



PROPOSED RULE MAKING

CR-102 (June 2004)

(Implements RCW 34.05.320)

Do **NOT** use for expedited rule making

Agency: Department of Social and Health Services, Health and Recovery Services Administration

- Preproposal Statement of Inquiry was filed as WSR 09-09-059; or
- Expedited Rule Making--Proposed notice was filed as WSR _____; or
- Proposal is exempt under RCW 34.05.310(4).

- Original Notice
- Supplemental Notice to WSR
- Continuance of WSR

Title of rule and other identifying information: (Describe Subject)

The department is amending WAC 388-530-2000 Covered – Outpatient drugs, devices, and drug-related supplies; and WAC 388-530-2100 Noncovered – Outpatient drugs and pharmaceutical supplies.

Hearing location(s):

Blake Office Park East – Rose Room
4500 – 10th Ave. SE
Lacey, Washington 98503
(One block north of the intersection of Pacific Ave. SE and Alhadeff Lane. A map or directions are available at <http://www.dshs.wa.gov/msa/rpau/docket.html> or by calling 360-664-6094)

Date: **September 8, 2009** Time: **10:00 a.m.**

Submit written comments to:

Name: DSHS Rules Coordinator
Address: PO Box 45850, Olympia WA, 98504-5850
Delivery: 4500 – 10th Ave. SE, Lacey, Washington 98503
E-mail: DSHSRPAURulesCoordinator@dshs.wa.gov
Fax: (360) 664-6185

by
5 p.m. on September 8, 2009

Assistance for persons with disabilities: Contact Jennisha Johnson, DSHS Rules Consultant by August 25, 2009
TTY (360) 664-6178 or (360) 664-6094 or
by e-mail at johnsjl4@dshs.wa.gov

Date of intended adoption: Not earlier than September 9, 2009
(Note: This is **NOT** the **effective** date)

Purpose of the proposal and its anticipated effects, including any changes in existing rules:

The Department is reducing the coverage of cough and cold products to a few basic products (expectorant, decongestant, cough suppressant, and saline dose drops).

Reasons supporting proposal:

These amendments are required to meet the legislatively mandated appropriation reduction in ESHB 1244 for prescription drugs.

Statutory authority for adoption:
RCW 74.04.050, RCW 74.08.090;
SSA §1927 [42 USC 1396r-8] (d)(2)(D)

Statute being implemented:
Chapter 564, Laws of 2009 § 1109 (ESHB 1244)

Is rule necessary because of a:

<input type="checkbox"/> Federal Law?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
<input type="checkbox"/> Federal Court Decision?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
<input type="checkbox"/> State Court Decision?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No

If yes, CITATION:

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: July 28, 2009
TIME: 9:43 AM

WSR 09-16-040

DATE
July 28, 2009

NAME (type or print)
Stephanie Schiller

SIGNATURE

TITLE
DSHS Rules Coordinator

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:
None

Name of proponent: (person or organization) Department of Social and Health Services

- Private
 Public
 Governmental

Name of agency personnel responsible for:

Name	Office Location	Phone
Drafting..... Wendy Boedigheimer	PO Box 45504, Olympia WA 98504-5504	(360) 725-1342
Implementation.... Siri A. Childs, Pharm D	PO Box 45506, Olympia WA 98504-5504	(360) 725-1564
Enforcement..... Siri A. Childs, Pharm D	PO Box 45506, Olympia WA 98504-5504	(360) 725-1564

Has a small business economic impact statement been prepared under chapter 19.85 RCW?

Yes. Attach copy of small business economic impact statement.

A copy of the statement may be obtained by contacting:

Name:

Address:

phone ()

fax ()

e-mail

No. Explain why no statement was prepared.

The Department analyzed the proposed rule amendments and concludes that they will impose no new costs on small businesses. The preparation of a comprehensive SBEIS is not required.

Is a cost-benefit analysis required under RCW 34.05.328?

Yes A preliminary cost-benefit analysis may be obtained by contacting:

Name: Dr. Siri Childs, Pharmacy Administrator

Address: PO Box 45560, Olympia WA 98504-5560

phone (360) 725-1564

fax (360) 586-9727

e-mail childsa@dshs.wa.gov

No: Please explain:

AMENDATORY SECTION (Amending WSR 09-05-007, filed 2/5/09, effective 3/8/09)

WAC 388-530-2000 Covered--Outpatient drugs, devices, and drug-related supplies. (1) The department covers:

(a) Outpatient drugs, including over-the-counter drugs, as defined in WAC 388-530-1050, subject to the limitations and requirements in this chapter, when:

(i) The drug is approved by the Food and Drug Administration (FDA);

(ii) The drug is for a medically accepted indication as defined in WAC 388-530-1050;

(iii) The drug is not excluded from coverage under WAC 388-530-2100;

(iv) The manufacturer has a signed drug rebate agreement with the federal Department of Health and Human Services (DHHS). Exceptions to the drug rebate requirement are described in WAC 388-530-7500 which describes the drug rebate program; and

(v) Prescribed by a provider with prescriptive authority (see exceptions for family planning and emergency contraception for women eighteen years of age and older in WAC 388-530-2000 (1)(b), and over-the-counter (OTC) drugs to promote smoking cessation in WAC 388-530-2000 (1)(g).

(b) Family planning drugs, devices, and drug-related supplies per chapter 388-532 WAC and as follows:

(i) Over-the-counter (OTC) family planning drugs, devices, and drug-related supplies without a prescription when the department determines it necessary for client access and safety.

(ii) Family planning drugs that do not meet the federal drug rebate requirement in WAC 388-530-7500 on a case-by-case basis; and

(iii) Contraceptive patches, contraceptive rings, and oral contraceptives, only when dispensed in at least a three-month supply, unless otherwise directed by the prescriber. There is no required minimum for how many cycles of emergency contraception may be dispensed.

(c) Prescription vitamins and mineral products, only as follows:

(i) When prescribed for clinically documented deficiencies;

(ii) Prenatal vitamins, when prescribed and dispensed to pregnant women; or

(iii) Fluoride prescribed for clients under the age of twenty-one.

(d) OTC drugs, vitamins, and minerals when determined by the department to be the least costly therapeutic alternative for a medically accepted indication. Subsection (1)(d) does not apply to products prescribed for the treatment of cough or cold symptoms. See WAC 388-530-2000(1)(i) and 388-530-2100(1)(b)(v) for coverage of products prescribed for the treatment of cough and cold symptoms.

(e) Drug-related devices and drug-related supplies as an outpatient pharmacy benefit when:

(i) Prescribed by a provider with prescribing authority;
(ii) Essential for the administration of a covered drug;
(iii) Not excluded from coverage under WAC 388-530-2100; and
(iv) Determined by the department, that a product covered under chapter 388-543 WAC Durable medical equipment and supplies should be available at retail pharmacies.

(f) Preservatives, flavoring and/or coloring agents, only when used as a suspending agent in a compound.

(g) Over-the-counter (OTC) drugs, without a prescription, to promote smoking cessation only for clients who are eighteen years of age or older and participating in a department-approved smoking cessation program. Limitation extensions as described in WAC 388-501-0169 are prohibited for the age and counseling requirements in this section.

(h) Prescription drugs to promote smoking cessation only for clients who are eighteen years of age or older and participating in a department-approved smoking cessation program. Limitation extensions as described in WAC 388-501-0169 are prohibited for the age and counseling requirements in this section.

(i) For the treatment of cough and cold symptoms:

(i) Only the following generic, single ingredient formulations:

(A) Guaifenesin 100 mg/5 ml liquid or syrup;

(B) Dextromethorphan 15 mg/5 ml liquid or syrup;

(C) Pseudoephedrine 30 mg or 60 mg tablets;

(D) Saline nasal spray 0.65%; and

(ii) Generic combination product dextromethorphan-guaifenesin 10-100 mg/5 ml syrup, including sugar-free formulations.

(2) The department does not reimburse for any drug, device, or drug-related supply not meeting the coverage requirements under this section.

AMENDATORY SECTION (Amending WSR 09-05-007, filed 2/5/09, effective 3/8/09)

WAC 388-530-2100 Noncovered--Outpatient drugs and pharmaceutical supplies. (1) The department does not cover:

(a) A drug that is:

(i) Not approved by the Food and Drug Administration (FDA); or

(ii) Prescribed for a nonmedically accepted indication, including diagnosis, dose, or dosage schedule that is not evidenced-based.

(b) A drug prescribed:

(i) For weight loss or gain;

(ii) For infertility, frigidity, impotency;

(iii) For sexual or erectile dysfunction; ((or))

(iv) For cosmetic purposes or hair growth; or

(v) For treatment of cough or cold symptoms, except as listed in WAC 388-530-2000(1)(i).

(c) Drugs used to treat sexual or erectile dysfunction, in accordance with section 1927 (d) (2) (K) of the Social Security Act, unless such drugs are used to treat a condition other than sexual

or erectile dysfunction, and these uses have been approved by the Food and Drug Administration.

(d) Drugs listed in the federal register as "less-than-effective" ("DESI" drugs) or which are identical, similar, or related to such drugs.

(e) Outpatient drugs for which the manufacturer requires as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or manufacturer's designee.

(f) A product:

(i) With an obsolete national drug code (NDC) for more than two years;

(ii) With a terminated NDC;

(iii) Whose shelf life has expired; or

(iv) Which does not have an eleven-digit NDC.

(g) Over-the-counter (OTC) drugs, vitamins, and minerals, except when determined by the department to be the least costly therapeutic alternative for a medically accepted indication.

(h) Any drug regularly supplied by other public agencies as an integral part of program activity (e.g., immunization vaccines for children).

(i) Free pharmaceutical samples.

(j) Over-the-counter or prescription drugs to promote smoking cessation unless the client is eighteen years old or older and participating in a department-approved cessation program.

(2) If a noncovered drug is prescribed through the early and periodic screening, diagnosis, and treatment (EPSDT) process, an authorization request may be submitted indicating that the request is EPSDT related, and the request will be evaluated according to the process in WAC 388-501-0165. (See WAC 388-534-0100 for EPSDT rules).

(3) A client can request an exception to rule (ETR) as described in WAC 388-501-0160.