



PROPOSED RULE MAKING

CR-102 (June 2012)

(Implements RCW 34.05.320)

Do **NOT** use for expedited rule making

Agency: Health Care Authority, Washington Apple Health

- Preproposal Statement of Inquiry was filed as WSR 14-21-096; or
- Expedited Rule Making--Proposed notice was filed as WSR _____; or
- Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1).

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

Title of rule and other identifying information:

WAC 182-530-2000 Covered – Outpatient drugs, devices, and drug-related supplies
 WAC 182-530-2100 Noncovered – Outpatient drugs, devices, and drug-related supplies
 WAC 182-530-3200 The department’s authorization process

Hearing location:

Health Care Authority
 Cherry Street Plaza Building; Sue Crystal Conf Rm 106A
 626 - 8th Avenue, Olympia WA 98504

Metered public parking is available street side around building. A map is available at:
http://www.hca.wa.gov/documents/directions_to_csp.pdf
 or directions can be obtained by calling: (360) 725-1000

Date: **April 26, 2016** Time: **10:00 a.m.**

Date of intended adoption: Not sooner than April 27, 2016
(Note: This is **NOT** the **effective** date)

Submit written comments to:

Name: HCA Rules Coordinator
 Address: PO Box 45504, Olympia WA, 98504-5504
 Delivery: 626 – 8th Avenue, Olympia WA 98504
 e-mail arc@hca.wa.gov
 fax (360) 586-9727

by **5:00 pm on April 26, 2016**

Assistance for persons with disabilities: Contact Amber Lougheed by April 22, 2016
 e-mail: amber.lougheed@hca.wa.gov or (360) 725-1349
 TTY (800) 848-5429 or 711

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

The proposed revisions clarify the agency’s coverage of smoking cessation products for pregnant women; change the minimum days’ supply required when dispensing contraceptives; update the coverage of vitamins, minerals, and enzymes; and change the minimum number of days to request authorization of an emergency fill.

Reasons supporting proposal: Complies with federal and state law regarding coverage of smoking cessation products for pregnant women

Statutory authority for adoption: RCW 41.05.021, 41.05.160

Statute being implemented: RCW 41.05.021, 41.05.160

Is rule necessary because of a:

- Federal Law? Yes No
 - Federal Court Decision? Yes No
 - State Court Decision? Yes No
- If yes, CITATION:

DATE
March 18, 2016

NAME
Wendy Barcus

SIGNATURE

TITLE
HCA Rules Coordinator

CODE REVISER USE ONLY

**OFFICE OF THE CODE REVISER
 STATE OF WASHINGTON
 FILED**

DATE: March 18, 2016

TIME: 9:07 AM

WSR 16-07-089

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: N/A

Name of proponent: Health Care Authority

- Private
 Public
 Governmental

Name of agency personnel responsible for:

Name	Office Location	Phone
Drafting..... Katie Pounds	PO Box 42716, Olympia WA, 98504-2716	(360) 725-1346
Implementation....Jodie Arneson	PO Box 45506, Olympia, WA 98504-5506	(360) 725-1410
Enforcement.....Jodie Arneson	PO Box 45506, Olympia, WA 98504-5506	(360) 725-1410

Has a small business economic impact statement been prepared under chapter 19.85 RCW or has a school district fiscal impact statement been prepared under section 1, chapter 210, Laws of 2012?

Yes. Attach copy of small business economic impact statement or school district fiscal 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 agency has determined that the proposed filing does not impose a disproportionate cost impact on small businesses or nonprofits.

Is a cost-benefit analysis required under RCW 34.05.328?

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

Name:

Address:

phone ()

fax ()

e-mail

No: Please explain:

RCW 34.05.328 does not apply to Health Care Authority rules unless requested by the Joint Administrative Rules Review Committee or applied voluntarily.

WAC 182-530-2000 Covered—Outpatient drugs, devices, and drug-related supplies. (1) The ~~((department))~~ medicaid agency covers:

(a) Outpatient drugs, including over-the-counter (OTC) drugs, as defined in WAC ~~((388-530-1050))~~ 182-530-1050, 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))~~ 182-530-1050;

(iii) The drug is not excluded from coverage under WAC ~~((388-530-2100))~~ 182-530-2100;

(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))~~ 182-530-7500; and

(v) The drug is prescribed by a provider with prescriptive authority ((+see)). Exceptions to the prescription requirement exist 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)) in (b) of this subsection, and for OTC drugs that promote smoking cessation in (g) of this subsection.

(b) Family planning drugs, devices, and drug-related supplies per chapter ~~((388-532))~~ 182-532 WAC and as follows:

(i) ~~((Over the counter (-) OTC ((+)))~~ family planning drugs, devices, and drug-related supplies without a prescription when the ~~((department))~~ agency 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))~~ 182-530-7500 on a case-by-case basis; and

(iii) Contraceptive patches, contraceptive rings, and oral contraceptives, ~~((only))~~ excluding emergency contraception, 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))~~ a one-year supply only, unless:

(A) A smaller supply is directed by the prescriber;

(B) A smaller supply is requested by the client; or

(C) The pharmacy does not have adequate stock.

(c) Vitamins, minerals, and enzymes when prescribed for:

(i) A medical condition caused by a clinically documented deficiency;

(ii) A United States Preventive Services Task Force recommendation with an A or B rating;

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

(iv) A clinically documented medical condition that causes vitamin, mineral, or enzyme deficiencies, and the deficiency cannot be treated through other dietary interventions.

(d) OTC drugs, vitamins, and minerals when determined by the ((department)) agency to be the least costly therapeutic alternative for a medically accepted indication. The ((department)) agency will maintain and publish a list of the covered OTC drugs available to clients which have been determined to be the least costly therapeutic alternatives for medically accepted indications. This subsection (1)(d) of this section 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)(i) under this subsection and WAC 182-530-2100 (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)) 182-530-2100; and

(iv) Determined by the ((department,)) agency that a product covered under chapter ((388-543)) 182-543 WAC related to durable medical equipment and supplies should be available at retail pharmacies.

(f) Preservatives, flavoring ((and/or)), 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)) age eighteen ((years of age)) or older and participating in ((a department approved)) an agency-approved smoking cessation program. Limitation extensions as described in WAC ((388-501-0169)) 182-501-0169 are prohibited for the age and counseling requirements in this section.

(h) ((Prescription)) Drugs prescribed to promote smoking cessation only for clients ((who are eighteen years of age or older and)) participating in ((a department approved)) an agency-approved smoking cessation program, or for clients who are pregnant with a verifiable estimated due date and receiving smoking cessation counseling from the prescribing provider. Limitation extensions as described in WAC ((388-501-0169)) 182-501-0169 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)) agency does not reimburse for any drug, device, or drug-related supply not meeting the coverage requirements under this section.

WAC 182-530-2100 Noncovered—Outpatient drugs and pharmaceutical supplies. (1) The medicaid agency 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;
 - (iv) For cosmetic purposes or hair growth; or
 - (v) For treatment of cough or cold symptoms, except as listed in WAC 182-530-2000 (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 as allowed under WAC 182-530-2000 (1)(i).
 - (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~~) OTC or prescription drugs to promote smoking cessation unless the client is age eighteen (~~(years-old)~~) or older and participating in (~~(a-medicaid)~~) an agency-approved cessation program, or is pregnant with a verifiable estimated due date and receiving smoking cessation counseling from the prescribing provider.
- (2) A noncovered drug can be requested through the exception to rule process as described in WAC 182-501-0160.
- (3) 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 182-501-0165. (See WAC 182-534-0100 for EPSDT rules.)

WAC 182-530-3200 The ((department's)) medicaid agency's authorization process. (1) The ((department)) agency may establish automated ways for pharmacies to meet authorization requirements for specified drugs, devices, and drug-related supplies, or circumstances as listed in WAC ((388-530-3000)) 182-530-3000 (3) and (4) including, but ((are)) not limited to:

(a) Use of expedited authorization codes as published in the ((department's)) agency's prescription drug program billing instructions and numbered memoranda;

(b) Use of specified values in national council of prescription drug programs (NCPDP) claim fields;

(c) Use of diagnosis codes; and

(d) Evidence of previous therapy within the ((department's)) agency's claim history.

(2) When the automated requirements in subsection (1) of this section do not apply or cannot be satisfied, the pharmacy provider must request authorization from the ((department)) agency before dispensing. The pharmacy provider must:

(a) Ensure the request states the medical diagnosis and includes medical justification for the drug, device, drug-related supply, or circumstance as listed in WAC ((388-530-3000)) 182-530-3000 (3) and (4); and

(b) Keep documentation on file of the prescriber's medical justification that is communicated to the pharmacy by the prescriber at the time the prescription is filled. The records must be retained for the period specified in WAC ((388-502-0020)) 182-502-0020(5).

(3) When the ((department)) agency receives the request for authorization:

(a) The ((department)) agency acknowledges receipt:

(i) Within twenty-four hours if the request is received during normal state business hours; or

(ii) Within twenty-four hours of opening for business on the next business day if received outside of normal state business hours.

(b) The ((department)) agency reviews all evidence submitted and takes one of the following actions within fifteen business days:

(i) Approves the request;

(ii) Denies the request if the requested service is not medically necessary; or

(iii) Requests the prescriber submit additional justifying information.

(A) The prescriber must submit the additional information within ten days of the ((department's)) agency's request.

(B) The ((department)) agency approves or denies the request within five business days of the receipt of the additional information.

(C) If the prescriber fails to provide the additional information within ten days, the ((department)) agency will deny the requested service. The ((department)) agency sends a copy of the request to the client at the time of denial.

(4) The ((department's)) agency's authorization may be based on, but not limited to:

(a) Requirements under this chapter and WAC ((388-501-0165)) 182-501-0165;

- (b) Client safety;
- (c) Appropriateness of drug therapy;
- (d) Quantity and duration of therapy;
- (e) Client age, gender, pregnancy status, or other demographics;

and

- (f) The least costly therapeutically equivalent alternative.

(5) The ~~((department))~~ agency evaluates request for authorization of covered drugs, devices, and drug-related supplies that exceed limitations in this chapter on a case-by-case basis in conjunction with subsection (4) of this section and WAC ~~((388-501-0169))~~ 182-501-0169.

(6) If a provider needs authorization to dispense a covered drug outside of normal state business hours, the provider may dispense the drug without authorization only in an emergency. The ~~((department))~~ agency must receive justification from the provider within ~~((seventy-two hours))~~ seven days of the fill date ~~((, excluding weekends and Washington state holidays,))~~ to be ~~((paid))~~ reimbursed for the emergency fill.

(7) The ~~((department))~~ agency may remove authorization requirements under WAC ~~((388-530-3000))~~ 182-530-3000 for, but not limited to, the following:

- (a) Prescriptions written by specific practitioners based on consistent high quality of care; or

- (b) Prescriptions filled at specific pharmacies and billed to the ~~((department))~~ agency at the pharmacies' lower acquisition cost.

(8) Authorization requirements in WAC ~~((388-530-3000))~~ 182-530-3000 are not a denial of service.

(9) Rejection of a claim due to the authorization requirements listed in WAC ~~((388-530-3000))~~ 182-530-3000 is not a denial of service.

(10) When a claim requires authorization, the pharmacy provider must request authorization from the ~~((department))~~ agency. If the pharmacist fails to request authorization as required, the ~~((department))~~ agency does not consider this a denial of service.

(11) Denials that result as part of the authorization process will be issued by the ~~((department))~~ agency in writing.

(12) The ~~((department's))~~ agency's authorization:

- (a) Is a decision of medical appropriateness; and
- (b) Does not guarantee payment.