina D. Sander
Mr. Daniel G. Sander

My name is Aurora Newcomb and I am a schedule coordinator at The Evergreen Clinic, I schedule patients for counseling and medication management. Time after time I have had the same issue with patients when I try to explain to them that the clinician that they are requesting cannot prescribe them controlled substances because the state doesn't allow him to have that kind of authority. Though he is labelled a clinician who practices naturopathy he does have the same amount of practice and experience that our other clinicians do. However, he does not have the same authorizations that a doctor of medicine, MD, or an advanced registered nurse practitioner, ARNP, have.

One of the most frustrating things is the obstacles presented in coordination of care. When there is an emergency patient that needs to see a prescriber, I have a ND with a time slot for the current week and I would be more than happy to get them in, but the care coordinator does not want to put that patient with someone who cannot prescribe controlled substances. So they have to wait for two weeks to get in with any of the ARNP's or MD's. The delay of care for patient is unbelievable because of the lack of prescribing authority that ND's have.

This immediately turns patients away from us because of a wait time, and because of the bad experience, it ruins the patient relationship we could have established. We have patients that love our ND and come here from over 40 miles just to see our ND, but they have to go to another prescriber and waste more money if they want to get a controlled substance. It's an inconvenience in so many ways, it wastes money and time for the patient and that supersedes any notions of ND's approaches to medicine. Patients tend to think an ND's ability to provide care is inhibited by their prescriptive authority because they won't get the medication they need or that they don't know how to handle their problems because they can't go the traditional route of medicine.

I know that ultimately, the medical industry is a business when it comes down to the nitty gritty. That doesn't mean we don't have to care about our patients. What good does helping our patients do if it's just going to cost them more money and time to get the help they need just because an ND does not have the same prescriptive authority as a ARNP and MD. I really hope the state can do something about this, I know Washington is huge about the naturopathy services that are provided, some other states doesn't even know what that practice is. Just because an ND has a holistic and natural approach to a helping a patient,

doesn't mean they shouldn't be given the same prescriptive authority as ARNP's or MD's, they just have a different way of doing things.

Thank you for taking the time to read this and I really hope it has some impact because our patients and ND's deserve more. If you have any questions feel free to contact me.

Aurora Newcomb, Scheduling Coordinator , The Evergreen Clinic

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I live with a chronic illness that I have been successful at treating and managing with the support of my naturopath. When she lost her ability to prescribe certain drugs, my already hard-to-manage illness became even harder to deal with. All of a sudden, I had to travel to and pay for multiple doctors just to get my needs met. Not one of the other doctors could provide the nearly-comprehensive care that my ND was providing. I lost time from work, from family, and from other parts of my life that already were in a fine balance because of my illness. I also was forced to try to develop relationships with multiple providers who didn't know me like my ND knows me and, frankly, were not as invested in my care because they did not see my illness holistically or see me as regularly. The medical bills became too heavy for my income level to support. The impacts on my time and finances got to be so heavy that I just stopped taking a couple of my meds and have chosen to "deal" when I know that I could be feeling and functioning better. Needless to say, this has had a negative impact on my health - I have had an increase in pain, increase in stress of many kinds.

Please expand the prescription authority for NDs in WA so that people like me can have our healthcare and life needs met.

Diana Falchuk, Seattle, WA

I am against expanding NDs' expansion of licensure to prescribe controlled substances. I am a psychiatric nurse practitioner with 15 years experience in managing patients who have a wide range of mental disorders. A number of my patients have worked with ND's for various health issues over the years. I have had concerns about a number of clinical issues. One is the lack of coordination of care. I have never received a call or copy of a progress note from a ND for purposes of care coordination. They seem to work in isolation. Second, many of my patients have told me that their ND has encouraged them to stop taking or reduce dosages of effective medications that I was prescribing. I do not think that as a group of providers they have a good understanding of psychiatric diagnosis and appropriate management that is standard of care in the psychiatric field. Philosophically I do not understand why they should be able to prescribe any psychiatric medications.

Lastly, I worked in a clinic where a naturopath was brought into the practice. He asked me if I would sign my signature on a prescription for a stimulant that he wrote. He did not seem to understand that I could not write a script for a patient I did not examine. I declined to do that. My considered his request to be unprofessional. I left the practice shortly thereafter.

Janice Stern, ARNP, Psychiatric Nurse Practitioner

I am writing in support of prescription expansion privileges for Naturopathic Physicians.
I have been a nurse for 18 years and have worked alongside ND's, MD's, ARNP's and PA's.
I believe ND's are very competent and have the education and foreknowledge to write prescriptions safely and manage patients care of controlled substances, CII through CV.
Angela Cotner BS, LPN

I work in a private mental health clinic. We have a Naturopath who specializes in Psychiatry in our clinic. I would prefer to send all of my patients to him as I feel a Naturopath has a broader base of knowledge. However I often have to choose another prescriber because the patient is in crisis and needs a controlled substance like Ativan for a few weeks. This has caused several of my patients extra waiting time when our Naturopath has availability but can not provide what the patient needs.
Please give Naturopaths the ability to prescribe controlled substances. They of all providers will use these with caution.

Jean Hammel, MA, LMHC

I am writing on behalf of myself and my primary healthcare provider, who is a Naturopathic physician. I have a long history of getting kidney stones and while we have reduced the number and frequency of their occurrences, I still, and will probably always be, a 'stone former'.

As you probably know, passing kidney stones is ridiculously painful, likened by many to childbirth, and is debilitating to say the least. My physician has been unable to write for any pain meds in these acute situations, forcing me to use an emergency room as a doctor's office at times. This is a huge expense to me and my insurance company, and a complete waste of my time, as well as those doctors' time, I'm sure they have much better things to do.

I did at one time have a Urologist involved with my care as well, having to have had lithotripsy at one point, but she is unwilling to write for pain meds for a patient who she never sees. And frankly, I have no need to see her except to write prescriptions.

I trust you will reconsider your decision on this matter for the sake of patient care and the invaluable doctor-patient relationship. My Naturopathic Doctor seeks to lessen the use of all medications, and I am sure these items will get treated no differently.

Shaun Bicknese

To Whom it May Concern, it has been brought to my attention that a committee is in the process of considering not expanding ND's prescriptive authority. I have been directly impacted by my naturopath not being able to write a prescription that would have improved my health more quickly and cheaper. What I think the committee forgets is that I have no other doctor for my primary care, and if the committee doesn't approve this authority, then the committee is taking away a "right" that I have to pick and chose my own doctor. I trust my naturopath, completely, I don't want to have to start the process of picking out a complete stranger to prescribe meds for my husband or myself.

Please reconsider giving Naturopaths the rights to prescribe medicines to their patients. Don't force us to go to someone else that will cost precious time, and money that most people can't afford to spend on a doctor visit instead of providing for their families.

Jorjan Werry

I would like to endorse the expansion of ND prescriptive authority for the following reasons:
* Financial Impact: **Increased costs** for visits to another practitioner solely for a prescription

* Time Inefficiency: **Loss of time from work or family** or similar inconveniences

* Coordination of Care: Disruption of the doctor patient relationship
The current limitations do not make any economic or medical sense and only contribute to decreasing of the quality of care of out-of-network caretakers at the expense of patients
Nick Hanzel

I am emailing to encourage the expansion of Naturopathic Doctor's prescription authority. It would save me time, money and allow continuity of care as I won't be required to see multiple doctors simply to obtain prescriptions. I have full faith and trust in the knowledge and care of my ND to provide me the correct prescriptions. Thank you for your consideration.

Mark

I'm writing to ask the DOH to reconsider their recommendation against the expansion of NDs to write prescriptions. As a long-time patient of both NDs and MDs, I have found that our family prefers NDs. It is more than an inconvenience to see our local ND, then have to go to an MD in order to get specific prescriptions, it's has a financial impact on us as well.

Multiple doctor visits means multiple co-pays, multiple insurance claims, multiple times spent traveling to different doctors. I've always been proud of our state's healthy view of Naturopathic Doctors as an option for those of us who view health in an holistic way.

Seth J. MacGillivray, President, American Railworks

I am writing to you with the hope that my words may have some impact on current legislation surrounding the prescriptive authority of Naturopaths. I am hoping that the Department of Health will expand the prescriptive authority for NDs. As it stands it is not in a patient's best interest. The current legislation makes it so that patient who is in need of a narcotic pain medication must go through a whole extra set of steps that are both a drain on finances and time. It seems to me that patients are punished for choosing to see a Naturopath. Additionally it seems as the Naturopath as a profession is less respected than other doctors due to the limitations that surround them.

I feel as though I have received the best care from any doctor that I have ever seen with my Naturopath. With other doctors, I feel like just another number being pushed in and out the door with as little as time spent on care as possible. It is sad and unfortunate that the majority of MD's are ruled by insurance companies and getting claim.

Now what is very unfair is that my ND operates on a different set of standards, yet she can not prescribe the same way another doctor can. It seems like the DOH is saying "you are not a real doctor, we don't trust you". So as a result we both suffer. My ND cannot give me the full spectrum of care possible and I have to go and see a second doctor just for their prescriptive authority.

Does this seem right? Dose it make sense? I implore you to think about it from a purely logical stand point.

It is an odd and expensive game that the DOH makes patients of ND's play. I am in pain and I need something stronger than Ibuprofen 400mg. My ND cannot write for said painkiller. I must spend more money and more time and see an additional doctor in order to get a prescription for a pain medication.

This is illogical and insulting.

Please review your current legislation and expand the prescriptive authority of Naturopaths.

Jessica Roberts

We, the naturopathic physicians of Washington State, have been informed by the WANP that your preliminary response is against granting NDs the right to prescribe additional controlled substances when necessary. Historically, the Washington DOH has been supportive of efforts to modernize and improve the naturopathic scope of practice to help NDs provide the best patient care possible. I trust with further clarification and understanding, this will be the case again. From personal testimony working with patients for over ten years, our lack of full prescriptive rights has been a detriment to patient satisfaction and continuity of care in many forms.

A naturopathic physician has obtained a doctoral degree in medicine—and along with that—the competence, ability, and responsibility to be a lifelong learner in order to stay current with the best practices in medicine and patient care. The philosophy of naturopathy does not exclude any good method of caring for their patients, including controlled medications when such a prescription is in the best interest of the patient’s health. We are governed by our Principles of Naturopathic Medicine and follow a therapeutic order, which means managing our patients care from least invasive methods toward more intensive ones, which can include controlled medications in certain cases. Each patient and their unique situation dictate this process.

NDs are known for taking their time and being thorough with their patients. We do not treat or act recklessly in our care toward our patients. We also use the proper consultations and referrals to specialists as appropriate, as should any other primary care provider. Personally, as part of my management of patients using controlled medications within our current scope, I have been accessing the Washington PMP Query since its initiation and I also have patients sign a controlled substance contract as part of maintaining their treatment safely. I have continually educated myself in pharmacology through CME seminars, certification programs, and numerous forms of peer reviewed literature. That being said, I treat

my patients with confidence. If I am unsure of something, I know how to take the right next steps in order to provide or refer continued care.

Our new patient intake coordinator tells me one hindrance for new patients scheduling with a naturopath is our prescribing limitations. Due to our limited prescriptive authority, our receptionists need to continually monitor potential patients wanting to schedule with a naturopath for possible services we cannot provide, and certainly should be able to provide. Some patients become very upset after waiting for their appointment and having paid their copay to just learn I cannot provide what they require. Patients have said to me numerous times, "but you're a doctor, why can't you provide a needed prescription?" Some have come from Oregon for example where NDs can prescribe controlled medications. These limitations have a seriously negative impact on our time, business, and being able to grow professionally with the advancements and changes in medicine. It also may create a situation where patient care and safety is compromised due to a delay in obtaining an appropriate and necessary prescription.

Patients do not want to be inconvenienced to see another provider for a particular prescription their naturopath cannot provide for numerous reasons, including loss of time and added costs. Additionally, medical doctors have told various patients of mine many times they do not want to be the provider whose only purpose is to just prescribe the patient's Adderall, Xanax, or Ambien prescription. This definitely frustrates our patients and the providers on both ends and is a prime example of an inefficient, uneconomical, and potentially unsafe medical practice. Patient safety is compromised by the lack of a therapeutic relationship, which, NDs prioritize on establishing through spending more time with our patients and our philosophy of treating the whole person. This well established relationship with our patients innately supports the patients safety through close monitoring of their treatments.

Another issue that frequently arises is a patient looking for naturopathic support coming off a controlled medication. Without controlled substance prescriptive authority CII-CV, we cannot titrate a patient off their particular medication while implementing an alternative treatment plan. I have lost many patients that I had an excellent therapeutic relationship with simply because I could not manage one aspect of their care—an example being their ADD stimulant medication. Even when patients love their naturopathic physician and have a history of established care, if there is a prescription they need that we cannot provide, they are compelled to move onto another provider who can prescribe it and start all over. Our patients may then need to wait days/weeks to see another provider, who may mistakenly judge them as a drug-seeking unestablished patient. Again, this situation is simply unfair, frustrates both the patient and the providers, and is a prime example of lost time and money due to inefficient patient care and patient safety.

In summary, NDs have the knowledge, responsibility, competence, and an established therapeutic relationship with their patients to provide for a setting of excellent patient care along with patient safety for the addition of being able to prescribe controlled medications. These statements are founded in fact, not speculation, as demonstrated by our long history of practicing medicine without harm and maintaining a current medical knowledge through continuing education. NDs are a strong commodity in the state of Washington willing to continue providing primary care medicine to its citizens. Please remove the barrier from Washington NDs scope of practice to optimize our patient care, and accept the expansion of our prescription authority to include scheduled medications CII-CV. Thank you.

Robert Christopher Cotner, ND
www.TheEvergreenClinic.com

We support the naturopathic docs with FULL prescriptive authority as they are an integral part of patient care in the systems!!

Kelly Knickerbocker

I am a naturopathic patient in Washington State; I have been one for about 20 years. My naturopathic physician has kept my immune system strong and my health stable as I have journeyed through some rather harrowing experiences in the past six years, including two total knee replacements and four years of breast cancer treatment (including surgery, radiation and chemotherapy).

The orthopedic surgeon (for the knee replacements) barely gave me 10 minutes per visit. He was often unavailable and unsympathetic to my special needs, like the severe pain associated with healing bones that had been surgically severed. My naturopathic physician has always given me the time I've needed (as should be the case with any Primary Care Physician). He shared my frustration when my pain reached an 8 (on the 1-10 pain scale) with no way to alleviate it. Even my pharmacist was appalled at my predicament. My only recourse was to search out and visit a pain management specialist (going through additional time and expense) just to get the prescriptions I needed to get through an extremely difficult and temporary situation.

In short, the fact that my own naturopathic physician could not help me with a needed prescription had the following result:

- It added to my suffering by delaying needed treatment
- It caused me to incur additional expenses
- It cost me additional time away from work when I was already missing extended time for my condition
- It disrupted the coordination of my total care (and hence the doctor/patient relationship) by requiring that there be another doctor involved. The time and communication involved in keeping a number of doctors up to speed on the patient's current condition is no small feat. Every additional doctor is an additional burden on the patient.

You would be serving the many patients in Washington State who have chosen naturopathic physicians as their Primary Care Physicians (PCP) if you would allow them to prescribe medications as any other physician.

Susan M. Rogers

I am writing in support of the expanded prescriptive authority for naturopathic physicians in Washington. I am a patient diagnosed with fibromyalgia, chronic fatigue and inflammatory polyarthritis and has been suffering from chronic pain for more than a decade. I am also a nurse for 22 years. I believe that I have a voice to make a recommendation to the legislature to change the law regarding the expanded prescriptive authority for naturopathic doctors.

I found that naturopathic medicine works effectively in chronic pain and depression specially if combined with pharmaceuticals including controlled substances. However, naturopathic doctors could not perform a more integrative approach due to their limited prescriptive authority.This has affected patients like me in many ways such as increased costs for visits to another practitioner solely for prescription, time loss,

delay of timely care, non- compliance and disrupted coordination of care which all adds up to their pain and suffering.

I fervently hope for naturopathic physicians to have expanded prescriptive authority so that they can practice the full extent of their education, experience and expertise thus providing the highest quality of care.
Erlynn Legaspi

Currently I see an ND and a MD. I see both because my ND was my primary care doctor and when he transferred to behavioral health, I went with a MD because of my pain medication prescription.

I have a somewhat unique story as I have been prescribed narcotic pain medication for 20 years due to car accidents as a youth and sports injuries as a teen. I have never abused the medication and have taken a very low dosage and low quantity the entire time.

I have also of course gone to pain specialists over the years. The last one I went to was very clear that if I was only there to have my medication regulated I was best returning to my primary care doctor but he would be happy to operate and possibly provide temporary relief through an operation on my neck.

My frustration with the exclusion of ND's on narcotic pain medication is quiet simply it is an exclusion that requires an individual to either see an ND for all primary car and then try to find an MD who is willing to monitor just pain medication. To that I would say good luck.

There are few things worse for me than the beginning of a new relationship with a doctor, because of the medication I take I am always viewed with extreme skepticism, it is hurtful, and humiliating. It is also understandable due to the weight of responsibility on every doctor MD or ND that prescribes this medication.

In my opinion the current law is a Naturopathic exclusion aimed at reducing the care received by ND's with the final result being a holistic approach to medicine missing a piece of the pie.

Thank you for your time, I truly hope you make the decision to allow ND's a better opportunity to completely treat their patients.

Jack L Greene

I would strongly encourage you to reconsider the current limitations on Naturopaths prescribing controlled substances. I see an incredible Naturopath in Kirkland and her care is invaluable to me! The idea that I would have to go see someone else who doesn't know me and doesn't know my history just for pain medication; if I am need is extremely disappointing. A new doctor isn't going to know me or truly know what kind of care works well for me. The relationship between patient and Doctor is just that a relationship that built overtime gives an incredibly high level quality care.

The current restrictions require the view that a Naturopath is incapable of responsibly doing their job which I know is not true. The skill sets my Naturopath has shown me over the past few years has been nothing short of incredible, encouraging, and life changing.

Please! Reconsider the unnecessary restriction on Naturopathic doctors and change the law to reflect the trust that I hold for Naturopaths.

Kristine Greene

I have reviewed the Department of Health draft report regarding the Sunrise Review and I am concerned that the report doesn't reflect the reality of primary care practice as a naturopathic physician and diminishes our ability to provide appropriate, safe, and cost-effective care to our patients.

I have practiced at the Institute of Complementary Medicine in Seattle for the last 20 years. I am the primary care physician for about 70% of my patients. I support the expansion of our prescriptive authority to prescribe, dispense and administer controlled substances from Schedule II-V.

As the naturopathic profession has evolved in Washington, it has become essential to the practice of primary care naturopathic medicine to be able to prescribe these medications to provide the most effective healthcare for our patients and fulfill our responsibilities as primary care physicians to our patients. Our holistic approach to treatment emphasizes disease prevention and optimizing wellness. While naturopathic physicians minimize the use of pharmaceuticals by utilizing natural medicines to support the individual's innate self-healing, there are times and cases when it is in the patient's best interest to prescribe a controlled substance for a limited period of time. As a profession we are perhaps best educated to minimize these prescriptions exactly in line with the goals of the DOH.

Many such cases could be cited but I will just give you two recent instances. In August I diagnosed a primary care patient with 3 kidney stones via CT. I emergently referred her to a urologist and she was scheduled for the next morning. However as the day progressed her pain increased to the point that she needed narcotic pain control. The urologist couldn't prescribe because she has not seen the patient and I could not due to my license restriction. The only option for the patient was to incur the expense and time of an emergency department visit. If I had been able to prescribe an opioid along with the NSAID I recommended, this patient would have had much faster pain control and saved herself and her insurance company considerable money.

This past Thursday, I had to tell a patient that I could not refill her prescription for the four Tramadol that she uses each month for severe menstrual pain. We have explored many options for this patient and this is the only medication that adequately controls her pain. I had to convince her to not go to her spine doctor and lie about back pain to get the medication and instead referred her to a gynecologist for the prescription. Another waste of money and it diminishes the patient's view of my ability to care for her.

Another instance that requires me to be able to prescribe these medications is when I am working with a patient to reduce their use of a controlled medication and a new prescription is needed for a lower dose. My experience is that when they go back to the prescribing provider, the provider may not support their efforts to decrease the medication with a goal of discontinuing it. Some patients may not be able to access

their original prescribing provider due to a variety of barriers (insurance, distance, financial, etc.), so they are forced to establish with a new provider solely to obtain the new prescription.

Upon request, I could cite more cases for anxiolytics, sedatives and opioids.

I am in complete agreement with the DOH that the issues of opiate abuse and over-prescription is a very serious issue and have certainly seen patients that have had or do have these issues. I have worked with patients to overcome dependency that resulted from inappropriate prescriptions by other providers.

I support the recommendations of the Washington Association of Naturopathic Physicians (WANP) to expand the education of naturopathic physicians prior to the ability to prescribe controlled substances. The DOH says we haven't received adequate education to safely prescribe opioid, antianxiety, sedative, hypnotics and amphetamine substances to treat common conditions seen in primary care practice. However, the core naturopathic medical education in this area provides a robust foundation upon which we can add additional training. Our successful use of continuing education inplemented with the last scope of expansion for all legend drugs and the controlled substances testosterone and codeine compounds provides sufficient assurance that the mechanism approved by the Washington legislature in 2005 works.

The extra CME hours proposed by the the WANP appear to exceed those required of other primary care providers already with this authority such as the ARNPs. If the DOH disagrees with the education suggestions of WANP, they should respond with a specific recommendation for additional education and hours of continuing education sufficient to overcome any perceived deficiencies to ensure public safety.

In summary, please reconsider DOH recommendations against the expansion of naturopathic physicians prescriptive authority.

Eileen Stretch ND

Essentially the DOH, through their conclusion (attached below) to not recommend expansion of the ND prescriptive authority, is creating an obstacle for patients that entrust Naturopathic Physicians for their primary care medicine. The common primary care issues that specifically are impacted include acute pain, anxiety and sleep dysfunction. This is illogical and ironic given the fact that many allied health providers with significantly less education in scheduled drug prescribing (Dentists, Podiatrists, Optometrist, PA and as examples, see http://www.doh.wa.gov/portals/1/Documents/Pubs/690158.pdf) can prescribe a far greater range of controlled substances. Naturopathic physicians have a proven safety record (see: http://www.doh.wa.gov/DataandStatisticalReports/HealthProfessionsRegulatoryActivitiesUDA.asp) and while the DOH Sunrise Review acknowledges this in the review, it then ignores this in it's recommendation against expanding ND controlled substance prescribing. The DOH does not adequately acknowledge the issue of "dual utilization", the need to see another primary care provider because the ND PCP cannot prescribe the necessary medication, as "disruption of continuity and coordination of care". That is illogical. Also surprising in the DOH conclusion is the lack of any recommendation for a continuing education/exam path for an ND PCP to be able to provide sufficient evidence of knowledge and safety regarding expanded scheduled drug prescription. Note, Oregon allows for NDs to have

expanded scheduled drug prescribing rights, and supports this with Continuing Medical Education requirements (see: http://www.oregon.gov/obnm/Pages/Pain-Management.aspx.). My conclusion is that the Naturopathic Scope of Practice Review is flawed in it's recommendation and will further hamper efforts of ND PCPs to meet the needs of WA citizens that decide on naturopathic medicine for their primary care. This will only add to unnecessary ED visits, "dual utilization" visits to other provider types, more "fragmented" care and more burden to the primary care medicine shortage. I would like to formally request that this decision be revisited.

Jonathan Bell, ND
Ballard Neighborhood Doctors, (a MD/ND integrated primary care clinic that participates in Medicaid and Medicare), Seattle, WA

I am Steve Uhrich the owner and executive director of Assessment and Treatment Associates.

My medical director is Dr. Amira Ahdut who is a Washington State licensed Naturopathic physician.

She sees all our patients for a wellness exam and creates a wellness treatment plan to ensure they have optimal health

To success in treatment. Many of these patient have chronic pain and Dr. Ahdut has tremendous success with non-opiate solutions.

But, there are cases where medication would be effective and necessary for my patients but due to the current laws regarding ND script rights she cannot

Prescribe the proper medications. This means they need to either go to their primary care doctor (if they even have one) or find a new one to work with.

This inefficiency takes time and increases the likelihood that the person may relapse. I would be in full support to allow ND's to have full prescription rights as I am confident that their underlying philosophy would be very responsible and one in which medications are the last resort. I have countless examples of addicted patients over the years who have a " drug seeking" attitude seeking out irresponsible doctors who will prescribe them dangerous medications without monitoring and oversight. I see far less risk with ND's versus MD's with respect to the abuse of power over these potentially lethal drugs.

Steve Uhrich, Executive Director, Assessment and Treatment Associates

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I am a Mental Health Therapist here in Seattle Washington. There are MANY times that i have needed to refer a client to a physician whom can prescribe medications-many clients wish to go to their Naturopathic Dr. and are not able to because they cannot prescribe the type of medication that many of my clients need. PLEASE consider expanding the prescription rights of these valued physicians.

Tracie Carlson MA LMHC

At the Public Hearing on July 17, 2014, I stated that if controlled substances were added to the prescriptive authority of naturopathic physicians, Bastyr would not add additional hours to the current curriculum but would instead adjust the curriculum to include education and training in pharmacology and medication management related to controlled substances.

The DOH Draft Sunrise Report also states, “Bastyr University, a primary educator of NDs in this region, has indicated it will only revise the current pharmacology training to include controlled substances rather than add hours to the training. The additional education and training the applicant proposes is not sufficient to address deficiencies in core training.”

I want to add to these statements that Bastyr University would be willing and able to develop and offer a continuing medical educational program on controlled substances through the University’s Department of Certificate, Community and Continuing Education, that could address any current deficiencies in core training to satisfy the new education requirements required by the legislature and the Board of Naturopathy. Bastyr University would also be pleased to offer its assistance in the development of the necessary education and training requirements to ensure public safety and optimal care by naturopathic physicians in the use of these new medications.

Finally, I am submitting a correction in the number of pharmacology hours in the Bastyr University curriculum. The correct number of required didactic hours is 88, not 60.5.

Jane Guiltinan, N.D., Dean and Professor, School of naturopathic Medicine, Bastyr University

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I am a Naturopathic advisor to the Office of Professional Regulation in Vermont. I was a contributor to the Vermont Report on Prescriptive Authority for Naturopathic Physicians. I would like to provide comments on Washington's report:

1. In regard to NPLEX, the state of VT did NOT review NPLEX. Rather I was in touch with NPLEX and received information on the exam, which I found to be incomplete after publishing the report. After the VT report was published I revisited the issue with NPLEX and received the information that the NPLEX Core Clinical Science Examination DOES evaluate clinical aspects of pharmacology. I recommend that Washington contact NPLEX directly and not rely on the NPLEX information in the VT report.

2. for the table on p 165. Under the column Pharmacology Education/ Continuing Education, this information is from the administrative rules, not the statute.

Also, the rules in Vermont will be updated to strike:

"Must pass National Board of Medical Examiners (“NBME”) pharmacology exam or the exam given in the Medical Pharmacology course in Department of Pharmacology through Continuing Medical Education at the University of Vermont’s College of Medicine, or a substantially equivalent exam"

and will be replaced with language stating in effect: "an examination created by the Office of Professional Regulation"

It was determined that NDs were not eligible to take the NBME and the University of VT exams were not appropriate as they test for introductory pharmacology training. The new Naturopathic Physicians Pharmacology Exam has been made available.

3. p 16 paragraph 4 there are two points to correct

a. The current formulary will sunset in 2015. NDs in VT will either be able to pursue a license endorsement to prescribe within their scope of training or have no prescribing authority at all.

b. I think it would be more appropriate to expand on "errs on the side of public protection." Naturopathic physicians in Vermont as well as other health practitioners must abide by 3 V.S.A. § 129a which regulates unprofessional conduct. This is an important component of the issue at hand. Although VT has removed the formulary, NDs still will only be prescribing within their scope of training. One reason VT chose this language and a 2 tiered system is to accommodate for the variation in training among ND programs. The Commissioner of Health, Harry Chen MD, even noted that although he has the authority to prescribe and legend or controlled substance, his scope of training is emergency medicine, which limits the medications he would prescribe.

Likewise, NDs have a variety of training and post graduate training options that will result in variability in prescription drug training. Perhaps Washington could consider another level of evaluation for those NDs with adequate training to allow prescribing of controlled substances.

4. Oregon and Arizona both have naturopathic colleges that provide training in controlled substances. However this report only looks at training from one school, Bastyr University in WA. I do not think a survey of one school can adequately describe the scope of training in controlled substances and I think the report is incomplete and deficient if information on the training at NCNM in Oregon and SCNM in AZ is not considered.

Thank you for considering my comments.

Sam Russo ND, LAc, RMSK, Vermont Naturopathic Clinic

Tarah Hollingsworth
8648 28th Way SE
Lacey, WA 98513

October 6, 2014

Department of Health
Attention Sherry Thomas
P.O. Box 47850
Olympia, WA 98504-7850

SUBJECT: Full prescriptive authority is necessary for Naturopathic Doctors to practice as primary care physicians especially under Medicaid

Dear Sherry Thomas,

I am writing in reference and to support 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).[i] It is crucial for ND's to have authoritative prescription capabilities for thousands of patients suffering in Washington State.

This is my personal account and point of view. The current health care system is failing the patient. I personally suffer from a devastating auto-immune disease that cost me over $14,000 dollars in co-pays in 2013. Let me point out that I have excellent health insurance and they have deferred the direct cost to me greatly. I also want to point out that I'm a fully employed contributing citizen of society and have served my country in the military. I have stepped up to the call of duty for this great country yet I have had a hard time receiving health and happiness in the state of Washington when it comes to receiving quality medical care use conventional doctors.

The main blame I place on my deteriorating health condition is due to the Washington regulations and laws that restrict ND's from providing me with medical prescriptions upfront, including Schedule II to V drugs, among other medical treatments. I have become a physician expert and I can state with substantial evidence that the worst, most detrimental health care I have personally received were given by conventional, non-ND physicians, Physician Assistances, and Nurse Practitioners. When I state "detrimental" I'm referring to almost killing me by prescribing me medication that I listed or stated I was allergic to and resulted in being hospitalized.

I have found that conventional physicians typically fail to take the time or effort to make a good choice. However, on the other hand the ND's that I have seen and are currently been seen by have made good choices for me. Unfortunately, ND's are restricted by laws and regulations that restrict them from healing me completely; therefore I have to had to juggle between conventional

physicians and ND's. This juggling between physicians has caused even more stress and frustration for me by delaying critical prescription refills and taking hours out of my work schedule.

There is absolutely no reason for this additional patient cost and time for this bureaucratic road block. I further strongly challenge the statement that restricting ND's from being able have broader prescribing abilities for Schedule II – IV will assist with decreasing the opiate abuse epidemic. My view is that there is already an epidemic with the current broken medical system. This is because the current state system forces people to juggle multiple doctors and amass more cost and time, therefore pain suffers will continue to look for opiates by other (non-physician) sources – for quicker pain relief and cost purposes.

Additionally, more regulations and laws will not decrease the opiate abuse since substance abusers (who initially just needed pain relief) can easily circumvent the current regulations and laws by purchasing them on the street and on-line. In fact, allowing ND's, who I have found to be more knowledgeable about the human body, will assist with people seeking and obtaining pain relievers and controlled substances properly and under a doctor's supervision thus helping to prevent addictions to start.

Without leading into an even longer rebuttal, I want to state and make sure it is **not under emphasized**, it is even ***more important*** for ND's that practice in the mental health field need the ability to prescribe all legend (under WAC 246-836-210,) and controlled substances (Schedules III, IV, and V of chapter 69.50 RCW). This **is the line** between quality of life and ***prevention of suicide***, the ultimate epidemic in Washington State.

Please, I beg you to help me and thousands of others to find relief by empowering ND's with all of the tools and prescribing ability that conventional physicians have. You can save lives by allowing this… including mine.

Sincerely,

Tarah Hollingsworth

[i] Naturopathic Scope of Practice Sunrise Review, December 2014

STATE OF WASHINGTON
DEPARTMENT OF HEALTH

October 2, 2014

Sherry Thomas
Washington State Department of Health
Health Systems Quality Assurance
PO Box 47850
Olympia, WA 98504-7850

RE: Board of Naturopathy's position on the 2014 Naturopathic Scope of Practice Sunrise Review

Dear Ms. Thomas:

I am writing in my role as Executive Director to the Board of Naturopathy (board) to convey the board's support for the proposed scope of practice expansion for naturopathic physicians in the state of Washington. That support includes the points listed below for consideration along with the draft legislation provided during the Sunrise Review process.

- General
  The practice of naturopathic medicine seeks to restore and maintain optimum health in patients by emphasizing the natural and inherent self-healing process. It is a distinct method of health care which is the art, science, philosophy and practice of diagnosis, treatment, and prevention of illness. A naturopathic medicine approach starts with the least invasive method possible and, on a case-by-case, patient-by-patient basis, includes other modalities as the naturopathic physician deems appropriate. The board's position is that the continuum of care and treatment modalities naturopathic physicians are able to provide should include the full range of medical options, including the use of those drugs regulated as controlled substances. Such expansion ensures that citizens of this state have the opportunity for greater health care options.

- Rule Making
  The board has reviewed the proposed bill request and determined that it does not contain a provision for rule making by the board. The board understands that the petitioner, Washington Association of Naturopathic Physicians (WANP), has indicated their intent to include such a provision, which the board supports. This would be similar to the successful rulemaking effort employed to implement chapter 158, Laws of 2005, when all legend drugs and the two controlled substances codeine and testosterone products in Schedules III, IV, and V were included in naturopathic scope of practice. That expansion included a requirement for additional training.

- Education/Training
  The board's position is that the foundation of naturopathic medical education is sound and the academic standards prove a curriculum strong in clinical pharmacology, prescription drug management, and patient safety monitoring. The board recognizes the example of the University of Washington School of Medicine curriculum, which incorporates significant training in pharmacology. Similarly, Bastyr University's School of Naturopathic Medicine has a curriculum robust in pharmacology that meets or exceeds that of the other prescribing professionals (e.g. advanced registered nurse practitioners, dentists, podiatrists, and optometrists).

  Additionally, it is the board's position that an increase in the naturopathic scope of care to include controlled substance prescribing would necessitate the implementation of additional specific training regarding those Schedule II through V drugs to a degree comparable to other health care professionals with similar prescribing authority.

- Continuing Education
  The board's position is that existing continuing education requirements should be increased by a minimum of 9-10 hours annually and that those increased hours be specific to pharmacology.

- Pain Management Considerations
  The board is aware that in the late 1990's there was a shift in Washington State, as there was across the United States, in the liberalization of laws governing opioid prescribing for the treatment of chronic non-cancer pain. Following that, the use of opioids dramatically increased which created the growing issue of misuse, abuse, and nonmedical use of these prescription drugs. As a result, opioid-related overdose deaths dramatically increased as well.

  The board acknowledges the concerns about consequences and risks of opioid use in the management of chronic pain and supports efforts to reduce those risks. The board's position is that naturopathic physicians who prescribe opioids must do so in a safe and effective manner to protect the patient.

  The board understands that the WANP (petitioner) intends to recommend inclusion of statutory language similar to that contained in Engrossed Substitute House Bill 2876 (Chapter 209, Laws of 2010). This would require the board to adopt rules regarding pain management as was required by the Dental Quality Assurance Commission, Board of Osteopathic Medicine and Surgery, Medical Quality Assurance Commission, Nursing Care Quality Assurance Commission, and Podiatric Medical Board. Such rules would include dosing criteria and guidance on specialty consultation, tracking clinical progress, and tracking opioid use. The board fully supports the inclusion of pain management standards for naturopathic physicians with consideration, as applied to the current controlled substance prescribing professionals, this would be appropriate to ensure public and patient safety.

- History of Safe Prescribing
  The board would like to state that, as supported by complaint history, there has been little evidence of safety concerns regarding naturopathic physicians' prescribing practices within their current prescribing authority. The board is confident this history of safe prescribing will continue once expanded prescriptive authority is granted.

The mission of the Board of Naturopathy is to be the Governor-appointed representatives for the people of Washington State in matters related to patient safety and determining acceptable standards of naturopathic medical care. As such, the board views the petitioner's Sunrise Review request as appropriate, with the above mentioned considerations, and supports efforts to expand the prescriptive scope of practice for naturopathic physicians.

Sincerely,

Chris Humberson R.Ph.

Chris Humberson, R.Ph., Executive Director
Board of Naturopathy

STATE OF WASHINGTON

HEALTH CARE AUTHORITY

626 8th Avenue, SE • P.O. Box 45502 • Olympia, Washington 98504-5502

October 6, 2014

Sherry Thomas, Policy Coordinator
Washington State Department of Health
Health Systems Quality Assurance
PO Box 47850, Olympia, WA 98504-7850

To Whom It May Concern:

This is in regards to the draft Naturopathic Scope of Practice Sunrise Review regarding the expansion of Naturopath's Prescriptive authority. There are several places in the document to which HCA would like to respond.

In regards to the statement on page 9, *"We received letters with concerns from the Association of Washington Health Plans (AWHP), Washington State Health Care Authority, (HCA)..."* It would be more accurate to characterize the perspective of HCA using the language, "The Authority 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," which was also in the letter.

The second point of clarification relates to the following language on page 10: "The HCA stated its primary concern is that an increase in prescriptive authority for NDs must include adequate pharmacology education and training. It was concerned with the vagueness of the language in the draft bill and suggested the addition of a requirement for a one-year residency." The letter of response HCA submitted was before the WANP submitted its comments to the public hearing of 7-27-14. Residencies in Naturopathy are not common place which the HCA was not aware of before the WANP response. After review of the proposed changes to their supplemental education, from 4 to 12 hours, and the addition of 10 hours of continuing medical education, specifically related to pharmacology, the HCA has less concern about the adequacy of pharmacology training as it relates to the limited prescriptive therapy described below. This relates not just to the change in educational requirements but to the fact that naturopaths already have the prescriptive authority to prescribe complex medications.

This section addresses the comment related to the concern for over prescription and overuse in patients on Medicaid. It is true that opioids have been overprescribed over the last several decades and that as a result, deaths related to the use of prescription opioids and rates of heroin use have increased. Almost without exception, these have occurred in patients on chronic therapy with opioids. Short term treatment with controlled substances is much safer and at times indicated. Additionally, evidence clearly supports, that chronic opioid and benzodiazepine therapy are recognized as no longer appropriate for the vast majority of patients and should not be prescribed without a structured plan and adequate practice supports in place by any primary care provider. As far as treating both children and adults with stimulants, the standard of care in the medical community is to attain a second opinion by a provider who specializes in the diagnosis and management of these conditions.

HCA acknowledges the higher rate of opioid use by Medicaid clients. We agree with WANP that Medicaid will include an expanded demographic of patients with the medical conditions of chronic pain and anxiety who are seen in the naturopathic primary care setting. Naturopathic physicians can offer a valuable contribution to Medicaid patient care with emphasis on dietary, lifestyle, prevention, patient education and other methods that decrease the need for opioid medications.

After reading the WANP response to the Public Comments of 7-27-14, The Health Care Authority would be supportive of this prescriptive authority change with limitations. After review and consideration of both the WANP response and the draft sunrise report, the HCA supports the expanded prescriptive authority for naturopaths but recommend it be limited to the treatment of acute conditions and for a limited amount of time. Treatment for chronic conditions requiring controlled substances should be done in collaboration with specialists.

The Washington State Legislature, under SB 5034 – Making 2013-2015 operating appropriations, directed the HCA to "reimburse for primary care services provided by naturopathic physicians." The HCA began contracting with NDs for participation in Medicaid in January 2014. Expanded naturopathic prescriptive authority will allow NDs to manage their primary care patients' when they have acute and time limited conditions requiring the use of controlled substances. In the acute setting this will reduce the disruption of care patients experience in having to find and schedule an appointment with a new provider for treatment with a controlled substance. This change may also reduce a number of unnecessary ED visits.

Allowing Naturopaths to prescribe controlled substances for acute and time limited periods is patient centered and with the additional educational activities described appears appropriate. Concurrent management with a specialist versed in the care of whatever chronic condition requires the chronic use of controlled substances is consistent with the standard of care practiced by other primary care providers.

Respectfully,

Charissa Fotinos, M.D., MSc
Deputy Chief Medical Officer

American Naturopathic Medical Association

A N M A HISTORY
1980-Present

ANMA Annual Conventions

1980 ANMA 1st Convention
Bally Hotel - Las Vegas, NV

1990 ANMA 10th Convention
Hacienda Hotel-Las Vegas, NV

2000-2014 ANMA Conventions
Riviera Hotel, Las Vegas, NV

ANMA Incorporated
1983

ANMA Position Papers Adopted
1990

ANMA Current and Past Presidents

Filippos Diamantis, N.D., Ph.D,
Donald C. Hayhurst, Ph.D., N.M.D.
Vera Joann Allison, R. N., N.M.D.
Joel Wallach, D.V.M., N.D.
Steve Nugent, Ph.D., N.M.D.
Charles Curtis, D.O., N.M.D.
George Schuchard III, D.D.S., N.M.D.

1990 – Present

ANMA Supports Fair Legislation Promoting Naturopathic Profession

September 24, 2014

Ms. Sherry Thomas
Washington State Department of Health
Health Systems Quality Assurance
PO Box 47850
Olympia, WA 98504-7850

Sherry.Thomas@DOH.WA.GOV

RE: Naturopathic Scope of Practice Sunrise Review

Dear Ms. Thomas,

American Naturopathic Medical Association (ANMA), the largest association of naturopaths in the United States supports the efforts by the Washington Department of Health to deny expanding prescription privileges to naturopaths. As the most active association ANMA receives many complaints regarding the prescription practices of this group and is convinced they should not be allowed to prescribe any allopathic medications.

Naturopathy has long been considered by many state legislatures as the “natural practice of healthcare, not a danger to the public”. This is also “public perception”. A majority of states do not license or allow for the allopathic practice of naturopathy, and certainly do not allow the inclusion of writing prescriptions. To grant the right to prescribe any form of drug to the naturopath is very confusing to the public and very dangerous considering the level of education.

Requests for expanding their prescriptive rights alone prove their real interest in healthcare is not naturopathic. This group has already proven they cannot be trusted with prescriptive privileges having already misled the states of WA & OR in their use of these rights. These two states have become “naturopathic prescription mills”. Licensed naturopaths practicing in unlicensed states but holding a state license and possible address in WA or OR write prescriptions causing the pharmacies to unwittingly provide drugs to patients in other states. These naturopaths operate without oversight or authority and admit openly to practicing illegally in state legislative hearings.

The current CMNE APPROVED schools of Naturopathic Medicine do not reach the level of current Medical Schools, and they are NOT considered schools of medicine by anyone except CNME. If naturopaths in WA want even more prescriptive rights it only makes sense that they should go to a real medical school approved and accredited by the Liaison Committee on Medical Education (LCME).

There does not appear to be any level of concern for the safety of the public in this Sunrise issue!

ANMA ADAMANTLY OPPOSES this sunrise provision and ADDITIONALLY RECOMMENDS, THE PRESCRIPTIVE RIGHTS WA NATUROPATHS PRESENTLY POSSESS BE RESCINDED.

Sincerely, Donald C. Hayhurst , Ph.D., NMD
President Emeritus-ANMA
Contact: Julie Morgan, admin@anma.org

cc Scott Fannin, DO, President Fax: 206.933.6529

cc Dale Reisner, MD, President Fax: 206-441-5863

Rebuttal and Suggested Corrections to
Draft Naturopathic Scope of Practice Sunrise Review

Responses from Washington Association of Naturopathic Physicians
Contact: Robert May, ND executive@wanp.org 206-547-2130

October 6, 2014

Executive Summary

The WANP is committed to the protection of public health and believes that naturopathic medicine offers a unique, valuable perspective and model for the Washington healthcare system. We support all efforts to curb and correct the epidemic of opioid over prescription and abuse. We strongly believe that the naturopathic model of care can help lessen the use of controlled substances and contribute alternatives to the need for opiate medications in particular and controlled substances in general.

Naturopathic physicians have a solid foundation of clinical pharmacology and a well-established history of safe prescribing in Washington at their current authority. With supplemental education, as was implemented in 2007, NDs will be able to utilize all the prescriptive tools appropriate to their primary care scope of practice in a manner that is safe and effective.

NDs spend more time with their patients, work from a whole person, comprehensive system of evaluation and are experts in a wide array of treatment strategies including many that involve diet, lifestyle and non-pharmacologic interventions. As evidenced in the high ratings of naturopathic clinics in the Washington Health Alliance survey, the public desires naturopathic care and this trend continues to increase. Washington will be well served to recognize the value of naturopathic medicine, the primary care status of NDs and the need for our doctors to have expanded prescriptive authority in order to provide safe and effective, optimal patient care.

Overview

The WANP has reviewed the draft report released by the Department of Health (DOH) on 9/23/14 and offers the following comments in response.

DOH places primary emphasis in this Sunrise Review on the issues of opiate abuse, over prescription and public safety. The WANP fully agrees with and shares these priorities and we support DOH efforts to address them. We also understand that the DOH is concerned about sufficiency of naturopathic medical education and training in relation to expanded prescriptive authority and public safety.

In the following, we offer commentary and rebuttal to specific sections of the draft report that we feel are incomplete and/or inaccurate and we request that DOH reconsider their original recommendation against this Sunrise proposal. If the DOH remains concerned about the WANP's specific recommendations for supplemental education and training,

we request that they identify and include the minimum requirements they feel would be sufficient to ensure public safety.

WANP Response to DOH Recommendation Rationales on pages 4 and 23

DOH Rationale #1: The applicant has not proven the current prescriptive authority is inadequate or problematic

The WANP provided examples of how current prescriptive authority is problematic in our submission to DOH on July 27, 2014. These examples clearly demonstrate the problematic nature of the current prescriptive authority for naturopathic physicians and their patients (referenced on pages 70-76 of the draft Sunrise report.) Furthermore, the WANP cites prior findings of the DOH in the 1992 ARNP Sunrise Review as strong support for our premise that current naturopathic prescriptive authority is inadequate and problematic.

An example from DOH report, page 9: "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 was not 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.

In reporting this, the DOH does not represent the clinical significance of this example and may give the impression that the need for a prescription from another practitioner was merely a mild inconvenience for the patient. As Dr. Krumm explained at the public testimony on July 17, 2014, (page 118 of DOH draft), this case was not about convenience. It was about a patient self-medicating with an inappropriate drug that had potential to interact with another drug the patient was taking and the consequences could have been fatal. The patient was in pain and was reluctant or resistant to seeing another provider. Dr. Krumm was eventually able to get a consult from a prescribing colleague, but by the time the consult and prescription were secured, the patient's pharmacy closed, and the patient continued to inappropriately self-medicate with a much less appropriate and higher risk drug until the next day. Fortunately, this case ended without a bad outcome, but it demonstrates the potential risk resulting from a delay in medically appropriate treatment. This case is not unique, and for NDs in smaller practices or isolated areas this collaborative, cross referral may not be possible in the time frame needed, and the consequences for patients could be severe.

This type of issue was identified for nurse practitioners and their patients in "Expansion of ARNP Prescriptive Authority" 1992 Sunrise Review, as noted in the following quote from page 8:

"Staff concludes that restricting ARNPs from prescribing schedule II-IV substances contributes to a lack of access to care, thus representing a serious risk to the public life, health or safety."

In addition, that report continues with the following, on page 9:

"Benefit to the public: Prescriptive authority expansion will allow/place the full range of drugs within the ARNP scope of practice. This would allow prescribing drugs which may be most appropriate, less costly, better tasting and may have less significant side effects. Staff concurs with this finding.**"**

The WANP submits that the rationale and conclusion put forward by the DOH for ARNPs in 1992 is reflective of the need and issues currently facing naturopathic physicians and their patients today. As the DOH noted above, expanded prescriptive authority allows a primary care provider to prescribe drugs 'most appropriate' to a patient's acute condition.

The WANP provided a list of common controlled medications appropriate for primary care and the DOH has not refuted the need for these medications in the primary care setting. The fact that NDs do not have access to these medications and that NDs are recognized in statute as primary care providers does prove that current prescriptive authority is problematic for naturopathic providers and patients.

The DOH report does not cite the example given by the WANP that the reclassification of the medication Tramadol as a controlled substance by the Washington Board of Pharmacy is another example of how the current limitation of naturopathic prescriptive authority is problematic. NDs have had access to Tramadol, and a history of prescribing it safely, for over 7 years - until August 2014. Because of this change in Tramadol's status, NDs and their patients no longer have access to this effective pain medication. In light of current federal and state attempts to better regulate controlled medications, this type of reclassification will continue to be a problem for NDs and their patients if they are not granted expanded prescriptive authority.

DOH Rationale #2: The applicant's proposal does not provide evidence of the disruption of continuity and coordination of care for naturopathic patients that were suggested in the applicant report.

The WANP comments above also provide evidence of the disruption of continuity of care for naturopathic patients. In addition, current prescriptive authority limitations further disrupt continuity of care and add to increased costs by contributing to unnecessary utilization of emergency room services. This is contrary to goals outlined by the Health Care Authority in the following report:

Emergency Department Utilization: Assumed Savings from Best Practices Implementation
Third Engrossed Substitute House Bill 2127, Chapter 7, Laws of 2012, 2nd Special Session
(Partial Veto) January 15, 2013

Washington State Health Care Authority Office of the Chief Medical Officer
http://www.hca.wa.gov/documents/legreports/report
3eshb2127emergencydeptutilization.pdf
"Next Steps:
The seven best practices adopted by hospitals represent just the first step in reducing unnecessary use of the emergency room. To address the demand side of emergency department care, our state must address the larger, systemic reasons why Medicaid clients go to the emergency room for their care. …. ***In some cases, a lack of adequate or timely access to primary care may contribute to unnecessary use of the emergency department. If a client does not have a primary care physician, or cannot be seen in a reasonable amount of time for a low acuity need, he or she may turn to the emergency department.*** *….."*

The WANP offers the following statement from page 3 from the 1992 ARNP Sunrise report and submits that this well-substantiated characterization of the impact of restricted prescriptive authority on nurse practitioners is pertinent today for naturopathic physicians and their patients.

"An ARNP's ability to adequately practice to his or her full potential has been weakened by the prohibition on prescribing schedules II-IV drugs. This results in fragmented, delayed and duplicative care being provided to patients. Delays in receiving necessary medications can lead to increased health risks and additional costs postponing needed treatment."

DOH Rationale #3: Full prescriptive authority is not necessary for NDs to practice as primary care physicians under Medicaid.

On February 15, 2013, after an extensive review the Vermont State Office of Professional Regulation issued Report on the Education and Clinical Training of Naturopathic Physicians, which included the following statement:

"As the naturopathic profession has evolved, the ability to prescribe primary care pharmaceuticals has become essential to the practice of naturopathic medicine in order to allow naturopathic physicians to meet patient demand, provide the most effective healthcare for their patients, and fulfill their role in Vermont as primary care physicians. Although naturopathic physicians try to minimize the use of pharmaceuticals by utilizing natural medicines to support the innate self-healing ability of the patient, there will be cases where it is in the best interest of the patent in a primary care setting to prescribe pharmaceuticals when doing so falls within the scope of a naturopathic physician's education and training."

The State of Vermont has determined that full prescriptive authority, including controlled substances II-V, is necessary for NDs to practice as primary care physicians and full prescriptive authority for NDs in VT was enacted in 2014. This finding parallels the recommendation from DOH in 1992 to grant full prescriptive authority for ARNPs.

The Washington State Legislature, under SB 5034 – Making 2013-2015 operating appropriations, directed the HCA to "reimburse for primary care services provided by

naturopathic physicians" and recognizes NDs as 'physicians' in the Medicaid system in the following:

- WAC 182-500-0085 Health Care Authority, Medical assistance. definitions—P. "Physician" means a doctor of medicine, osteopathy, naturopathy, or podiatry who is legally authorized to perform the functions of the profession by the state in which the services are performed.

The HCA began contracting with NDs for participation in Medicaid in January 2014. Passage of the proposed legislation under the Sunrise Review will allow NDs to more effectively provide the primary care services they perform for Medicaid clients as required by the legislature.

The WANP disagrees with the DOH conclusion that expanded prescriptive authority is not necessary for NDs to participate in Medicaid. Primary care is not defined by 'provider type' but by a core set of services, including diagnosis, treatment, and coordination of care, including management of acute conditions. Patients who select a naturopathic physician as their primary care provider should not be subject to discrimination regarding delivery of these basic services. This includes being able to expect their primary care provider is able to address acute conditions where the most appropriate care is prescription of a controlled substance. Examples of this include acute anxiety, severe sprains and fractures, and kidney stones. Certain chronic conditions, such as ADHD, may also require the use of a controlled substance. NDs see all of these types of cases and currently are unable to provide the most appropriate treatment. As ND participation in Medicaid expands and more of our doctors practice in rural and underserved areas, the greater the need will be for them to have the ability to manage the range of conditions common to primary care practice.

DOH Rationale #4: 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.

Referrals for chronic opioid therapy, particularly at doses greater than 100-120MED, are well described in the Interagency Guideline on Opioid Dosing for Chronic Non-cancer Pain and academic literature and the WANP agrees that these patients should be co-managed between a primary care provider and a board certified pain specialist.

However, referrals are *not* clinically appropriate for most controlled substance prescriptions for acute cases in primary care practices. An acute case, by its very nature, requires appropriate and timely treatment. Any delay in treatment due to referrals can put a patient's care and safety at risk.

The WANP agrees that controlled substances pose a significant risk to public health due to overdose, abuse and misuse and that only qualified healthcare professionals should prescribe these substances. However, we believe that with implementation of the WANP's recommended supplemental education and increased continuing education that NDs will meet these requirements and will continue the safe prescribing history they

have had with controlled medications since 2007. That prescribing history has included controlled substances testosterone and codeine-containing compounds as well as the recently reclassified drug Tramadol, now a scheduled medication.

DOH Rationale #5: The applicant has not shown NDs 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 desire to add eight hours of additional education and 10 hours of continuing education is not sufficient to overcome the deficiencies.

Naturopathic physicians have had expanded prescriptive authority since 2007 that has included all legend drugs and the controlled substances testosterone and codeine-containing (opiate) compounds. According to the Naturopathy Program at the Department of Health, there have been no complaints against NDs for issues related to prescribing *within* the current scope of practice.

In 2005, the legislature expanded naturopathic prescriptive authority to include all legend substances and the controlled substances testosterone and codeine-containing compounds. In response to that scope expansion, DOH developed and implemented WAC 246-836-211 "Authorization regarding controlled substances" requiring NDs to complete four hours of supplemental education in order to be able to apply for a DEA number (required for prescribing controlled substances.) Since that time, NDs have had a very safe record of prescribing with no record of formal disciplinary action against NDs for prescriptions within the current scope of authority. It should be emphasized that NDs have been safely prescribing opiate pain medications, limited to codeine products and tramadol, in the primary care setting since 2007 for acute and chronic conditions, including pain. This affirms that the continuing education model introduced by the legislature in 2005 and implemented by DOH in 2007 was successful and that the supplemental education was built upon a strong core naturopathic education in clinical sciences including pharmacology and pharmacotherapeutics. We are confident that application of this same model in implementing additional educational requirements in controlled substances will be sufficient to protect the public.

The WANP believes the proposed legislation, with the addition of recommended amendments to requiring rule-making to develop adequate education and training in controlled substances, will be sufficient to ensure public safety. If the DOH believes alternate educational requirements would better protect public health, the WANP encourages DOH to identify the minimum amount of education necessary for public safety and include this in the final report for consideration in rule making.

DOH Rationale #6: The department does not see a need to increase access to prescription opioid pain medications that are included in this proposal because:

6.1 Prescription opioid related overdoses and deaths have reached epidemic levels.

The WANP recognizes the severity of the problem with opiate overuse and abuse in the US and supports an aggressive strategy to address this problem. Naturopathic medicine

offers an alternative approach to primary care that focuses on elements of diet, lifestyle, patient education and prevention as well as many non-drug techniques (e.g., naturopathic manipulation and other physical medicine techniques) that can be a valuable addition to the Washington health care system.

However in some acute cases, a short-term opioid prescription for a carefully screened patient may in fact be the most medically appropriate treatment. As primary care providers, NDs need the ability to provide the most appropriate medication necessary and in a manner that does not put patients at risk due to unnecessary delay. Like every other primary care provider, NDs take great care to follow established guidelines to prevent medication misuse, abuse and diversion, and fortunately they have access to systems such as the State's Prescription Monitoring Program, Opiated Dosing Guidelines and the Agency Medical Directors Group Guidelines as a resource and to help screen for drug-seeking patients.

6.2 Data has shown a correlation between the rise in overdose deaths and states that have expanded the use of prescription opioids.

The WANP requests the DOH identify the states with an increase in overdose deaths to clarify if any of these states have included licensure for naturopathic physicians, and assess if this data is relevant to naturopathic physicians in Washington.

6.3 The U.S. Drug Enforcement Administration (DEA) on August 22, 2014, announced final rules reclassifying hydrocodone combination products, such as Vicodin, from a Schedule III to Schedule II controlled substance, including tighter restrictions on prescribing these products, citing the "substantial evidence of potential abuse."

Reclassification of controlled substances is an appropriate and necessary response on the part of the DEA and is likely to impact additional medications in the future. The WANP has shared the example of the reclassification of Tramadol and the impact this has had on naturopathic physicians who no longer have access to this medication under current prescriptive authority. This has interrupted the care of naturopathic patients and could result in use of less effective medications or the need for prescriptive referral to other types of primary care practitioners. Expanded prescriptive authority for NDs in Washington is necessary to ensure continued access to other medications that may be reclassified in the future.

6.4 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.

The DOH rationale here suggests that a moratorium on new prescriptive authority for any type of provider is needed in Washington, including MDs, DOs, ARNPs and PAs. However, this clearly would not serve the public interest. Such an action would compound the primary care shortage, increase dual utilization, and disrupt continuity of care in the same manner that is occurring for naturopathic physicians and their patients in the current system.

The WANP does not feel that this type of indiscriminate, quantitative approach to the overuse of opioids in Washington is to be recommended. Instead, we believe that a qualitative focus on health promotion, patient education and inclusion of non-pharmaceutical treatments, such as those offered by NDs within an integrated and expanded scope of prescriptive authority is best suited to address this epidemic issue.

Naturopathic medical education has a strong core of clinical pharmacology training. It also includes a unique context and perspective for healthcare that includes more time with patients, in-depth diagnoses, and an emphasis on alternative non-drug therapeutics that will be valuable in countering the current trend towards the over prescription of controlled substances. This whole person, individualized approach to primary care will also lessen the need for controlled substance prescriptions and assist those patients currently taking opiates and other controlled substances to decrease or eliminate the need for these drugs. Expanded prescriptive authority in conjunction with the naturopathic focus on natural therapeutics will enable NDs to offer optimal coordination and continuity of patient care.

Efficacy of this 'naturopathic approach' is found in the following studies and provides evidence that naturopathic physicians can help patients decrease the use of controlled substances:

Characteristics of ND practice and comparison to conventional primary care, Integr Med Insights. 2014 May 19;9:7-15. doi: 10.4137/IMI.S14124. eCollection 2014. Naturopathic practice at North American academic institutions: description of 300,483 visits and comparison to conventional primary care. Chamberlin S, Oberg E, Hanes D, Calabrese C.
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4039213/

Summary: Based on survey data from the Center for Disease Control, naturopathic primary care providers spend twice as much time per year with patients as conventional providers. This suggests more face-to-face time between NDs and their patients. The study also reports that NDs routinely employ a holistic orientation towards diet and physical activity as interventions, which may be more appropriate for musculoskeletal pain in which trial data suggests positive outcomes.

Utilization, patient satisfaction, and cost implications of acupuncture, massage, and naturopathic medicine offered as covered health benefits: a comparison of two delivery models. Altern Therapies. Jul-Aug 2001;7(4):66-70. Stewart D, Weeks J, Bent S. Utilization, patient satisfaction, and cost implications of acupuncture, massage, and naturopathic medicine offered as covered health benefits: a comparison of two delivery models.

Summary: Survey data from several hundred adults in Washington and Oregon indicated approximately 50% of those surveyed perceived a decrease in their use of pharmaceutical treatments.

"Attitudes Toward Naturopathic Medicine", a telephone survey of 606 individuals, 18+ years of age in Ontario, Canada, conducted by Innovative Research Group, Inc. (Toronto/Vancouver) reports that nearly 3 in 10 (28%) ND patients in Ontario, Canada, feel NDs have either significantly or noticeably reduced their use of prescription medication.

Sunrise Criteria Review from DOH draft report page 21

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

DOH: "NDs are currently a thoroughly regulated profession. The public health and safety benefit of expanding their prescriptive authority hasn't been proven, and the potential for harm is present. 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. The department does not see a need to increase access to these medications.

Naturopathic schools include training in pharmacology that varies in content and length, which must compete for class time with the training provided in botanicals, nutrition, homeopathy and other naturopathic principles. It does not include sufficient training specific to controlled substances, and Bastyr University, a primary educator of NDs in this region, has indicated it will only revise the current pharmacology training to include controlled substances rather than add hours to the training. The additional education and training the applicant proposes is not sufficient to address deficiencies in core training."

WANP: The applicant agrees that naturopathic medicine is a thoroughly regulated profession. NDs have an established safety record for their current prescriptive authority that includes limited controlled substances in schedules III-V. The DOH summarizes that, "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 its relationship to this proposal, we have previously provided DOH with numerous references (see Appendix B). It also included references to support the anticipated increased shortage due to the expansion of Medicaid." This evidence (Appendix B) establishes the readily apparent potential for public harm due to lack of access to primary care. Restricting NDs from prescribing schedule II-V substances contributes to a lack of access to care, thus representing a serious risk to the public's life, health or safety.

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

DOH: "There are adequate laws and rules in place to assure the public of initial and continued professional ability for the current ND scope of practice. The proposal under review does not contain this assurance because 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."

WANP: WANP agrees that "there are adequate laws and rules in place to assure the public of initial and continued professional ability for the current ND scope of practice." These laws and rules have been proven effective at protecting the public as the naturopathic profession and scope of practice has evolved to better meet Washington healthcare needs. Specifically, the use of supplemental education, approved by the legislature in 2005 and the DOH via rules in 2007 for the initial inclusion of controlled substances in the naturopathic prescriptive authority, has proven effective as evidenced in the safe prescribing history of NDs since 2007. This model forms the basis for the supplemental and continuing education in this proposal. Furthermore, the proposed additional education meets or exceeds that of other provider types with full prescriptive authority as evidenced in the applicant's submissions (see items 8, 13 and 14 below under WANP comments on specific draft text).

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

DOH: "The current naturopathic scope of practice protects the public. The applicant has not demonstrated that continuity and coordination of care is being unduly disrupted with the current prescriptive authority. Primary care providers regularly refer patients to other practitioners as needed. In addition, the epidemic of opioid abuses and the correlation to increased prescribing of these substances clearly shows that there is already enough (or too much) access to these medications."

WANP: We request DOH to consider that in the 1992 ARNP sunrise it found that prescriptive authority expansion for ARNPs would benefit the public because "This would allow prescribing drugs which may be most appropriate, less costly, better tasting and may have less significant side effects." Furthermore, the DOH concluded "it seems likely that overall cost of medical care would potentially be decreased by elimination of duplication, double billing and reduced emergency referrals for filling of Schedule II-IV prescriptions." These facts have not changed and are not dependent on the license type of the provider.

The WANP recognizes that appropriate referrals are integral to primary care practice. However, the WANP does not agree that referral to the ER or attempts to refer patients to other PCPs for acute conditions requiring controlled substances would be considered best practice. The WANP supports state efforts to confront the opiate abuse epidemic and supports use of all State resources, including the Prescription Monitoring Program, Opiate Dosing Guidelines, and Agency Medical Directors Group Guidelines.

WANP Comments on specific Draft Report text

1. DOH reports testimony of Bastyr University on page 9.
"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."

WANP: Resources exist to provide supplemental education needed to train NDs in expanded prescriptive authority. Bastyr University confirms interest and ability in developing and offering supplemental education to fulfill any requirements enacted by the legislature related to this legislation. The WANP understands that Dr. Jane Guiltinan, Dean of Naturopathic Medicine at Bastyr University will be submitting confirmation of this separately.

In addition, the WANP has learned that due to a curriculum revision underway at Bastyr University, the correct number of contact hours for ND pharmacology was inaccurately reported to DOH. Rather than 60.5 hours in the core ND curriculum, this total is actually 88 hours – and there is an elective with an additional 20 hours available to ND students.

2. DOH report identifies opposition to Sunrise Review on page 9:
"We received 15 letters in opposition to the proposal from organizations, including the Washington State Medical Association (WSMA) that was undersigned by a number of organizations representing physicians in various specialties; Washington Osteopathic Medical Association (WOMA); Washington Academy of Family Physicians; Providence Health and Services; Washington State Medical Quality Assurance Commission; and other health care providers. We received letters with concerns from the Association of Washington Health Plans (AWHP), Washington State Health Care Authority (HCA), and Washington East Asian Medicine Association (WEAMA). (See Appendix D for written comments received.):

WANP: It is unclear why DOH included the HCA letter in the paragraph describing letters of opposition. The HCA concluded their letter with the following statement of provisional support for expanding naturopathic prescriptive authority:

"The Authority 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."

In addition, it is unclear why DOH included the letter from WEAMA in this category when that letter did not address the topic of controlled substances at all, but rather acupuncture which is not a subject of this Sunrise Review.

3. DOH reports implies NDs limited to 'natural therapeutics' on page 10:
"NDs 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."

WANP: We are unable to determine the specific source for the statement the DOH attributes to the AANP on page 10. However, the current AANP website (http://www.naturopathic.org/content.asp?contentid=60) includes the following statement:

"NDs are trained to utilize prescription drugs, although the emphasis of naturopathic medicine is the use of natural healing agents."

We support this statement and note that it is consistent with WANP perspective that NDs are able to utilize prescription medications in the context of finding more natural, non-pharmaceutical treatments wherever appropriate. In the case of controlled substances and opiate medications, this broader emphasis on 'natural healing agents' will allow NDs to use less opiate medication and to assist patients with finding non-opiate treatments for those already taking them.

4. DOH report suggests prescriptive authority for providers with less training than MDs is dangerous on page 10:
"MDs and DOs 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 in legislative efforts such as ESHB 2876 (Chapter 209, Laws of 2010)."

WANP: This DOH statement does not reference or acknowledge that ARNPs and PAs (as well as Dentists, Podiatrists and Optometrists) currently have prescriptive authority for controlled substances and that both have less education and training than MDs and DOs. Neither ARNPs nor PAs have access to or are required to complete residencies prior to licensure.

5. DOH report cites concerns about naturopathic education on page 10:
"AWHP 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."

"The HCA stated its primary concern is that an increase in prescriptive authority for NDs must include adequate pharmacology education and training. It was concerned with the vagueness of the language in the draft bill and suggested the addition of a requirement for a one-year residency."

WANP: The above comments were submitted to DOH originally without benefit of the details of naturopathic education. These details were submitted by WANP in response to the DOH "Follow Up Questions to Applicant" on July 9, 2014. Kathryn Kolan, representing WSMA, noted the lack of distribution of this information in her testimony at the public hearing on July 17, 2014 (page 125 of draft Report.)

6. DOH report cites objection to NDs performing acupuncture on page 11:
"WEAMA sent a letter with concerns about one of the references WANP provided to show support of NDs being considered primary care physicians. The reference was to a Department of Labor and Industries definition regarding coverage of health practitioners not covered by another classification who diagnose, treat, and care for patients (WAC 296-17A-6109). It included acupuncture in the list of remedies these NDs may use. WEAMA requested to go on record in this report to state that acupuncture is not within naturopaths' scope of practice."

WANP: WEAMA's comments did not address the focus of this Sunrise Review and should not be counted in the tally of letters of opposition. This Sunrise is explicitly limited to expansion of naturopathic prescriptive authority for controlled substances.

7. DOH report is unclear about Medicaid patient population on pages 11 and 13:
Page 11: "The applicant 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."

Page 13: "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…. Data shows that states with higher sales of prescription opioids have higher rates of overdose deaths. In addition: 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."

WANP: The DOH citation of CDC data confirms that Medicaid expansion will include an increased percentage of patients with medical conditions requiring management of opioid prescriptions in the naturopathic primary care setting. Naturopathic physicians can offer a valuable contribution to Medicaid patient care with emphasis on dietary, lifestyle, prevention, patient education and other methods that decrease the need for opioid medications. However, in certain cases a controlled medication may indeed be the most medically appropriate treatment. As stated before, in some cases a delay in a medically necessary prescription can compromise patient safety. Expanded naturopathic prescriptive authority will allow NDs to manage these patients more safely and effectively and will also reduce costs and disruption of care caused by the need for additional office visits.

8. DOH report criticizes naturopathic core education and WANP recommendation for supplemental education on pages 13 – 14:
"The applicant has not 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. An additional eight hours of training and additional continuing education for controlled substance prescribing for NDs, without evidence of a strong foundation within the core naturopathic training, will not be sufficient to protect the public.

WANP: The naturopathic profession has been evolving over the years to meet the changing needs of Washington citizens. In 2005, the legislature expanded naturopathic prescriptive authority to include all legend substances and the controlled substances testosterone and codeine-containing compounds. In response to that scope expansion, DOH developed and implemented WAC 246-836-211 "Authorization regarding controlled substances" requiring NDs to complete four hours of supplemental education in order to be able to apply for a DEA number (required for prescribing controlled substances.) Since that time, NDs have had a very safe record of prescribing with no

record of formal disciplinary action against NDs for prescriptions within the current scope of authority. It should be emphasized that NDs have been safely prescribing opiate pain medications, limited to codeine products and tramadol, in the primary care setting since 2007 for acute and chronic conditions, including pain. This affirms that the continuing education model introduced by the legislature in 2005 and implemented by DOH in 2007 was successful and that the supplemental education was built upon a strong core naturopathic education in clinical sciences including pharmacology and pharmacotherapeutics (see WAC details below).

WAC 246-836-211 – Authorization regarding controlled substances

(1) Upon approval by the board, naturopathic physicians may obtain a current Federal Drug Enforcement Administration registration. The board may approve naturopathic physicians who have:

(a)Provided documentation of a current Federal Drug Enforcement Administration registration from another state; or

(b)Submitted an attestation of at least four hours of instruction. Instruction must be part of a graduate level course from a school approved under chapter 18.36A, 18.71, 18.57, or 18.79 RCW. Instruction must include the following:

(i) Principles of medication selection;

(ii) Patient selection and therapeutics education;

(iii) Problem identification and assessment;

(iv) Knowledge of interactions, if any;

(v) Evaluation of outcome;

(vi) Recognition and management of complications and untoward reactions; and

(vii) Education in pain management and drug seeking behaviors.

(2) The naturopathic physicians must retain training documentation at least five years from the attestation date.

In this Sunrise Review, the WANP has recommended 12 hours of supplemental education, not 8 hours according to the DOH Sunrise Draft Report, and an increase of annual continuing competency requirements to 30 hours per year with 10 of those hours in pharmacology. These requirements are comparable to and exceed the requirements for ARNPs in Washington State.

If DOH feels the recommended supplemental educational requirements are insufficient, the WANP requests that they specify what minimum amount of additional education would be sufficient. The WANP shares the concern for public safety in the practice of naturopathic medicine and in particular with regard to the increased risks associated with controlled substance prescriptions.

9. DOH report suggest no evidence for naturopathic safe prescription record on page 15:

"The applicant states that NDs 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. WANP speculates that NDs have been prescribing these medications safely (note: no data was provided to support or refute this assertion)."

WANP: The WANP did not speculate on the safety record of ND prescribing. On June 19, 2014, the WANP contacted the DOH Naturopathy program and asked the following: "…how many, if any, complaints there have been against NDs for issues related to the currently authorized controlled substances, i.e. testosterone and codeine?"

We received this response:

"Since the effective date of the expanded scope (November 2, 2007), there haven't been any complaints related to prescribing substances that are in the authorized scope (i.e. legend drugs; codeine and testosterone products). There have been a total of 216 complaints received since November 2, 2007. Of those, 24 were related to prescribing outside statutory scope of practice. 4 of those were closed without action, 9 ended in the issuance of Stipulation to Informal Dispositions (STIDs), and there are still 11 in process."

Further, the Vermont Office of Professional Development found that "the safety records of NDs in states with licensure are typically better than those of MDs and DOs in these states." The report also noted, "the safety record of naturopathic physicians regarding pharmacologic substances is well demonstrated in the northwest where NDs have broad prescriptive authority. Jury Verdicts Northwest, a legal database which records court cases in Washington and Oregon, the area of the country with the largest number of naturopathic physicians, shows no judgments for malpractice against N.D.s since the database was started in 1983 through 2010."

10. DOH report states Council on Naturopathic Medical Education has no standard for pharmacology training on page 15:
"There are no CNME standards for pharmacology training."

WANP: We contacted CNME and got the following reply from Daniel Seitz, JD, EdD, Executive Director of CNME:

"The report is not entirely accurate. CNME Accreditation Standard VI, "Program of Study," states the following under Section B.5:

> The academic component provides an in-depth study of the human body, as well as instruction in a variety of therapeutic and clinical subject areas relevant to the practice of naturopathic medicine; where appropriate, instruction includes related experiences in laboratory settings designed to reinforce and augment students' classroom learning. The following subject matter/courses are included:
>
> ...
>
> **f.** Pharmacology and pharmacognosy

As you can see from this excerpt, we do not specify the depth to which pharmacology must be covered. Interestingly, LCME's [Liaison Committee for Medical Education]

curriculum standard for MD training does not even reference pharmacology..... If you compare the ND and MD curriculum standards, you'll see that the ND standards are far more specific regarding required subject matter."

11. DOH report cites Vermont assessment of ND educational standards for clinical pharmacology on page 16:

The Vermont report recommended a conservative approach to ND prescribing that "errs on the side of public protection." It included 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 the naturopathic physician is competent to treat based on that ND's training and experience."

WANP: The WANP recommendations are based on the successful integration of expanded naturopathic prescriptive authority to include all legend drugs and certain controlled medications, passed by the legislature in 2005, and the demonstrated safety record for the profession since that time, with the addition of supplemental education requirements and an increase in the annual CEU requirement for naturopathic physicians.

As outlined in the Vermont report, other states have adopted various means of implementing expanded naturopathic prescriptive authority. As explicitly stated in the WANP Applicant report, we recommend and will ask the legislature to require the Board of Naturopathy to initiate formal rulemaking to develop the most appropriate process and regulatory means for Washington state. We request the DOH to identify the recommendations they feel would be sufficient to protect the public in this regard.

12. DOH report identifies nature of RN pharmacology training on page 17:
"Education to become an RN includes pharmacology education and principles to appropriately and safely administer medications and assess patients' responses to them."

WANP: In assessing the core nursing education, as it relates to pharmacology, it is important to note that Bachelor's level RN education does not appear to include diagnosis or prescription of medications. In comparison, naturopathic medical education includes diagnosis and prescription of medications, both didactically and clinically.

13. DOH report outlines ARNP continuing education requirements on page 17:
"WAC 246-840-360 requires that ARNPs meet the following requirements to renew their licenses every two years:

"Minimum of 250 hours of independent clinical practice in the ARNP role; and Completion of 30 continuing education hours relevant to the area of certification and scope of practice.

Initial application for ARNP prescriptive authority requires at least 30 contact hours of education in pharmacotherapeutics…."

WANP: Core naturopathic education includes 70 – 90 hours in clinical pharmacology. Revised contact hours from Bastyr University indicate that ND students have a mandatory requirement for 88 hours of pharmacology course work and an elective option for an additional 20 hours.

14. DOH report outlines ARNP p. 17 - 18
"Renewal of ARNP 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).

WANP: The WANP is recommending that the ND requirement for continuing competency be increased from the current 20 hours per year to 30 hours per year with 10 of those hours specifically in pharmacology.
This will exceed the requirements for ARNP licensure renewal that amounts to 15 hours every 2 years in pharmacology in addition to a general requirement for 30 hours of continuing education every 2-year renewal.

15. DOH report cites examples of other ND quality assurance provisions on page 18:
"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."

WANP: As mentioned previously, other states have various prerequisites in place for ND prescriptive authority of controlled substances. WANP recommends and will request the legislature to ensure that legislation includes the provision to require formal rulemaking by the Board of Naturopathy to determine the most effective and appropriate regulatory process for Washington State.

16. DOH report cites evolution of ARNP prescriptive authority on page 19
"The prescriptive authority of ARNPs has evolved in response to specific needs in the healthcare system. These have included evidence that ARNPs 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 NDs practice within King, Pierce and Snohomish counties. A map provided by the applicant shows that more than half of all NDs licensed in Washington are in King County alone, and ten counties have none."

WANP: In the same manner that ARNP scope and authority have evolved over time, so has naturopathic practice and prescriptive authority. The previous expansion of prescriptive authority in 2005 and the addition of NDs to Medicaid are recent examples of how our profession is changing to more fully contribute to the overall health care system and specifically to the care and well being of Washington residents.

We anticipate this will continue with eventual recognition in Medicare and more eligibility for NDs to practice in underserved areas and with populations dependent on federal programs for their health care. As part of our July 27, 2014 submission to the DOH, the WANP submitted evidence for ND interest in rural / underserved practice in the study conducted at Bastyr University. To date, lack of opportunities and prior lack of eligibility to participate in Medicaid have constrained the practice of NDs to more populous counties.

October 6, 2014

TO: Department of Health

FROM: Jane Guiltinan, ND, Dean, School of Naturopathic Medicine, Bastyr University

RE: DOH Draft Sunrise Report

At the Public Hearing on July 17, 2014, I stated that if controlled substances were added to the prescriptive authority of naturopathic physicians, Bastyr would not add additional hours to the current curriculum but would instead adjust the curriculum to include education and training in pharmacology and medication management related to controlled substances.

The DOH Draft Sunrise Report also states, "Bastyr University, a primary educator of NDs in this region, has indicated it will only revise the current pharmacology training to include controlled substances rather than add hours to the training. The additional education and training the applicant proposes is not sufficient to address deficiencies in core training."

I want to add to these statements that Bastyr University would be willing and able to develop and offer a continuing medical educational program on controlled substances through the University's Department of Certificate, Community and Continuing Education, that could address any current deficiencies in core training to satisfy the new education requirements required by the legislature and the Board of Naturopathy. Bastyr University would also be pleased to offer its assistance in the development of the necessary education and training requirements to ensure public safety and optimal care by naturopathic physicians in the use of these new medications.

Finally, I am submitting a correction in the number of pharmacology hours in the Bastyr University curriculum. The correct number of required didactic hours is 88, not 60.5.

Thank you for considering my additional comments.

Sincerely,

Jane Guiltinan, N.D.
Dean and Professor, School of naturopathic Medicine
Bastyr University