



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 (HRSA)

- Preproposal Statement of Inquiry was filed as WSR 08-10-109; 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)

WAC 388-530-1000 Outpatient drug program--General
 WAC 388-530-2000 Covered –outpatient drugs, devices, and drug-related supplies.
 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://www1.dshs.wa.gov/msa/rpau/docket.html> or by calling 360-664-6094)

Date: **January 6, 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 **5:00 p.m. on January 6, 2009**

Assistance for persons with disabilities: Contact Jennisha Johnson, DSHS Rules Consultant by December 24, 2008
 TTY (360) 664-6178 or (360) 664-6094 or
 by e-mail at johnsjl4@dshs.wa.gov

Date of intended adoption: Not earlier than January 7, 2009
 (Note: This is **NOT** the **effective** date)

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

The purpose of the proposed amendment is to update a cross reference and to clarify that the department does not cover over-the-counter drugs, vitamins, and minerals except when determined by the department to be the least costly therapeutic alternative for a medically accepted indication.

Reasons supporting proposal: The department continues to support transparent Outpatient Drug Program rules.

Statutory authority for adoption:
 RCW 74.08.090, 74.04.050, 74.09.530 and 74.09.700

Statute being implemented:
 RCW 74.08.090, 74.04.050, 74.09.530 and 74.09.700

Is rule necessary because of a:

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

If yes, CITATION:

DATE
 November 25, 2008

NAME (type or print)
 Stephanie Schiller

SIGNATUR

TITLE
 DSHS Rules Coordinator

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
 STATE OF WASHINGTON
 FILED

DATE: December 01, 2008
TIME: 2:55 PM

WSR 08-24-078

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,
Health and Recovery Services Administration

- Private
- Public
- Governmental

Name of agency personnel responsible for:

Name	Office Location	Phone
Drafting..... Jonell O. Blatt	PO Box 45504 Olympia, WA 988504-5504	(360) 725-1571
Implementation.... Dr. Siri Childs	PO Box 45506 Olympia, WA 98504-5506	(360) 725-1564
Enforcement..... Dr. Siri Childs	PO Box 45506 Olympia, WA 98504-5506	(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 has analyzed the proposed rule and concludes that no new costs will be imposed on small businesses affected by the rule change. Therefore, the preparation of a comprehensive SBEIS is not required under RCW 19.85.030.

Is a cost-benefit analysis required under RCW 34.05.328?

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

Name: Jonell O. Blatt

Address: PO Box 45504
Olympia, WA 98504-5504

phone (360) 725-1571

fax (360) 586-9727

e-mail blattjo@dshs.wa.gov

No: Please explain:

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AMENDATORY SECTION (Amending WSR 08-21-107, filed 10/16/08, effective 11/16/08)

WAC 388-530-1000 Outpatient drug program--General. (1) The purpose of the outpatient drug program is to reimburse providers for outpatient drugs, vitamins, minerals, devices, and drug-related supplies according to department rules and subject to the limitations and requirements in this chapter.

(2) The department reimburses for outpatient drugs, vitamins, minerals, devices, and pharmaceutical supplies that are:

(a) Covered. Refer to WAC 388-530-2000 for covered drugs, vitamins, minerals, devices, and drug-related supplies and to WAC 388-530-2100 for noncovered drugs and drug-related supplies;

(b) 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)(~~(a)(v)~~)(g);

(c) Within the scope of an eligible client's medical assistance program;

(d) Medically necessary as defined in WAC 388-500-0005 and determined according to the process found in WAC 388-501-0165; and

(e) Authorized, as required within this chapter;

(f) Billed according to WAC 388-502-0150 and 388-502-0160; and

(g) Billed according to the requirements of this chapter.

(3) Coverage determinations for the department are made by the department's pharmacists or medical consultants in accordance with applicable federal law. The department's determination may include consultation with the drug use review (DUR) board.

(4) The department may not reimburse for prescriptions written by healthcare practitioners whose application for a core provider agreement (CPA) has been denied, or whose CPA has been terminated.

(5) The department may not reimburse for prescriptions written by non-CPA healthcare practitioners who do not have a current core provider agreement with the department when the department determines there is a potential danger to the client's health and/or safety.

AMENDATORY SECTION (Amending WSR 08-21-107, filed 10/16/08, effective 11/16/08)

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.

(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.

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

~~((+f))~~ (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 providing sufficient funds are appropriated by the state legislature. Limitation extensions as described in WAC 388-501-0169 are prohibited for the age and counseling requirements in this section.

~~((+g))~~ (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

providing sufficient funds are appropriated by the state legislature. Limitation extensions as described in WAC 388-501-0169 are prohibited for the age and counseling requirements in this section.

(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 08-21-107, filed 10/16/08, effective 11/16/08)

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.

(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).

~~((h))~~ (i) Free pharmaceutical samples.

~~((i))~~ (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) A client can request an exception to rule (ETR) as

described in WAC 388-501-0160.