



PROPOSED RULE MAKING

CR-102 (July 2022)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

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STATE OF WASHINGTON
FILED

DATE: August 23, 2022
TIME: 12:29 PM

WSR 22-17-135

Agency: Office of the Insurance Commissioner

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

- Preproposal Statement of Inquiry was filed as WSR 22-13-066 ; 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) Prescription Drug Cost Sharing—Enrollee contribution calculation Implementation of SSB 5610 (Chapter 228, Laws of 2022)

Insurance Commissioner Matter R 2022-05

Hearing location(s):

Date:	Time:	Location: (be specific)	Comment:
09/28/2022	9:00	Via Zoom	Registration at: https://www.insurance.wa.gov/cost-sharing-prescription-drugs-r-2022-05

Date of intended adoption: 10/7/2022 (Note: This is **NOT** the **effective** date)

Submit written comments to:

Name: Barb Jones
 Address: 302 Sid Snyder Ave., SW, Suite 200
 Olympia, WA 98501
 Email: rulescoordinator@oic.wa.gov
 Fax: 360-586-3109
 Other: www.insurance.wa.gov
 By (date) 10/3/2022

Assistance for persons with disabilities:

Contact Katie Bennett
 Phone: 360-725-7013
 Fax: 360-586-2023
 TTY: 360-586-0241
 Email: Katie.Bennett@oic.wa.gov
 Other:
 By (date) 10/3/2022

Purpose of the proposal and its anticipated effects, including any changes in existing rules: Implementation of SSB 5610 (Chapter 228, Laws of 2022)—Prescription Drug Cost Sharing—Enrollee Contribution Calculation. The rulemaking will provide consistency and transparency to enrollees using third party payment assistance. The definitions of cost sharing and out-of-pocket maximum are clarified to include coupons and carriers are required to provide enrollees disclosure of their benefits and appeal rights when third party payments are used.

Reasons supporting proposal: Given the input of interested parties, rulemaking is needed to clarify any potential ambiguity in implementation, thereby providing the consumer protection the legislation intended.

Statutory authority for adoption: Section 1 subsection 3 SSB 5610 Chapter 228, Laws of 2022.

Statute being implemented: SSB 5610 (Chapter 228, Laws of 2022)

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:

Type of proponent: Private Public Governmental

Name of proponent: (person or organization) Mike Kreidler, Insurance Commissioner

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting:	Barb Jones	302 Sid Snyder Ave, SW Suite 200 Olympia WA 98501	360-725-7041
Implementation:	Molly Nollette	5000 Capitol Blvd.,SE Tumwater, WA 98501	360-725-7117
Enforcement:	Charles Malone	5000 Capitol Blvd.,SE Tumwater, WA 98501	360-725-7050

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: Simon Casson

Address: PO Box 40260, Olympia, WA 98504

Phone: 360-725-7038

Fax: 360-586-3109

TTY:

Email: Simon.Casson@OIC.wa.gov

Other:

No: Please explain:

Regulatory Fairness Act and Small Business Economic Impact Statement

Note: The [Governor's Office for Regulatory Innovation and Assistance \(ORIA\)](#) provides support in completing this part.

(1) Identification of exemptions:

This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see [chapter 19.85 RCW](#)). For additional information on exemptions, consult the [exemption guide published by ORIA](#). 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 19.85.025\(4\)](#) (does not affect small businesses).

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

Explanation of how the above exemption(s) applies to the proposed rule: Substitute Senate Bill 5610 Cost Sharing for Prescriptions Drugs was passed to address consumer complaints about the inconsistency with the use of discount prescription drug cards, assistance programs and/or coupons. The legislation provides direction for applying payments to cost-sharing amounts and the out-of-pocket maximum, except in specified conditions.

The Commissioner is pursuing rulemaking to address definitions within current regulations and undefined terms used in chapter 228, laws of 2022 for consistency with the intent of the law. Further, consumers' exceptions and appeals process will be reviewed for compliance.

RCW 19.85 states that "...an agency shall prepare a small business economic impact statement: (i) If the proposed rule will impose more than minor costs on businesses in an industry¹..." The Small Business Economic Impact Statement (SBEIS) must include "...a brief description of the reporting, recordkeeping, and other compliance requirements of the proposed rule, and the kinds of professional services that a small business is likely to need in order to comply with such requirements... To determine whether the proposed rule will have a disproportionate cost impact on small businesses²".

This rule proposal, or portions of the proposal, are exempt from requirements of the Regulatory Fairness Act under

- RCW 19.85.025(4) – the businesses that must comply with the proposed rule are not small businesses, under chapter 19.85 RCW. The OIC has found that none of the existing health insurance issuers may be considered small businesses under the definition found in RCW 19.85.020(3).

The average number of employees per firm was determined below using Bureau of Labor Statistics data:

Average number of firms: 58

Average annual employment over 12 months: 6,777

Average number of employees per firm: 118

The average number of employees for a Direct Health and Medical Insurance Carrier is 118 employees, above the small business threshold of 50 under chapter 19.85.020(3).

OIC determines that this rule is exempt from small business economic impact statement requirements.

(2) Scope of exemptions: *Check one.*

- The rule proposal is fully exempt (*skip section 3*). Exemptions identified above apply to all portions of the rule proposal.
- The rule proposal is partially exempt (*complete section 3*). The exemptions identified above apply to portions of the rule proposal, but less than the entire rule proposal. Provide details here (consider using [this template from ORIA](#)):
- The rule proposal is not exempt (*complete section 3*). No exemptions were identified above.

(3) Small business economic impact statement: *Complete this section if any portion is not exempt.*

If any portion of 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 minor cost analysis and how the agency determined the proposed rule did not impose more-than-minor costs. _____
- Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses and a small business economic impact statement is required. Insert the required small business economic impact statement here:

¹ Chapter 19.85.030: <http://app.leg.wa.gov/RCW/default.aspx?cite=19.85.030>

² RCW 19.85.040: <http://app.leg.wa.gov/RCW/default.aspx?cite=19.85.040>

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: August 23, 2022

Signature:

Name: Mike Kreidler



Title: Insurance Commissioner

WAC 284-43-5080 Prescription drug benefit design. (1) A carrier may design its prescription drug benefit to include cost control measures, including requiring preferred drug substitution in a given therapeutic class, if the restriction is for a less expensive, equally therapeutic alternative product available to treat the condition.

(2) A carrier may include elements in its prescription drug benefit design that, where clinically feasible, create incentives for the use of generic drugs. Examples of permitted incentives include, but are not limited to, refusal to pay for higher cost drugs until it can be shown that a lower cost drug or medication is not effective (also known as step therapy protocols or fail-first policies), establishing a preferred brand and nonpreferred brand formulary, or otherwise limiting the benefit to the use of a generic drug in lieu of brand name drugs, subject to a substitution process as set forth in subsection (3) of this section.

(3) A carrier may include a preauthorization requirement for its prescription drug benefit and its substitution process, based on accepted peer reviewed clinical studies, Federal Drug Administration black box warnings, the fact that the drug is available over-the-counter, objective and relevant clinical information about the enrollee's condition, specific medical necessity criteria, patient safety, or other criteria that meet an accepted, medically applicable standard of care.

(4) A carrier may require an enrollee to try an AB-rated generic equivalent or a biological product that is an interchangeable biological product prior to providing coverage for the equivalent branded prescription drug.

(5) A nongrandfathered health plan issued or renewed on or after January 1, 2023, that provides coverage for prescription drugs must comply with RCW 48.43.435.

(a) For the purposes of this subsection, any cost sharing amount paid directly by or on behalf of the enrollee by another person for a covered prescription drug, at the time it is rendered, must be applied in full toward the enrollee's applicable cost-sharing as defined in WAC 284-43-0160 and out-of-pocket maximum as defined in RCW 48.43.005 consistent with RCW 48.43.435.

(b) If an enrollee requests an exception under RCW 48.43.420 or appeals a denial of an exception request, and the request or appeal is still pending, any amount paid by or on behalf of an enrollee for a covered prescription drug must be applied towards the enrollee's contribution to any applicable deductible, copayment, coinsurance, or out-of-pocket maximum until the review is resolved and the status of the request is communicated to the carrier.

(c) The health carrier must disclose to the enrollee information about when third-party payments, including payments made through application of a manufacturer drug coupon or other manufacturer discount, are applied towards the enrollee's annual cost-sharing obligations, including applicable deductibles, copayments, coinsurances, or out-of-pocket maximums. The disclosure shall be included in the certificate of coverage (also commonly referred to as the member booklet or member handbook). Carriers are not required to use verbatim language from either the statute or regulation; however, the information provided to the enrollee about the application of third-party payments

must be sufficiently detailed to address the situations set forth in RCW 48.43.435 (1)(a)(i) through (iii).