



# PROPOSED RULE MAKING

## CR-102 (December 2017) (Implements RCW 34.05.320)

Do NOT use for expedited rule making

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STATE OF WASHINGTON  
FILED

DATE: September 16, 2019

TIME: 3:49 PM

WSR 19-19-064

Agency: Health Care Authority

Original Notice

Supplemental Notice to WSR \_\_\_\_\_

Continuance of WSR \_\_\_\_\_

Preproposal Statement of Inquiry was filed as WSR 19-11-078 ; 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); or

Proposal is exempt under RCW \_\_\_\_\_.

Title of rule and other identifying information: (describe subject) WAC 182-530-2000 Covered—Outpatient drugs, devices, and drug-related supplies; WAC 182-530-2100 Noncovered—Outpatient drugs and pharmaceutical supplies

### Hearing location(s):

Date:	Time:	Location: (be specific)	Comment:
October 22, 2019	10:00 AM	Health Care Authority Cherry Street Plaza <b>Sue Crystal Rm 106A</b> 626 8 <sup>th</sup> Ave, Olympia WA 98504	Metered public parking is available street side around building. A map is available at: <a href="https://www.hca.wa.gov/assets/program/Driving-parking-checkin-instructions.pdf">https://www.hca.wa.gov/assets/program/Driving-parking-checkin-instructions.pdf</a> or directions can be obtained by calling: (360) 725-1000

Date of intended adoption: Not sooner than October 23, 2019 (Note: This is **NOT** the **effective** date)

### Submit written comments to:

Name: HCA Rules Coordinator

Address: PO Box 42716, Olympia WA 98504-2716

Email: [arc@hca.wa.gov](mailto:arc@hca.wa.gov)

Fax: (360) 586-9727

Other:

By (date) October 22, 2019

### Assistance for persons with disabilities:

Contact Amber Lougheed

Phone: (360) 725-1349

Fax: (360) 586-9727

TTY: Telecommunication Relay Services (TRS): 711

Email: [amber.lougheed@hca.wa.gov](mailto:amber.lougheed@hca.wa.gov)

Other:

By (date) October 11, 2019

Purpose of the proposal and its anticipated effects, including any changes in existing rules: The agency is removing language exceptions to prescription requirements for OTC products to promote smoking cessation. The agency is also updating language and adding products to comply with the Centers for Medicare & Medicaid Services (CMS) prescription requirements and the Apple Health Preferred Drug List (PDL).

**Reasons supporting proposal:** See purpose.

**Statutory authority for adoption:** RCW 41.05.021, 41.05.160; Sec. 1927. [42 U.S.C. 1396r-8](d)(2)(D); Sec. 1927. [42 U.S.C. 1396r-8](d)(2)(G); Sec. 1927. [42 U.S.C. 1396r-8](d)(7)(A); Sec. 1927. [42. U.S.C. 1396r-8](k)(4)

**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:

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

**Name of proponent:** (person or organization) Health Care Authority  Private  
 Public  
 Governmental

**Name of agency personnel responsible for:**

	Name	Office Location	Phone
Drafting:	Michael Williams	PO Box 42716, Olympia WA 98504-2716	(360) 725-1346
Implementation:	Charles Agte	PO Box 45502, Olympia WA 98504-2716	(360) 725-1301
Enforcement:	Charles Agte	PO Box 45502, Olympia WA 98504-2716	(360) 725-1301

**Is a school district fiscal impact statement required under RCW 28A.305.135?**  Yes  No

If yes, insert statement here:

The public may obtain a copy of the school district fiscal impact statement by contacting:

Name:  
Address:  
Phone:  
Fax:  
TTY:  
Email:  
Other:

**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:  
TTY:  
Email:  
Other:

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.

**Regulatory Fairness Act Cost Considerations for a Small Business Economic Impact Statement:**

This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see chapter 19.85 RCW). Please check the box for any applicable exemption(s):

This rule proposal, or portions of the proposal, is exempt under RCW 19.85.061 because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with, and describe the consequences to the state if the rule is not adopted.

Citation and description:

This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by RCW 34.05.313 before filing the notice of this proposed rule.

This rule proposal, or portions of the proposal, is exempt under the provisions of RCW 15.65.570(2) because it was adopted by a referendum.

This rule proposal, or portions of the proposal, is exempt under RCW 19.85.025(3). Check all that apply:

RCW 34.05.310 (4)(b)  
(Internal government operations)

RCW 34.05.310 (4)(e)  
(Dictated by statute)

RCW 34.05.310 (4)(c)  
(Incorporation by reference)

RCW 34.05.310 (4)(f)  
(Set or adjust fees)

RCW 34.05.310 (4)(d)  
(Correct or clarify language)

RCW 34.05.310 (4)(g)  
((i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit)

This rule proposal, or portions of the proposal, is exempt under RCW \_\_\_\_\_.

Explanation of exemptions, if necessary:

**COMPLETE THIS SECTION ONLY IF NO EXEMPTION APPLIES**

If the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

No Briefly summarize the agency's analysis showing how costs were calculated. This rulemaking does not impose any cost on small businesses.

Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses, and a small business economic impact statement is required. Insert statement here:

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

Name:

Address:

Phone:

Fax:

TTY:

Email:

Other:

**Date:** September 16, 2019

**Name:** Wendy Barcus

**Title:** HCA Rules Coordinator

**Signature:**



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

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

(iii) The drug is not excluded from coverage under WAC 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 182-530-7500; and

(v) The drug is prescribed by a provider with prescriptive authority. Exceptions to the prescription requirement exist for family planning and emergency contraception 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 182-532 WAC and as follows:

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

(ii) Family planning drugs that do not meet the federal drug rebate requirement in WAC 182-530-7500 on a case-by-case basis; and

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

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

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

(C) The pharmacy does not have adequate stock.

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

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

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

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

(iv) Fluoride for clients under age twenty-one; or

(v) 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 agency to be the least costly therapeutic alternative for a medically accepted indication. (~~(The agency will maintain and publish a list of the covered OTC drugs available to clients which have been)~~) All covered OTC products determined to be the least costly therapeutic alternatives for medically accepted indications will be included on the agency's published apple health preferred drug list. This subsection (~~((1)(d) of this section)~~) does not apply to products prescribed for the treatment of cough or cold symptoms. See this subsection (1) (~~((i)~~

under)) (h) of this ((subsection)) section 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 182-530-2100; and

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

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

(g) OTC and prescription drugs (~~(, without a prescription,)~~) to promote ~~((smoking))~~ tobacco/nicotine cessation ~~((only for clients age eighteen or older and participating in an agency-approved smoking cessation program. Limitation extensions as described in WAC 182-501-0169 are prohibited for the age and counseling requirements in this section.~~

~~(h) Drugs prescribed to promote smoking cessation only for clients participating in 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 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).~~

~~(h) 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.)) products for the treatment of cough and cold:~~

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

~~(ii) Dextromethorphan/Guaifenesin 10 mg - 100/5 ml liquid or syrup, including sugar-free formulations;~~

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

~~(iv) Phenylephrine 10 mg tablets;~~

~~(v) Phenylephrine 2.5 mg/ml liquid or syrup;~~

~~(vi) Pseudoephedrine 30 mg and 60 mg tablets;~~

~~(vii) Pseudoephedrine 15 mg/5 ml liquid or syrup; and~~

~~(viii) Saline 0.65% nasal spray.~~

(2) The 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) OTC or prescription drugs to promote smoking cessation unless the client is age eighteen or older and participating in 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.)