

TO: ALL INTERESTED PARTIES

FROM: HOLLY MERCER
EXECUTIVE DIRECTOR

DATE: October 22, 2009

SUBJECT: ADMINISTRATIVE RULEMAKING HEARING REGARDING THE ADOPTION OF THE AMENDMENTS TO ADMINISTRATIVE RULES OAR 851-056-0000, 0006, 0010, 0016, 0020, AND 0024, (RULES FOR DELEGATION OF DISPENSING FUNCTIONS BY NURSE PRESCRIBERS, AND ANTIBIOTIC PRESCRIBING FOR EXPEDITED PARTNER THERAPY.)

On Thursday, November 19, 2009 at 9:00 a.m., the Oregon State Board of Nursing will hold a hearing regarding adoption of the amendments to administrative rules OAR 851-056-0000, 0006, 0010, 0016, 0020, and 0024 (rules for delegation of dispensing functions by nurse prescribers, and antibiotic prescribing for expedited partner therapy). 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 678.380 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 November 17, 2009 and I will see that they are incorporated into the testimony received at the hearing and considered by the Board at their November 19, 2009 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

KC Cotton
Rules Coordinator

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

(971) 673-0638
Telephone

RULE CAPTION

Rules for Delegation of Dispensing Functions by Nurse Prescribers, and Antibiotic Prescribing for Expedited Partner Therapy.
Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.

November 19, 2009	9:00 a.m.	17938 S.W. Upper Boones Ferry Road	James McDonald
Hearing Date	Time	Portland, Oregon 97224	Board President
		Location	Hearings Officer

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

RULEMAKING ACTION

ADOPT: OAR 851-056-0007

AMEND: OAR 851-056-0000, 0006, 0010, 0016, 0020, 0024

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 678.380, 678.390
Stat. Auth.

Other Authority

ORS 678.410
Stats. Implemented

RULE SUMMARY

These rules permit nurse prescribers (clinical nurse specialists and nurse practitioners) with dispensing authority issued by the Oregon State Board of Nursing to delegate certain non-judgmental dispensing functions to staff provided that medication is prepackaged and labeled with identifying information.

They also permit nurse prescribers (clinical nurse specialists and nurse practitioners) to provide a prescription for partner(s) of a patient they see with a diagnosed sexually transmitted infection per Department of Human Services guidelines.

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.

November 17, 2009 -- 5:00 p.m.

Last Day for Public Comment
Last day to submit written comments to the Rules Coordinator

Signature

KC Cotton
Printed name

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, 0006, 0007, 0010, 0016, 0020, 0024

Rules for Delegation of Dispensing Functions by Nurse Prescribers, and Antibiotic Prescribing for Expedited Partner Therapy.

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

Statutory Authority: ORS 678.380, 678.390

Other Authority:

Stats. Implemented: ORS 678.410

Need for the Rule(s): The passage of Senate Bill 605 and House Bill 3022 (Legislative Session 2009) necessitated these proposed administrative rules.

Documents Relied Upon, and where they are available:

- Division 56 of the Oregon Nurse Practice Act.
- Senate Bill 605 and House Bill 3022 (enrolled) (Legislative Session 2009).

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

There is no fiscal or economic impact.

How were small businesses involved in the development of this rule? Not applicable.

Administrative Rule Advisory Committee consulted?: No, however the Oregon State Board of Nursing participated in stakeholder meetings to develop a legislative concept with advisory committees generated by the sponsoring bodies.

If not, why?:

Authorized Signer KC Cotton Printed name Date

DRAFT

~~[Bracketed and strikethrough material is proposed to be deleted.]~~
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

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

Stat. Auth.: ORS 678.150

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

Application Requirements for Initial Prescriptive Authority in Oregon

851-056-0006

- (5) Evidence of successful completion of required clinical education in patient management. An applicant may be considered to meet this requirement through:
- (a) Completion of **graduate level nursing academic credits, or continuing education credits accredited by a national nursing accrediting body that include** a directly supervised clinical practicum of not less than 150 hours ~~[which includes]~~ **containing evidence of clinical experiences in** differential diagnosis and applied pharmacological management of patients congruent with the specialty role ~~[sought for academic or continuing education credit];~~ or
 - (b) Evidence of unencumbered prescriptive authority in another state or U.S. jurisdiction, including a U.S. federal institution or facility with a minimum of 400 hours utilizing prescriptive authority and patient management within the past two years.
- (6) Evidence of successful completion of accredited graduate level nursing courses documented by CE or academic credit. Such courses must include physical assessment, pathophysiology, and clinical management sufficient to prepare the applicant for safe prescribing with individual patients. Integrated courses taken before January 1, 1996 may be considered if content otherwise meets all requirements for equivalency.
- (7) Applicants for initial certification as a nurse practitioner shall meet all requirements for prescriptive authority. Clinical nurse specialists may obtain and renew certification with the Board without prescriptive authority.
- (8) Initial applicants seeking prescriptive authority who do not meet Oregon's pharmacology requirements shall complete a pharmacology course from a list approved by the Board, equal to a minimum of 45 contact hours.
- (9) Nurse practitioners who were certified in Oregon prior to July 1, 1997, and who did not have prescriptive authority as of that date, are not required to obtain or renew with prescriptive authority.

Stat. Auth.: ORS 678.150

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

Comment [t1]: Initial language changes submitted by Kelly Goudreau, Portland VA. Additional language added to reflect concern that hours be accredited by an appropriate national nursing body such as ANCC.

DRAFT

~~[Bracketed and strikethrough material is proposed to be deleted.]~~
Bolded and underlined material is proposed to be added.

Prescription Requirements

851-056-0010

- (8) Clinical nurse specialists and nurse practitioners with prescriptive authority are authorized to prescribe:
- (a) Over-the-counter drugs;
 - (b) Appliances and devices;
 - (c) Orphan drugs; and
 - (d) Limited access drugs;

(e) Antibiotics to partner(s) of patients diagnosed with a sexually transmitted disease without first examining the partner of the patient, consistent with Department of Human Services guidelines.

Stat. Auth.: ORS 678.150

Stats. Implemented: ORS 678.370, 678.372, 678.375, 678.380, 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:
- (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 guidelines from the Department of Human Services** or is not ~~within~~ the scope of practice or type of client population served;

Stat. Auth: ORS 678.111, 678.113, 678.150

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

Dispensing Authority

851-056-0020

- (1) An "applicant" for dispensing authority must be an unencumbered Oregon certified nurse practitioner or clinical nurse specialist with prescriptive authority in good standing with the Oregon State Board of Nursing.
- (2) Applicants shall submit an application and information as required by the Board.
- (3) Applicants must demonstrate, through a description of the clinical nurse specialist's or nurse practitioner's patient population, a lack of readily available access to pharmacy services as provided in ORS 678.390 and that the grant of dispensing authority to the applicant would correct this lack of access.
- (4) The applicant shall show evidence of completion of the following dispensing program:
- (a) Documented review of content regarding safe dispensing listed below:
 - (A) Board of Nursing handbook "Nurse Practitioner and Clinical Nurse Specialist Prescriptive Authority in Oregon";
 - (B) The Drug Enforcement Administration Pharmacist's Manual (2004);
 - (C) OAR 851 Division 56;
 - (D) ORS Chapter 689 and OAR Chapter 855;
 - (E) U.S. Consumer Product Safety Commission publication "Poison Prevention Packaging: A Text for Pharmacists and Physicians," and;
 - (F) The Institute for Safe Medication Practices (ISMP) "List of Error-Prone Abbreviations, Symbols, and Dose Designations" (2006 **Z**); and

Comment [t2]: Sent out for review to Oregon Department of Human Services, Oregon State Board of Pharmacy, Oregon Nurses Association, and posted on OSBN listserv.

Comment [t3]: See comment t2. Guidelines are in progress and are being reviewed jointly by DHS, OSBN and the OBOP.

DRAFT

~~[Bracketed and strikethrough material is proposed to be deleted.]~~
Bolded and underlined material is proposed to be added.

- (G) Information on available electronic or hard copy prescription drug references which provide information to professionals authorized to dispense prescription medications.

- (b) Successful self examination as provided by the Board on these materials.

Stat. Auth.: ORS 678.390

Stats. Implemented: ORS 678.670, 678.375, 678.385, 678.390

Drug Delivery and Dispensing 851-056-0024

- (1) Policies and procedures: A nurse practitioner or clinical nurse specialist with dispensing authority shall follow procedures established by federal and state law for:
- (a) Drug dispensing, storage, security and accountability;
 - (b) Maintenance of all drug records;
 - (c) Procedures for procurement of drugs.
- (2) Dispensing:
- (a) Drugs shall be prepackaged by a pharmacy or manufacturer registered with the Oregon State Board of Pharmacy, and provide on the label:
 - (A) The name and strength of the drug. If the drug does not have a brand name, then the generic name of the drug and the drug manufacturer must be on the label.
 - (B) The quantity of the drug;
 - (C) Cautionary statements, if any, required by law;
 - (D) The name, address, and phone number of the practitioner's practice site; and
 - (E) The manufacturer's expiration date, or an earlier date if preferable, after which the patient should not use the drug.
 - (b) The nurse practitioner or clinical nurse specialist shall personally dispense drugs which require hand labeling with the following information:**
 - (A) Name of the patient;**
 - (B) Directions for use; and**
 - (C) Physical description, including any identification code that may appear on tablets and capsules.**
 - (c) The nurse practitioner or clinical nurse specialist may delegate the dispensing function to staff assistants under limited circumstances where the staff assistant performs technical support that does not require prescriptive judgment. The staff assistant can dispense only those drugs that are pre-labeled by the dispensing pharmacy with the following information:**
 - (A) Name of the patient;**
 - (B) Name of the prescriber;**
 - (C) Directions for use; and**
 - (D) A physical description, including any identification code that may appear on tablets and capsules.**
 - (E) Staff assistants may complete and label the drug with the patient's address, date of dispensing, and initials of dispensing personnel and distribute them to the patient.**
 - (d) Drugs shall be dispensed in containers complying with the federal Poison Prevention Packaging Act unless the patient requests a non-complying container.
 - (e) The nurse practitioner or clinical nurse specialist shall provide a means for patients

Comment [t4]: Suggested language submitted by OHSU on 9-2-09. Verbal consultation with Gary Miner, Oregon Board of Pharmacy and written email consultation with Susan King and Jack Dempsey from ONA.

DRAFT

~~[Bracketed and strikethrough material is proposed to be deleted.]~~
Bolded and underlined material is proposed to be added.

to receive verbal and written information on drugs dispensed to the patient. The written drug information shall include:

- (A) Drug name and class;
 - (B) Proper use and storage;
 - (C) Common side effects;
 - (D) Precautions and contraindications; and
 - (E) Significant drug interactions.
- (3) Drug security, storage and disposal:
- (a) In the absence of the person authorized to dispense and prescribe, drugs shall be kept in a locked cabinet or drug room which is sufficiently secure to deny access to unauthorized persons.
 - (b) Controlled substances shall be maintained in a secure, locked container at all times.
 - (c) All drugs shall be stored in areas which will assure proper sanitation, temperature, light, ventilation, and moisture control.
 - (d) Drugs which are outdated, damaged, deteriorated, misbranded, or adulterated shall be physically separated from other drugs until they are destroyed or returned to their supplier.
 - (e) Controlled substances, which are expired, deteriorated, or unwanted, shall be disposed of in conformance with current State and Federal Regulations, including but not limited to, 21 CFR 1307.21 and OAR 855-080-0105.
- (4) Drug records:
- (a) A drug dispensing record shall be maintained separately from the patient record and kept for a minimum of three years. The dispensing record shall show, at a minimum, the following:
 - (A) Name of patient;
 - (B) Brand name of drug, or generic name and manufacturer or distributor;
 - (C) Date of dispensing; and
 - (D) Initials of nurse practitioner or clinical nurse specialist.
 - (b) A physical copy of the prescription for each medication dispensed shall be retained in the patient chart and shall be produced upon request.
 - (c) All records required by these rules or by federal or state law shall be readily retrievable and available for inspection by the Board and the Board of Pharmacy.
 - (d) A patient record shall be maintained for all patients to whom the nurse practitioner or clinical nurse specialist dispenses medications.
- (5) Clinical nurse specialists and nurse practitioners with dispensing authority shall be responsible for safe storage, distribution, and destruction of all drugs under their authority.
- (6) Clinical nurse specialists and nurse practitioners granted dispensing authority under this rule shall comply with the labeling and record keeping requirements of OAR 851-050-0164.
- (7) A person granted dispensing authority under this rule shall have available at the dispensing site a hard copy or electronic version of prescription drug reference works commonly used by professionals authorized to dispense prescription medications.
- (8) A person granted dispensing authority under this rule shall permit representatives of the Oregon State Board of Pharmacy, upon receipt of a complaint about that person's dispensing practices and notice to the Board of Nursing, to inspect a dispensing site.

Stat. Auth.: ORS 678.390

Stats. Implemented: ORS 673.390