



Oregon

John A. Kitzhaber, MD, Governor

Board of Nursing

17938 SW Upper Boones Ferry Rd

Portland, OR 97224-7012

(971) 673-0685

Fax: (971) 673-0684

Oregon.BN.INFO@state.or.us

www.oregon.gov/OSBN

TO: ALL INTERESTED PARTIES

FROM: HOLLY MERCER
EXECUTIVE DIRECTOR

DATE: AUGUST 2011

**SUBJECT: ADMINISTRATIVE RULEMAKING HEARING REGARDING THE
ADOPTION OF THE AMENDMENTS TO OAR 851-056-0000, 0010,
0012, and 0016 (CLINICAL NURSE SPECIALIST AND NURSE
PRACTITIONER AUTHORITY TO PRESCRIBE AND DISPENSE).**

On Thursday, September 22, 2011 at 9:00 a.m., the Oregon State Board of Nursing will hold a hearing regarding the adoption of the proposed amendments to Oregon Administrative Rules 851-056-0000, 0010, 0012, and 0016 (Clinical Nurse Specialist and Nurse Practitioner authority to prescribe and dispense). This hearing will be held in the conference room of the Oregon State Board of Nursing, 17938 S.W. Upper Boones Ferry Road, Portland, Oregon.

Attached is a copy of the Notice of Proposed Rulemaking for this hearing. The Board is authorized by ORS 678.385 and 678.390 to establish and amend such rules.

If you are unable to attend the hearing, you may submit your comments to me in writing by September 20, 2011 and I will see that they are incorporated into the testimony received at the hearing and considered by the Board at their September 22, 2011 meeting.

The Board looks forward to receiving your input.

Secretary of State
NOTICE OF PROPOSED RULEMAKING HEARING*

A Statement of Need and Fiscal Impact accompanies this form.

Oregon Board of Nursing
Agency and Division

851
Administrative Rules Chapter Number

Peggy Lightfoot
Rules Coordinator

17938 S.W. Upper Boones Ferry Road, Portland, OR 97224
Address

(971) 673-0638
Telephone

RULE CAPTION

Rules to clarify nurse prescriber authority related to off label, compounded, and grandfathered drugs.
Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.

September 22, 2011	9:00 a.m.	17938 S.W. Upper Boones Ferry Road Portland, Oregon 97224	Pat Markesino Board President Hearings Officer
Hearing Date	Time	Location	

Auxiliary aids for persons with disabilities are available upon advance request.

RULEMAKING ACTION

ADOPT:

AMEND: OAR 851-056-0000, 0010, 0012, 0016

REPEAL:

RENUMBER: Secure approval of rule numbers with the Administrative Rules Unit prior to filing.

AMEND & RENUMBER: Secure approval of rule numbers with the Administrative Rules Unit prior to filing.

ORS 678.385, 678.390
Stat. Auth.

Other Authority

ORS 678.370, 678.372, 678.375, 678.380, 678.390
Stats. Implemented

RULE SUMMARY

These rules cover the authority of the Clinical Nurse Specialist and Nurse Practitioner to prescribe and dispense drugs. These rule amendments clarify their ability to prescribe off label, compounded, and grandfathered drugs.

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing the negative economic impact of the rule on business.

September 20, 2011 -- 5:00 p.m.

Last Day for Public Comment

Last day to submit written comments to the Rules Coordinator

Signature

Peggy Lightfoot
Printed name

August 1, 2011
Date

*The *Oregon Bulletin* is published on the 1st of each month and updates the rule text found in the Oregon Administrative Rules Compilation. Notice forms must be submitted to the Administrative Rules Unit, Oregon State Archives, 800 Summer Street NE, Salem, Oregon 97310 by 5:00 pm on the 15th day of the preceding month unless this deadline falls on a Saturday, Sunday or legal holiday when Notice forms are accepted until 5:00pm on the preceding workday. ARC 920-2005

Secretary of State
STATEMENT OF NEED AND FISCAL IMPACT
A Notice of Proposed Rulemaking Hearing or a Notice of Proposed Rulemaking accompanies this form.

Oregon State Board of Nursing
Agency and Division

851
Administrative Rules Chapter Number

In the Matter of: OAR 851-056-0000, 0010, 0012, 0016

Rules to clarify nurse prescriber authority related to off label, compounded, and grandfathered drugs.

Rule Caption: (Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.)

Statutory Authority: ORS 678.385, 678.390

Other Authority: ORS 678.370, 678.372, 678.375, 678.380, 678.390

Stats. Implemented: ORS 678.370, 678.372, 678.375, 678.380, 678.390

Need for the Rule(s): A petition was received by nurse prescribers to clarify their authority related to off label, compounded, and grandfathered drugs.

Documents Relied Upon, and where they are available:

- ◆ Oregon Revised Statutes, Chapter 855
- ◆ Nurse Practice Act, Division 56
- ◆ www.fda.gov
- ◆ www.oregon.gov/pharmacy
- ◆ "Guidance for FDA Staff and Industry: Marketed Unapproved Drugs--Compliance Policy Guide" (June 2006) www.fda.gov

Fiscal and Economic Impact, including Statement of Cost of Compliance:

There is no fiscal impact. These rules clarify current regulations.

How were small businesses involved in the development of this rule?

The proposed rules have been distributed on a public List-Serv for comment and review.

Administrative Rule Advisory Committee consulted?: Yes

If not, why?:

Authorized Signer

Peggy Lightfoot
Printed name

August 1, 2011
Date

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Bolded and underlined material is proposed to be added.

DIVISION 56

Clinical Nurse Specialist and Nurse Practitioner Authority to Prescribe and Dispense

Definitions

851-056-0000

- (1) "Addiction" means a primary, chronic, neurobiological disease with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving. Neither physical dependence nor tolerance alone, as defined by these rules, constitutes addiction.
- (2) "Administer" means the direct application of a drug or device, whether by injection, inhalation, ingestion, or any other means to the body of a patient or research subject.
- (3) "Assessment" means a process of collecting information regarding a client's health status including, but not limited to, illness, response to illness, health risks of individuals, families and groups, resources, strengths and weaknesses, coping behaviors, and the environment. The skills employed during the assessment process may include, but are not limited to, obtaining client histories, conducting physical examinations, and ordering, interpreting, and conducting a broad range of diagnostic procedures (e.g., laboratory studies, EKGs, and X-rays).
- (4) "Client(s) or patient(s)" means a family, group or individual who has been assessed by and has a client/patient record established by the clinical nurse specialist or nurse practitioner.
- (5) "Clinical education in patient management" means a set of structured learning activities, including but not limited to, supervised clinical practice in the pharmacological management of individual clients, as well as other learning activities to promote understanding of pharmacological interventions.
- (6) "Compounded Drug" means a combination preparation the active ingredients of which are components of an FDA approved drug, or a drug which is still in common usage and predates the FDA approval process.**
- ~~{(6)}~~**(7)** "Diagnosis" means identification of actual or potential health problems or need for intervention based on analysis of the data collected.
- ~~{(7)}~~**(8)** "Differential diagnosis" means the process of determining a medical diagnosis from among similar diseases and conditions based upon collection and analysis of clinical data.
- ~~{(8)}~~**(9)** "Discrete pharmacology course" means an advanced pharmacology course with pharmacologically specific requirements, objectives, and content, which is offered for academic or continuing education credit, and is not integrated into other coursework.
- ~~{(9)}~~**(10)** "Dispense" or "dispensing" means the labeling and distribution of a medication to the clinical nurse specialist's or nurse practitioner's client which is prepackaged by a manufacturer registered with the State Board of Pharmacy, or repackaged by a pharmacist licensed with the State Board of Pharmacy.
- ~~{(10)}~~**(11)** "Dispensing authority" means to prepare and deliver substances to the client provided the authority is exercised in compliance with applicable federal and state laws.
- ~~{(11)}~~**(12)** "Distribute" means the delivery of a drug other than by administering or dispensing, such as prepackaged samples.
- ~~{(12)}~~**(13)** "Functional impairment" means:
 - (a) Practicing nursing when unable/unfit to perform procedures and/or make decisions due to physical impairment as evidenced by documented deterioration of functioning in the practice setting and/or by assessment of a health care provider

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qualified to diagnose physical condition/status.

- (b) Practicing nursing when unable/unfit to perform procedures and/or make decisions due to psychological or mental impairment as evidenced by documented deterioration of functioning in the practice setting, and/or by the assessment of a health care provider qualified to diagnose mental condition/status.
- (c) Practicing nursing when physical or mental ability to practice is impaired by use of drugs, alcohol, or mind-altering substances.

(14) "Legend Drug" means:

- (a) a drug which is required by federal law, prior to being dispensed or delivered, to be labeled with the following statement: "Caution: federal law prohibits dispensing without a prescription" or**
- (b) a drug which is required by any applicable federal or state law or regulation to be dispensed by prescription only or restricted to use by practitioners only.**

(15) "Off Label" means the use of an FDA approved drug for other than FDA approved indications or dosing.

(16) "Orphan Drug" means a drug which has received orphan status from the US Food and Drug Administration because it targets a disease which affects less than 200,000 persons in the US.

~~[(13)]~~**(17)** "Pain" means an unpleasant sensory and emotional experience related to adverse nociceptive or neuropathic stimuli. It may also be idiopathic in nature.

- (a) "Acute pain" is brief and responds to timely intervention or subsides as healing takes place. Inadequate treatment may delay recovery. Such pain responds to anti-inflammatory and opioid medications, as well as to other approaches.
- (b) "Chronic pain" is on going or frequently recurring and may become unresponsive to intervention over time.
- (c) "Intractable pain" means a pain state in which the cause cannot be removed or otherwise treated and no relief or cure has been found after reasonable efforts.

~~[(14)]~~**(18)** "Pharmacodynamics" means the study of the biochemical and physiologic effects of drugs and their mechanism of action.

~~[(15)]~~**(19)** "Pharmacokinetics" means the action of drugs in the body over a period of time.

~~[(16)]~~**(20)** "Pharmacotherapeutics" means the study of the uses of drugs in the treatment of disease.

~~[(17)]~~**(21)** "Physical dependence" means the physiologic adaptation to the presence of a medication characterized by withdrawal when its use is stopped abruptly.

~~[(18)]~~**(22)** "Prescribe" means a written, verbal, or electronic legal directive to procure or designate for use legend drugs or controlled substances. Additionally, a prescription may be issued or required for use of over-the-counter medications.

~~[(19)]~~**(23)** "Prescribing authority" means the legal permission to determine which drugs and controlled substances shall be used by or administered to a client.

~~[(20)]~~**(24)** "Specialty" means the defined area of expertise such as that provided by academic education, clinical training, and may include additional legal or professional credentialing mechanisms.

~~[(21)]~~**(25)** "Target audience" means a population for whom an educational program is designed.

~~[(22)]~~**(26)** "Therapeutic device" means an instrument or an apparatus intended for use in diagnosis or treatment and in the prevention of disease or maintenance or restoration of health.

~~[(23)]~~**(27)** "Tolerance" means the physiologic adaptation to a controlled substance over time, resulting in the need to increase the dose to achieve the same effect, or in a reduction of response with repeated administration.

Stat. Auth.: ORS 678.150

Stats. Implemented: ORS 678.370, 678.372, 678.375, 678.380, 678.385, 678.390

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Prescription Requirements

851-056-0010

- (1) A written prescription shall include the date, printed name, legal signature, specialty category/title, business address, and telephone number of the prescribing nurse practitioner or clinical nurse specialist in addition to the required patient and drug information.
- (2) An electronically transmitted prescription as defined in OAR 855-006-0015 of the Pharmacy Act shall include the name and immediate contact information of the prescriber and be electronically encrypted or in some manner protected by up-to-date technology from unauthorized access, alteration or use. Controlled substances have additional restrictions as defined by the DEA which shall be followed.
- (3) A tamper resistant prescription shall meet criteria as defined in OAR 855-006-0015 of the Pharmacy Act.
- (4) Prescriptions may be written for over-the-counter drugs, durable medical equipment (DME) and devices.
- (5) Prescriptions shall be signed by the prescriber with the abbreviated specialty title of the nurse practitioner as per OAR 851-050-0005(9) or the title CNS as per OAR 851-054-0015.
- (6) The nurse practitioner or clinical nurse specialist shall comply with all applicable laws and rules in prescribing, administering, and distributing drugs, including compliance with the labeling requirements of ORS Chapter 689.
- (7) A nurse practitioner or clinical nurse specialist shall only prescribe controlled substances in conjunction with their own valid and current DEA registration number appropriate to the classification level of the controlled substance.
- (8) Clinical nurse specialists and nurse practitioners with prescriptive authority are authorized to prescribe **legend and controlled substances in Schedule II-V. Additionally, they may prescribe:**
 - (a) Over-the-counter drugs;
 - (b) Appliances and devices;
 - (c) Orphan drugs;
 - (d) Limited access drugs; ~~and~~
 - (e) Antibiotics to partner(s) of patients diagnosed with a sexually transmitted infection without first examining the partner of the patient, consistent with Department of Human Services guidelines regarding Expedited Partner Therapy; **and**
 - (f) **Off label.**
- (9) **All prescribed, dispensed, and distributed drugs shall have Food and Drug Administration (FDA) approval except in the following situations:**
 - (a) **Compounded drugs;**
 - (b) **Drugs provided through a United States IRB approved clinical trial;**
 - (c) **Drugs prescribed under limited access programs;**
 - (d) **Drugs which are still in common usage and predate the FDA approval process.**

Stat. Auth.: ORS 678.150

Stats. Implemented: ORS 678.370, 678.372, 678.375, 678.380, 678.385, 678.390

Standards for Clinical Nurse Specialists and Nurse Practitioners with Prescriptive Authority

851-056-0012

- (1) Evaluation of appropriate prescribing by the Board is constructed based on the following premises:
 - (a) Nurse practitioners may provide care for specialized client populations within each

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- nurse practitioner category/scope of practice;
- (b) Clinical nurse specialists may provide care for individuals and populations within their specialty scope of practice;
 - (c) Prescribing is limited by the individual's scope of practice and knowledge base within that scope of practice;
 - (d) Clinical nurse specialists and nurse practitioners may prescribe the drugs appropriate for patients within their scope of practice as defined by OAR 851-050-0005; or OAR 851-054-0020 and 0021;
 - (e) Clinical nurse specialists and nurse practitioners shall be held independently accountable for their prescribing decisions;
 - (f) All drugs prescribed shall have Food and Drug Administration (FDA) approval **unless mentioned as an exception in OAR 851-056-0010.**

Stat. Auth.: ORS 678.385

Stats. Implemented: ORS 678.385, 678.390

Conduct Derogatory to the Standards for Prescriptive or Dispensing Authority 851-056-0016

- (1) The Board may deny, suspend or revoke the authority to write prescriptions and/or dispense drugs for the causes identified in ORS 678.111(1) or with proof that the authority has been abused.
- (2) The abuse of the prescriptive or dispensing authority constitutes conduct derogatory to nursing standards and is defined as:
 - (a) Prescribing, dispensing or distributing drugs which are not FDA approved unless done ~~[through protocol registration in a United States Institutional Review Board or Expanded Access authorized clinical trial.]~~ **in accordance with the Boards policies and regulations on exceptions.**
 - (b) Prescribing, dispensing, administering, or distributing drugs for other than therapeutic or prophylactic purposes;
 - (c) Prescribing, dispensing, or distributing drugs to an individual who is not the clinical nurse specialist's or nurse practitioner's client unless written under Expedited Partner Therapy guidelines from the Department of Human Services or is not within the scope of practice or type of client population served;
 - (d) Prescribing, dispensing, or distributing drugs for personal use;
 - (e) Prescribing, dispensing, administering, or distributing drugs while functionally impaired;
 - (f) Prescribing, dispensing, administering, or distributing drugs in an unsafe or unlawful manner or without adequate instructions to the client according to acceptable and prevailing standards or practice;
 - (g) Prescribing, dispensing, or distributing drugs which are specifically restricted under federal law;
 - (h) Failure to properly assess and document client assessment when prescribing, dispensing, administering, or distributing drugs;
 - (i) Selling, purchasing, trading, or offering to sell, purchase or trade any drug sample;
 - (j) Dispensing medications without dispensing authority granted by the Board or other dispensing authority issued by the State of Oregon; and
 - (k) Charging a client or any third party payer in a grossly negligent manner.

Stat. Auth: ORS 678.111, 678.113, 678.150

Stats. Implemented: ORS 678.350, 678.370, 678.372, 678.375, 678.380, 678.385