2-8

Secretary of State
Certificate and Order for Filing

PERMANENT ADMINISTRATIVE RULES

I certify that the attached copies* are true, full and correct copies of the PERMANENT Rule(s) adopted on January 27, 2010 by the
Date prior to or same as filing date

Oregon Board of Pharmacy — OAR Chapter 855
Agency and Division — Administrative Rules Chapter Number

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Rules Coordinator — Address — Telephone

to become effective Upon filing — Rulemaking Notice was published in the January 2010 *Oregon Bulletin.***
Date upon filing or later — Month and Year

BP 1-2010

RULE CAPTION

Provide regulatory framework to permit prescribing and dispensing of drugs for Expedited Partner Therapy (EPT)
Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.

RULEMAKING ACTION

List each rule number separately, 000-000-0000.

ADOPT: 855-041-4000, 855-041-4005, 855-043-0003

AMEND: 855-043-0110, 855-043-0130, 855-043-0210, 855-043-0300, 855-043-0310

REPEAL:

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

AMEND & RENUMBER: 855-043-0001 to 855-043-0005, 855-043-0120 to 855-043-0002

FILED
FEB 0 8 2010
ARCHIVES DIVISION
SECRETARY OF STATE

ORS 689.205 — ORS 678.390
Stat. Auth. — Other Authority

Chapter 522 Oregon Laws 2009
Stats. Implemented

RULE SUMMARY

These amendments and new rules will permit pharmacists, nurse practitioners, Clinical Nurse Specialists and other practitioners regulated by rules in Division 41 and 43 to prescribe and dispense, within their scope of practice, specified drugs for an unnamed patient when the prescription is identified as "for EPT Therapy". The rules provide a labeling protocol when the patient's name is unknown. There are also minor rule amendments in Division 43 to incorporate changes necessitated by recent legislation.

Authorized Signer — Gary A. Schnabel — 2/2/2010
Printed name — Date

*With this original, file one photocopy of certificate, one paper copy of rules listed in Rulemaking Actions, and electronic copy of rules.
**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 5:00 pm on the preceding workday.

Expedited Partner Therapy

855-041-4000

Purpose

(1) There is substantial evidence that rates of re-infection with certain sexually transmitted diseases can be reduced by treating all sexual partners for the disease, even when the treating clinician has not examined those partners. This practice is known as Expedited Partner Therapy.

(2) Because of the important public health implications, the 2009 Oregon Legislature passed HB 3022 authorizing this practice. This law permits health professional regulatory boards to adopt rules permitting practitioners to practice Expedited Partner Therapy.

(3) The law specifies that a prescription issued in the practice of Expedited Partner Therapy is valid, even if the name of the patient the prescription is intended for is not on the prescription.

Stat. Auth.: ORS 689.205
Stats. Implemented: Chapter 522 Oregon Laws 2009

855-041-4005

(1) Expedited Partner Therapy (EPT) means the practice of prescribing or dispensing an antibiotic drug for the treatment of a sexually transmitted disease to the partner of a patient without first examining that partner.

(2) Notwithstanding any other rules in this division that mandate requirements for a valid prescription and for labeling, when a prescription is marked EPT or a similar notation by the prescribing practitioner, this rule shall govern.

(3) An EPT prescription may only be dispensed for a drug that has been determined by the Department of Human Services (DHS) to be appropriately used for EPT.

Prescription

(4) An EPT treatment protocol must conform to the following:

(a) It must include a prescription for each named or unnamed partner of the patient;

(b) It must contain a hand written or electronic signature of the prescribing practitioner;

(c) The practitioner must identify the prescription in the following manner:

(A) Write "for EPT," or a similar notation, on the face of the prescription;

(B) For a verbal order, the practitioner must identify the prescription as an "EPT Prescription," or similar identification;

(C) The practitioner must identify the prescription for each partner either by including the name of the patient, such as "John Doe – Partner 1" or by labeling the prescription as "EPT Partner"

(d) An EPT Prescription expires 30 days after the date written;

(e) An EPT Prescription may not be refilled;

(f) If any component of the prescription is missing, the pharmacist must contact the prescriber or the prescriber's agent and must record the additional information on the prescription.

(5) A patient may give the prescription to each unnamed partner for that person to fill at a pharmacy of their choice; or the patient may give all prescriptions to one pharmacy and then give the dispensed drugs to each unnamed partner.

Labeling

(6) The pharmacist must label the drug for the named patient in accordance with normal procedures as specified in the other rules of this division, however when either the patient or partner is unnamed, the pharmacy may create a unique identifier and use that instead of a name for both labeling and record keeping purposes.

(7) The pharmacist must assign a separate and unique identifier to each prescription and clearly identity this number on each corresponding prescription label.

Counseling

(8) The pharmacist is not required to obtain an EPT patient's or partner's name, address, or demographics; however, the pharmacist must:

(a) Provide counseling in the form of written patient information to accompany each prescription for each partner and ask the patient about any known allergies or other drugs being taken by each partner. The pharmacist should advise the patient to encourage each partner to call the pharmacist before taking the drug if they have experienced any adverse effect from a drug in the past or if they are taking other drugs;

(b) Document counseling.

Records

(9) All documentation required by this rule must be attached to the prescription and must be referenced to each partner's prescription. Such documentation must be retained in accordance with the other rules in this division and must be made available to the Board upon request.

Stat. Auth.: ORS 689.205
Stats. Implemented: Chapter 522 Oregon Laws 2009

BOARD OF PHARMACY

DIVISION 43

PRACTITIONER DISPENSING

855-043-0001 [Renumbered to 855-043-0005]

855-043-0002 [Renumbered from 855-043-0120]

Definitions

In this division of rules:

(1) "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 by:

(a) A practitioner or the practitioner's authorized agent; or

(b) The patient at the direction of the practitioner.

(2) "Dispense" or "Dispensing" means the preparation and delivery of a prescription drug pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug.

(3) "Formulary" means a list of drugs or a list of disease states or health conditions, or preventative measures such as immunization or birth control approved by the Board or by the Department of Human Services (DHS).

(4) "Health Officer" means a physician licensed by the Oregon Medical Board or the Oregon Board of Naturopathic Medicine and employed by or under contract with a county or district health department or DHS.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155

855-043-0003

Expedited Partner Therapy

(1) Expedited Partner Therapy (EPT) means the practice of prescribing or dispensing an antibiotic drug for the treatment of a sexually transmitted disease to the partner of a patient without first examining that partner.

(2) An EPT prescription may only be dispensed for a drug and a disease that has been determined by DHS to be appropriately addressed by EPT.

Stat. Auth.: ORS 689.205
Stats. Implemented: Chapter 522 Oregon Laws 2009

855-043-0005 [Renumbered from 855-043-0001]

Practitioner Labeling

All drugs dispensed by a practitioner must be labeled with the following information:

(1) Name, address and telephone number of the practitioner;

(2) Date;

(3) Name of the patient or the owner of the animal for which the drug is dispensed. If the prescription is for an animal, the species of the animal for which the drug is dispensed;

(4) Name of drug, strength, the quantity dispensed. When a generic name is used, the label must also contain the name of the manufacturer or distributor;

(5) Direction for use;

(6) Required precautionary information regarding controlled substances;

(7) Such other cautionary information as required for patient safety; and

(8) An expiration date after which the patient should not use the drug or medicine. The expiration date on a drugs dispensed must be the same as that on the original container unless, in the practitioner's professional judgment, a shorter expiration date is warranted. A drug must not be dispensed after the expiration date of the drug.

(9) Not withstanding the labeling requirements in this rule, when a drug is dispensed in the practice of an Expedited Partner Therapy treatment protocol, the name of the patient or the patient's partner may be omitted from the label.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, ORS 689.505, Chapter 522 Oregon Laws 2009

Non-Pharmacy Dispensing Drug Outlets

County Health Clinics

855-043-0110

Purpose and Scope

(1) A Registered Nurse who is licensed with the Oregon State Board of Nursing, and who is an employee of a local health department established under the authority of a county or district board of health may dispense a drug or device to a client of the health department for purposes of caries prevention, birth control, or prevention or treatment of a communicable disease.

(2) Such dispensing shall be pursuant to the order of a person authorized to prescribe a drug or device, and shall be subject to rules jointly adopted by the Board and DHS.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155

855-043-0130

Drug Delivery and Control

(1) The health officer is responsible for the establishment of policies and procedures that include:

(a) Procedures for drug dispensing, storage, security, and accountability;

(b) Maintenance of all drug records required by federal and state law;

(c) Procedures for procurement of drugs.

(2) Dispensing:

(a) A drug may only be dispensed by a practitioner who has been given dispensing privileges by their licensing board or by a Registered Nurse;

(b) A drug must be dispensed in a container complying with the federal Poison Prevention Packaging Act unless the patient requests a non-complying container;

(c) A Registered Nurses may only dispense a drug listed in, or for a condition listed in, the formulary;

(d) Each drug that is dispensed must be labeled with the following information:

(A) Name of patient;

(B) Name of prescriber;

(C) Name, address, and phone number of the clinic;

(D) Date of dispensing;

(E) 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 stated;

(F) Directions for use;

(G) Initials of the person dispensing;

(H) Cautionary statements, if any, as required by law;

(I) Manufacturer's expiration date, or an earlier date if preferable, after which the patient should not use the drug.

(e) A drug information fact sheet must accompany each drug dispensed from a county health clinic.

(3) Repackaged Drugs. A drug repackaged for dispensing must be in a container meeting USP standards and labeled to identify at a minimum:

(a) Brand name, or generic name and manufacturer;

(b) Strength;

(c) Lot number;

(d) Manufacturer's expiration date or an earlier date if preferable. An internal control number which references manufacturer and lot number may be used.

(4) Drug Security, Storage, and Disposal:

(a) In the absence of a dispensing practitioner or a Registered Nurse, drugs must be kept in a locked drug cabinet or drug room which is sufficiently secure to deny access to unauthorized persons. Only dispensing practitioners and Registered Nurses may have a key to the drug cabinet or drug room. In their absence, the drug cabinet or drug room must remain locked.

(b) All drugs must be stored in areas which will assure proper sanitation, temperature, light, ventilation and moisture control as recommended by the manufacturer.

(c) Drugs which are outdated, damaged, deteriorated, misbranded, or adulterated must be quarantined and physically separated from other drugs until they are destroyed or returned to their supplier.

(5) Drug Records;

(a) A dispensing record must be maintained separately from the patient chart and kept for a minimum of three years. The record must show, at a minimum, the following:

(A) Name of patient;

(B) Brand name of drug, or generic name and name of manufacturer or distributor;

(C) Date;

(D) Initials of person dispensing the prescription.

(b) All records of receipt and disposal of drugs must be kept for a minimum of three years;

(c) All records required by these rules or by federal and state law must be readily retrievable and available for inspection by the Board.

(6) Not withstanding any other requirements in this rule, when a drug is dispensed in the practice of an Expedited Partner Therapy treatment protocol, the name of the patient may be omitted from the label, the patient's name may be omitted from the records and a drug may be dispensed to the patient to be given to the patient's partner even if the partner has not been examined by a licensed health care provider acting within their scope of practice.

Stat. Auth.: ORS 689.205, ORS 689.605
Stats. Implemented: ORS 689.155, Chapter 522 Oregon Laws 2009

Nurse Practitioner and Clinical Nurse Specialist Dispensing

855-043-0210

Purpose and Scope

The Oregon State Board of Nursing may grant to a certified nurse practitioner or Clinical Nurse Specialist the privilege of writing prescriptions described in the formulary under ORS 678.385. A certified nurse practitioner or Clinical Nurse Specialist may submit an application to the Oregon State Board of Nursing to dispense prescription drugs. An application for the authority to dispense prescription drugs as authorized by ORS 678.385 shall include evidence of completion of a prescription drug dispensing training program jointly developed and adopted by rule by the Oregon State Board of Nursing (851-050-0162) and the State Board of Pharmacy. The training program shall be as follows:

(1) Documented review of content regarding safe dispensing listed below:

(a) Board of Nursing handbook "Prescriptive Authority in Oregon for Nurse Practitioners and Clinical Nurse Specialists";

(b) The Drug Enforcement Administration Pharmacist's Manual (2004);

(c) OAR 851, Division 56;

(d) ORS Chapter 689 and OAR chapter 855;

(e) US Consumer Product Safety Commission publication "Poison Prevention Packaging: A Text for Pharmacist's and Physicians;"

(f) The Institute for Safe Medication Practices (ISMP) "List of Error-Prone Abbreviations, Symbols, and Dose Designations" (Nov.2006); and

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

(2) Successful self examination as provided by the Board of Nursing on these materials.

Stat. Auth.: ORS 678.390, ORS 689.205
Stats. Implemented: ORS 689.205

Family Planning Clinics

855-043-0300

Purpose and Scope

(1) A practitioner who has been given dispensing privileges by their licensing board, or a Registered Nurse, who is an employee of a clinic that is registered with the Board and is supported by DHS for purposes of providing public health family planning services, may dispense drugs or devices to clients for the purpose of birth control, the treatment of amenorrhea, hormone deficiencies, urinary tract infections or sexually transmitted diseases.

(2) Such dispensing must be pursuant to the prescription of a person authorized to prescribe a drug or device, and is subject to rules jointly adopted by the Board and DHS.

Stat. Auth.: ORS689.205
Stats. Implemented: ORS 689.305

855-043-0310

Drug Delivery and Control

(l) Policies and Procedures. The licensed facility is responsible for the following:

(a) Maintaining written policies and procedures for drug dispensing, storage, security, and accountability;

(b) Maintenance of all drug records required by federal and state law; and

(c) Establishing procedures for procurement of drugs.

(2) Dispensing:

(a) Nonjudgmental dispensing functions may be delegated to staff assistants when the accuracy and completeness of the prescription is verified by a practitioner who has been given dispensing privileges by their licensing board, or by a Registered Nurse, prior to being delivered or transferred to the patient.

(b) A drug must be dispensed in a containers complying with the federal Poison Prevention Packaging Act unless the patient requests a non-complying container.

(c) A prescription must be labeled with the following information:

(A) Name of patient;

(B) Name of prescriber;

(C) Name, address, and phone number of the clinic;

(D) Date of dispensing;

(E) 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 stated;

(F) Directions for use;

(G) Initials of the person dispensing;

(H) Cautionary statements, if any, as required by law; and

(I) Manufacturer's expiration date, or an earlier date if preferable, after which the patient should not use the drug.

(d) The prescriber must verbally counsel the patient concerning all new medications and a drug information fact sheet must accompany all drugs dispensed from a family planning clinic.

(3) Repackaged drugs. Drugs repackaged for dispensing must be in a container meeting USP standards and labeled to identify at a minimum:

(a) Brand name, or generic name and manufacturer;

(b) Strength;

(c) Lot number; and

(d) Manufacturer's expiration date, or an earlier date if preferable. An internal control number which references manufacturer and lot number may be utilized.

(4) Drug security, storage, and disposal:

(a) In the absence of a physician, pharmacist, Registered Nurse, Clinical Nurse Specialist, or nurse practitioner, all drugs must be kept in a locked drug cabinet or drug room that is sufficiently secure to deny access to unauthorized persons. Only physicians, pharmacists, Registered Nurses, Clinical Nurse Specialists or nurse practitioners shall have a key to the drug cabinet or drug room. In their absence, the drug cabinet or drug room must remain locked.

(b) All drugs must be stored in areas which will assure proper sanitation, temperature, light, ventilation, and moisture control as recommended by the manufacturer.

(c) Drugs which are outdated, damaged, deteriorated, misbranded, or adulterated must be quarantined and physically separated from other drugs until they are destroyed or returned to their supplier.

(5) Drug records:

(a) A dispensing record must be maintained separately from the patient chart and kept for a minimum of three years. The record must show, at a minimum, the following:

(A) Name of patient;

(B) Brand name of drug, or generic name and name of manufacturer or distributor;

(C) Date of dispensing; and

(D) Initials of person dispensing the prescription;

(b) All records of receipt and disposal of drugs must be kept for a minimum of three years.

(c) All records required by these rules or by federal and state law must be readily retrievable and available for inspection by the Board.

(6) A consultant pharmacist must conduct and document an annual inspection of the clinic in accordance with the directions of the Board. The completed report form must be filed in the clinic, and be available to the Board for inspection for three years.

(7) Not withstanding any other requirements in this rule, when a drug is dispensed in the practice of an Expedited Partner Therapy treatment protocol, the name of the patient may be omitted from the label, the patient's name may be omitted from the records and a drug may be dispensed to the patient to be given to the patient's partner even if the partner has not been examined by a licensed health care provider acting within their scope of practice.

Stat. Auth.: ORS689.205
Stats. Implemented: ORS 689.305, Chapter 522 Oregon Laws 2009

From: Karen S MacLean <Karen.S.MacLean@state.or.us>
To: Julie A YAMAKA
CC: Chrisy Hennigan
Date: Monday, February 22, 2010 10:06 AM
Subject: FW: 855-041 for S of S 2.2.10

Hi Julie -

Still no voice, but I'm at the office today. They've decided to call the first part of 855-041-4005 "Procedures".

I've added this to the attached. Please let me know if you need anything more.

Thanks,
Karen

Karen S. MacLean,
Administrative Director
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From: Tony Burtt
Sent: Monday, February 22, 2010 8:49 AM
To: Karen S MacLean
Subject: RE: 855-041 for S of S 2.2.10

"Procedures" Will you tell Julie?
T

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