BEFORE THE
BOARD OF NATUROPATHIC MEDICINE
STATE OF OREGON

In the Matter of the License of: Vanessa Esteves, N.D., Licensee.	Case No. N15-03-06 NOTICE OF PROPOSED DISCIPLINARY ACTION AND OPPORTUNITY FOR HEARING

1.

The Board of Naturopathic Medicine (Board) is the state agency responsible for licensing, regulating and disciplining naturopathic physicians in the State of Oregon. Vanessa Esteves, N.D. (Licensee) is a licensed naturopathic physician in Oregon, and is subject to the jurisdiction of the Board.

2.

The Board conducted an investigation based on concerns with Licensee's prescribing practices, which arose during the review of information gathered in the course of a separate investigation. Based on the results of this investigation and pursuant to ORS 685.110(8) and (14), ORS 685.990(2), and OAR 850-050-0190(2), the Board hereby proposes to take disciplinary action against Licensee's license to practice naturopathic medicine and assess a civil penalty against Licensee for violations of ORS 685.110(8) and (14), OAR 850-050-0010(1)(c)(A) and 850-050-0190(3) and (12), as described in the following paragraphs. For each violation, the Board may impose a civil penalty up to $5,000, a term of probation, letter of reprimand and license limitation, suspension, or revocation without amending its Notice.

3.

Prescribing Outside the Formulary

Patient A established care with Licensee on or about February 14, 2012, having previously been under the care of a Family Nurse Practitioner in the same clinic. Licensee prescribed 100 mg of Seconal Sodium (secobarbital sodium) to Patient A as a sedative for sleep, from between 10 to 30 tablets per month, from April 5, 2012 through at least March 17, 2015.

Secobarbital sodium is a barbiturate. Barbiturates are excluded from the compendium for use as a sedative, OAR 850-060-0226(8) (f). By prescribing a barbiturate as a sedative, Licensee prescribed off the naturopathic formulary, in violation of OAR 850-050-0190(12). Doing so continuously and repeatedly for a period of over two years is aggravating factor under OAR 850-050-0010(2)(a)(B) and, therefore subjects Licensee to formal license discipline.

4.

Negligence and Negligent Prescribing

Opiates are commonly prescribed for short-term, acute conditions. Long term opiate use carries a risk of patient harm due to abuse or addiction. Long-term use of opiates to treat chronic pain requires a higher degree of assessment, screening, documentation, and record keeping to mitigate this risk. Patients should be pre-screened for risk of opioid abuse, multi-drug use, and other risk factors. Pain progress should be monitored and re-assessed on a monthly basis. Periodic physical exams and blood chemistry should be performed to assess toxicity risks. Patients should be screened monthly for compliance with contract and for multi-drug use through exam and drug screening.

The Washington Agency Medical Directors' Group has issued an Interagency Guideline on Opioid Dosing for Chronic Non-Cancer Pain (2010 Update) (hereafter referred to as Washington Guideline). This publication establishes an opioid dosing guideline of 120 milligrams (mg) as the maximum allowable morphine equivalent daily dose (MED) over a 24 hour period. Appendix A, Table 5 of the Washington Guideline provides the equianalgesic dose to convert other opioids to the morphine equivalent. A higher dose than 120 mg MED must be documented and if the dose is not decreased, further explanation must be provided.

Furthermore when patients who are monitored, screened, examined and re-assessed are found to be non-compliant, non-compliance is not merely to be noted; non-compliance must be appropriately managed.

Patient A

Patient A received pain medication from Licensee. Licensee regularly prescribed Patient A 15 mg oxycodone #90, 10 mg methadone #360, increasing those dosages from February 2012 to October 2012 and into the present. Prescriptions in November 2013 and January 2014, equating to a total daily MED of approximately 1165, are well above the 120 MED dosing guideline. Licensee prescribed100 mg secobarbital sodium #20 daily, with an increase in October 2012 to #30 daily. The secobarbital sodium was decreased and subsequently increased between November 2, 2013 and August 7, 2014. Patient A's chart contains no information to support a MED above 120 mg. Licensee regularly used Patient Health Questionnaire-9 (PHQ-9) and Screening, Brief, Intervention, Referral to Treatment (SBIRT) to screen Patient A for abuse potential. Patient A admitted to using marijuana occasionally. Patient A's cardiologist and law enforcement reported Patient A exhibiting slurred speech, the inability to converse, and the inability to walk or stand, but without the odor of alcohol, indicating Patient A heavily under the influence of barbiturates, opiates, or both. Patient A reported oxycodone, methadone and secobarbital sodium drugs or the scripts for them were "lost" or "stolen" on three occasions (11/7/2012; 6/8/2013; 5/14/2014), and changed her story about the loss or theft, or about what was lost, on two of those occasions. Patient A failed to report receiving opiate prescriptions from another provider on July 14, 2013, and continued receiving regular refills of opiates from Licensee. The opiates or barbiturates prescribed to Patient A were not present in her urinary drug screens on 6 occasions (12/9/2013; 12/14/2013; 4/29/2014; 6/10/2014; 9/9/2014; 1/22/2015). Licensee consistently refilled prescriptions for Patient A.

By prescribing opiates in dosages over 120 MED for multiple years without findings to support that dosage; failing to appropriately manage Patient A's opiate abuse after screening for it and observing it through opiate use discontinuance or titration, or referral to a specialist; continuing to refill Patient A's opiate and barbiturate prescriptions after repeated reports by

Patient A of lost or stolen medications and urinary drug screens that were negative for Patient A's prescribed medications while positive for marijuana; prescribing off the naturopathic formulary approximately three years, and for prescribing secobarbital sodium in combination with opiates, Licensee committed negligence related to the practice of naturopathic medicine in violation of ORS 685.110(8), and engaged in negligent prescribing in violation of OAR 850-050-0010(1)(c)(A).

Patient B

Patient B presented to Licensee November 7, 2013 with chronic pain medication use and history of addiction. She admitted opioid dependency to Licensee and expressed a desire to titrate her opioid use down. Patient B received pain medication from Licensee. Licensee regularly prescribed Patient B 10 mg oxycodone #120 daily, and 10 mg methadone #180 daily, for 15 months, equating to a daily MED of approximately 835, well above 120 mg. Patient B's chart contains no information to support a MED above 120 mg. There is no record that Licensee entered a pain contract with Patient B. Licensee documented only one urinary drug screen for Patient B on Patient B's initial visit. Licensee notes that pain described by Patient B is not the type of pain to be treated with oxycodone or methadone and reports suspicions of narcotic pain tolerance, but continues to refill Patient B's prescription. There is no record in the charts of Licensee referring Patient B to a pain or addiction specialist. By prescribing opiates in dosages over 120 MED without findings to support that dosage; for failing to appropriately manage Patient B's opiate abuse after Patient B presented with an opiate addiction, or after screening for it; for failing to establish a pain contract with Patient B; and for conducting only one urinary drug screen for a patient on maintenance methadone, Licensee engaged in negligent prescribing, in violation of the standards of and committed negligence related to the practice of naturopathic medicine, in violation of ORS 685.110(8), and also committed negligent prescribing in violation of OAR 850-050-0010(1)(c)(A).

Patient C

Patient C presented to Licensee on February 18, 2014, with prior use of methadone, hydrocodone and alprazolam. On March 1, 2014, when Licensee reported Patient C complained of back pain, Licensee prescribed 10 mg methadone #180, equating to a daily MED of approximately 771, well above 120 mg. Licensee regularly prescribed 10 mg methadone #180 through March 2015. April 1, 2014, Patient C reported shoulder pain and Licensee renewed the 10 mg methadone prescription with minimal assessment, through at least March 18, 2015. Licensee used PHQ-9 and SBIRT to screen Patient C for abuse potential, but did not titrate Patient C's opiate use down or refer patient to an addiction specialist. Patient C's chart contains no information to support a MED above 120 mg. By prescribing opiates in dosages over 120 MED without findings to support that dosage; and for failing to appropriately manage Patient C's opiate abuse after screening for it, Licensee engaged in negligence related to the practice of naturopathic medicine, in violation of ORS 685.110(8), and in negligent prescribing in violation of OAR 850-050-0010(1)(c)(A).

As described in the paragraphs above, Licensee's records for Patients A through C do not contain objective findings to support the prescription doses of controlled substances prescribed to Patients A through C. Licensee did not account for risk factors, signs of drug diversion, use of unprescribed substances (marijuana), current symptoms or changes in medical condition while Licensee prescribed and continued to refill prescriptions. Licensee routinely monitored these patients, but did not manage their care properly when addiction and diversion were evident or by responding to negative monitoring results, which is inconsistent with the standard of care in chronic pain management.

5.

Conduct or Practice which might Constitute a Danger to the Health or Safety of a Patient or the Public

The Washington Guideline, the Opioid Prescribing Guidelines, and the OHSU Guideline all establish how to manage patients with evidence of opioid diversion, including specialty referral if necessary, immediate discontinuation of opioid prescriptions, and institution of opioid withdrawal therapies if called for. Secobarbital sodium is a central depressant that can act synergistically with opiates, increasing the likelihood for adverse events. Additionally, the use of secobarbital sodium with opiates creates a magnified risk of dulled reaction times, contraindicating the operation of cars or equipment while taking them.

Patient A

Licensee prescribed 100 mg secobarbital sodium #20 daily, with an increase in October 2012 to #30. The secobarbital sodium was prescribed with fluctuating dosages until at least August 2014.

Drug Diversion – Danger to Public Health or Safety

Patient drug diversion, or the unlawful sale or gift of a prescription drug from the patient to an individual to whom the drugs provided were not prescribed, presents significant public health risks for many reasons including unreliability of dosages, absence of physician monitoring of the person(s) to whom the drugs are diverted, and potential harmful interaction with prescribed drugs or existing health conditions. Potential risks of drug diversion to the public receiving the diverted drugs include drug abuse, addiction, subsequent heroin addiction after opioid diversion, and death. Signs of drug diversion include repeated reports of those drugs being lost or stolen, absence of prescribed drugs from the urinary drug screens of the person to whom they are prescribed; and, obtaining multiple, simultaneous prescriptions from multiple providers.

Patient A

Licensee regularly prescribed Patient A oxycodone, methadone, and secobarbital sodium from February 2012 through at least March 17, 2015. Patient A reported her medications stolen on November 7, 2012 and obtained additional oxycodone and methadone from Licensee; on June 8, 2013, Patient A reported her medications lost at the hospital, but then reported her daughter may have stolen or discarded those medications. Licensee recorded a plan to acquire hospital records and speak with a hospital nurse to verify Patient A's story, but refilled Patient A's methadone and oxycodone prescriptions without doing so, and Patient A's charts show no follow up by Licensee with hospital or hospital nurse; on July 13, 2013, Patient A underwent a urinary drug screen at the hospital that was positive for oxycodone, methadone, and barbiturates, as well as for marijuana; on July 15, 2013, the PDMP shows that Patient A received hydromorphone and methadone prescriptions from another provider, but Licensee's charts on Patient A do not show those prescriptions and Licensee refilled Patient A's prescriptions for oxycodone, methadone, and secobarbital sodium on July 16, 2013; on December 9, 2013 in the hospital emergency room, Patient A's methadone levels were found to be lower than what she was prescribed; on December 14, 2013, Licensee performed a urinary drug screen on Patient A and it was negative for oxycodone, yet Licensee refilled Patient A's prescriptions for oxycodone and methadone; on April 29, 2014, Patient A's urinary drug screen was negative for barbiturates; on May 14, 2014, Patient A reported losing her oxycodone prescription script, but then later claimed she had lost her methadone prescription script; on June 10, 2014, a urinary drug screen was negative for barbiturates; on September 9, 2014 Patient A reports vomiting and losing three days of medication, but is given a urinary drug screen, which is negative for barbiturates; on January 22, 2015, Patient A received a urinary drug screen, which was negative for barbiturates; and, Licensee repeatedly notes in Patient A's charts that Patient A has an opiate addiction and will taper Patient A's medications, but also writes that she does not believe Patient A's dosages are high and makes no changes to Patient A's dosages. Licensee did not discontinue Patient A's opiate prescriptions and treat her or have her admitted for treatment for withdrawal. Licensee did

not titrate Patient A's opiate use down. Licensee did not complete a referral of Patient A to a pain or addiction specialist. Licensee did not discontinue any of Patient A's opioid or barbiturate prescriptions or have her admitted for treatment.

By failing to discontinue prescribing opiates and barbiturates to Patient A when presented with evidence of drug diversion, Licensee created a danger to public health and safety, in violation of ORS 678.110(14).

6.

Charting Omissions and Errors

A naturopathic physician must maintain complete and accurate patient charts to ensure a patient receives proper care from his or her treating naturopath and from any subsequent health provider. Preparing or maintaining an inaccurate or incomplete patient chart is conduct in violation of ORS 685.110(8), (14) and OAR 850-050-0190(3).

Patient A

On February 14, 2012, Licensee noted refilling Patient A's medications, but does not note which medications were refilled or in what dosages. On August 6, 2013, Licensee wrote a prescription for a Fentanyl patch for Patient A, but did not note why; on or about November 2013 through August 2014, Licensee wrote Patient A prescriptions for secobarbital sodium tablets between 10 mg and 20 mg, but made no notes as to why the changes in dosage; on or about April 17, 2014, Licensee changed dosages in Patient A's oxycodone, and also prescribed Ketoconazole Topical in a 2% solution, and Bacitracin Topical at 500 I.U., but made no notes as to why. By failing to chart why she was prescribing medications, dosages, or why dosages were changed, Licensee made charting omissions that were negligent and unprofessional in violation of ORS 685.110(8) and OAR 850-050-0190(3).

Licensee recorded planning to acquire hospital records for Patient A to confirm Patient's report that medications were lost at the hospital or stolen. Patient's chart does not indicate that any hospital records were requested or received. Licensee again made charting omissions in violation of ORS 685.110(8) and OAR 850-050-0190(3).

Patient C

On September 13, 2014, Licensee wrote Patient C a prescription for Oxyburtin Chloride, but made no notes as to why; on or around September 13, 2014 through November 8, 2014, Licensee wrote Patient C prescriptions for Trazodone, Erythromycin, Methadone refills, Amoxicillin and Flexeril were written for Patient C, but there are no notes as to why. Licensee made charting omissions in violation of ORS 685.110(8) and OAR 850-050-0190(3).

Because these charting omissions were serious, repeated and continuous, the Board considers their circumstances to be an aggravating factor under OAR 850-050-0010(2), and discipline is proposed for the charting violations listed above.

7.

Definitions that may be relevant to this Notice are contained in ORS 685.010 and OAR 850-010-0005.

8.

For the foregoing violations, the Board proposes the following discipline:

1. Civil penalties in the total amount of thirty five thousand dollars ($35,000);

The following discipline is appropriate for each of the foregoing violations individually; however, for all of the foregoing violations, the Board proposes:

2. Six months of restriction on her federal Drug Enforcement Agency registration, effective upon the signing of the Order, prohibiting Licensee from prescribing opiates, or any schedule federal Drug Enforcement Agency Schedule II, IIN, III, or IIIN drugs during that time.

3. Three years probation with the following conditions:

   a. For three consecutive calendar years following the effective date of this Order, Licensee shall submit to the Board a quarterly prescription log of any and all prescriptions she writes for any substance listed on the federal Drug Enforcement Agency's Schedules II through V during that quarter;

b. After her DEA license restrictions are lifted, Licensee shall submit quarterly reports on 10 patient charts for patients to whom Licensee prescribes, administers, dispenses or orders an opiate or opioid, to a naturopathic physician who is pre-approved by the Board, for review under the following terms:

A) In each report the reviewing naturopathic physician prepares for the Board, he or she shall include a checklist for each patient chart he or she reviews that answers at least the following questions:

i) Does the patient chart contain an adequate objective assessment of the patient?

ii) Did Licensee order and evaluate appropriate laboratory tests?

iii) Was a physical examination necessary for a patient visit, and if necessary, did Licensee complete an adequate physical exam?

iv) Did Licensee adequately document and chart all prescriptions?

v) Was the PDMP consulted on the patient before every refill to ensure against dual prescribing?

vi) Was a pain contract entered with every patient to whom Licensee prescribed opiates or opioids?

v) If a pain contract was entered and violated, or if other signs of abuse or addiction appeared, did Licensee adequately titrate or discontinue prescriptions of opiates and opioids, and otherwise properly manage the patient's care?

B) The reviewing naturopathic physician shall submit a report to the Board within thirty days of the end of each quarter, and in it shall note any concerns with Licensee's patient care during the prior quarter;

C) Licensee shall be solely responsible for any professional fees or expenses associated with the quarterly reviews required under paragraph (3)(b); and

D) The Board may extend the time during Licensee must submit quarterly reports, based on its review of the reviewing naturopathic physician's reports; and,

c. Licensee shall comply with the statutes, rules and orders of the Board.

4. In lieu of the chart review described in paragraph (3)(b) above, Licensee shall practice for 50 hours under the direct-in-person supervision of a licensed naturopathic doctor who specializes in pain management and addiction and who is pre-approved by the Board, shall be solely responsible for any professional fees or expenses associated with such supervision, and Licensee shall comply with the statues, rules and order of the Board.

5. In addition to the Board's regular continuing education requirements, 15 Continuing Education credits shall be obtained by Licensee during her probationary period, at the Licensee's own expense, and as follows: six (6) credit hours in pain management; six (6) credit hours in recognizing and managing patients with drug addiction; and six (3) credit hours in managing difficult patients. Compliance with any other term of this Notice shall not be accepted as fulfillment or partial fulfillment of these additional continuing education requirements.

9.

NOTICE OF OPPORTUNITY FOR HEARING

Licensee is entitled to a hearing as provided by the Administrative Procedures Act (ORS Chapter 183). If you want a hearing, you must file a written request for hearing with the Board within 21 days from the date this notice was mailed. You must mail any request for hearing to Oregon Board of Naturopathic Medicine, 800 NE Oregon Street, Suite 407, Portland, OR 97232. The request for hearing must be received by the Board within 21 days from the date of mailing of this notice, and must be accompanied by a written answer to the charges contained in this Notice. If a request for hearing is not received within 21 days, the right to hearing is waived.

10.

If you request a hearing, you will be notified of the time and place of the hearing. Before the hearing, you will receive information on the procedures, right of representation, and other rights of parties related to the conduct of the hearing. An administrative law judge from the Office of Administrative Hearings will preside at any hearing. ORS 183.635.

11.

An answer is required to this Notice, pursuant to OAR 850-001-0015, due to the complexity of the matters alleged above. The answer shall be made in writing to the Board and shall include an admission or denial of each factual matter alleged in this Notice, and a short plain statement of each relevant affirmative defense Licensee may have. Except for good cause, factual matters alleged in this notice and not denied in the answer shall be presumed admitted;

failure to raise a particular defense in the answer will be considered a waiver of such defense; and new matters alleged in the answer (affirmative defenses) shall be presumed to be denied by the agency and evidence shall not be taken on any issue not raised in the Notice and answer.

12.

If you fail to request a hearing within 21 days, withdraw a request for a hearing, notify the Board or administrative law judge that you will not appear or fail to appear at a scheduled hearing, the Board may issue a final order by default. If the Board issues a default order, the contents of the Board's file automatically becomes part of the evidentiary record of this disciplinary action for the purpose of proving a prima facie case.

NOTICE TO ACTIVE DUTY SERVICEMEMBERS: Active duty service members have a right to stay these proceedings under the federal Service members Civil Relief Act. For more information contact the Oregon State Bar at 800-452-8260, the Oregon Military Department at 800-452-7500 or the nearest United States Armed Forces Legal Assistance Office through http://legalassistance.law.af.mil.

DATED this 21st day of June 2016.

BOARD OF NATUROPATHIC MEDICINE
State of Oregon

Anne Walsh, Executive Director