



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: December 03, 2020

TIME: 4:17 PM

WSR 21-01-021

Agency: Health Care Authority

Original Notice

Supplemental Notice to WSR _____

Continuance of WSR _____

Preproposal Statement of Inquiry was filed as WSR 19-14-098 ; 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 182-530-7900 Drugs purchased under the Public Health Service (PHS) Act.

Hearing location(s):

Date:	Time:	Location: (be specific)	Comment:
January 26, 2021	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 instead.	The attend the virtual public hearing, you must register at the following link: https://attendee.gotowebinar.com/register/5895859935949871883 . Webinar ID: 563-710-843 After registering, you will receive a confirmation email containing the information about joining the webinar.

Date of intended adoption: Not sooner than January 27, 2021 (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) January 26, 2021

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) January 8, 2021

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

The agency previously filed this proposal under WSR 20-02-073, and held a public hearing on February 4, 2020. Stakeholder comments and then the subsequent public health emergency further delayed this rulemaking. In accordance with RCW [34.05.335\(3\)](#), the agency is refiling this proposal without change and will hold a second public hearing. Comments and testimony that were previously submitted on this proposal under WSR 20-02-073 will be included in the agency's Concise Explanatory Statement (CES).

The agency is revising this section to clarify that as part of participation in the 340B program, providers must agree, via an annual attestation form, that all claims for Washington Apple Health clients in both fee-for-service and managed care are subject to their respective 340B rules. The agency is amending subsection (4) to include under the Medicaid fee-for-service program.

Reasons supporting proposal: See Purpose.

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:	Valerie Freudenstein	PO Box 42716, Olympia WA 98504-2716	360-725-1344
Implementation:	Natalia Oxford Wilson	PO Box 45510, Olympia, WA 98504-5510	360-725-1861
Enforcement:	Natalia Oxford Wilson	PO Box 45510, Olympia, WA 98504-5510	360-725-1861

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. The proposed 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: December 3, 2020	Signature: 
Name: Wendy Barcus	
Title: HCA Rules Coordinator	

WAC 182-530-7900 Drugs purchased under the Public Health Service (PHS) Act. (1) Providers dispensing or administering 340B drugs to Washington apple health clients are required to submit their valid medicaid provider number(s) or national provider identification (NPI) number to the PHS health resources and services administration, office of pharmacy affairs. See WAC 182-530-7500 for information on the drug rebate program.

(2) Drugs purchased under section 340B of the Public Health Service (PHS) Act can be billed to Washington apple health only by PHS-qualified entities. The Washington medicaid rebate process excludes 340B claims from invoicing only when the drug is billed by a medicaid provider number or national provider identification (NPI) number listed on the PHS office of pharmacy affairs national medicaid exclusion file. See WAC 182-530-7500 for information on the drug rebate program.

(3) As part of participation in the 340B program, providers must submit a completed annual attestation form (HCA 13-0047) to the agency acknowledging that all claims for Washington apple health clients in both fee-for-service and managed care are subject to their respective 340B rules. Providers who fail to submit a completed attestation form to the agency may receive a compliance audit and be at risk of duplicate discounts.

~~((4))~~ (4) With the exception of claim types identified in subsection ~~((4))~~ (5) of this section, all 340B purchased drugs under the medicaid fee-for-service program must be billed to the medicaid agency at the 340B actual acquisition cost (340B AAC).

~~((4))~~ (5) Exceptions to the 340B AAC billing requirement are only made for:

(a) Outpatient hospital claims paid under the enhanced ambulatory payment group (EAPG) methodology (see WAC 182-550-7000); and

(b) Ambulatory surgery claims paid under payment groups methodology.