PROPOSED RULE MAKING

CR-102 (December 2017)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: November 18, 2020
TIME: 10:40 AM

WSR 20-23-121

Agency: Health Care Authority

☒ **Original Notice**

☐ **Supplemental Notice to WSR _____**

☐ **Continuance of WSR _____**

☒ **Preproposal Statement of Inquiry was filed as WSR** 20-15-034 **; 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; WAC182-530-2100 – Noncovered – Outpatient drugs and pharmaceutical supplies.

Hearing location(s):

Date:	**Time:**	**Location:** (be specific)	**Comment:**
December 22, 2020	10:00 AM	In response to the coronavirus disease 2019 (COVID-19) public health emergency, the agency will not provide a physical location for this hearing. This promotes social distancing and the safety of the citizens of Washington State. A virtual public hearing, without a physical meeting space, will be held.	To attend the virtual public hearing, you must register at the following link: https://attendee.gotowebinar.com/register/1401671028006212364 **Webinar ID:** 814-017-931 After registering, you will receive a confirmation email containing the information about joining the webinar.

Date of intended adoption: Not sooner than December 23, 2020 (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
Fax: (360) 586-9727
Other:
By (date) December 22, 2020

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
Other:
By (date) December 11, 2020

Purpose of the proposal and its anticipated effects, including any changes in existing rules: The agency is amending WAC 182-530-2000 to replace the list of covered generic products for the treatment of cough and cold. The proposed rules cover only those products with a preferred status on the Apple Health preferred drug list (AHPDL) on the date a prescription is dispensed. The agency is also amending WAC 182-530-2100 to correct references to 182-530-2000 that changed as part of this rule making. .

Reasons supporting proposal: This change allows the agency to: 1) align access across fee-for-service and managed care organization coverage for cough and cold products; and 2) easily make adjustments based on product availability and cost effectiveness.

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:

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:	Melinda Froud	PO Box 42716, Olympia WA 98504-2716	360-725-1408
Implementation:	Amy Irwin	PO Box 45502, Olympia, WA 98504-5502	360-725-1673
Enforcement:	Amy Irwin	PO Box 45502, Olympia, WA 98504-5502	360-725-1673

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)(c) (Incorporation by reference)
- ☐ RCW 34.05.310 (4)(d) (Correct or clarify language)
- ☐ RCW 34.05.310 (4)(e) (Dictated by statute)
- ☐ RCW 34.05.310 (4)(f) (Set or adjust fees)
- ☐ 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 rule does not impose any costs on 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: November 18, 2020	**Signature:** 
Name: Wendy Barcus	
Title: HCA Rules Coordinator	

AMENDATORY SECTION (Amending WSR 19-22-016, filed 10/25/19, effective 11/25/19)

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.

(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. 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 does not apply to products prescribed for the treatment of cough or cold symptoms. See this subsection (1)(h) of this 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 to promote tobacco/nicotine cessation.

(h) ((~~The following generic 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~~)), only those products included with a preferred status on the apple health preferred drug list (PDL), as described in WAC 182-530-4100, on the date a client's prescription is dispensed.

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

AMENDATORY SECTION (Amending WSR 19-22-016, filed 10/25/19, effective 11/25/19)

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)~~)) (h).

(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).

(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.

(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.)