

WSR 22-17-135
PROPOSED RULES
OFFICE OF THE
INSURANCE COMMISSIONER

[Insurance Commissioner Matter R 2022-05—Filed August 23, 2022, 12:29 p.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 22-13-066.

Title of Rule and Other Identifying Information: Prescription drug cost sharing—Enrollee contribution calculation, implementation of SSB 5610 (chapter 228, Laws of 2022).

Hearing Location(s): On September 28, 2022, at 9:00 [a.m.], via Zoom. Register at <https://www.insurance.wa.gov/cost-sharing-prescription-drugs-r-2022-05>.

Date of Intended Adoption: October 7, 2022.

Submit Written Comments to: Barb Jones, 302 Sid Snyder Avenue S.W., Suite 200, Olympia, WA 98501, email rulescoordinator@oic.wa.gov, fax 360-586-3109, www.insurance.wa.gov, by October 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, by October 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 rule making 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, rule making is needed to clarify any potential ambiguity in implementation, thereby providing the consumer protection the legislation intended.

Statutory Authority for Adoption: Section 1(3), chapter 228, Laws of 2022, SSB 5610.

Statute Being Implemented: SSB 5610 (chapter 228, Laws of 2022).

Rule is not necessitated by federal law, federal or state court decision.

Name of Proponent: Mike Kreidler, insurance commissioner, governmental.

Name of Agency Personnel Responsible for Drafting: Barb Jones, 302 Sid Snyder Avenue S.W., Suite 200, Olympia, WA 98501, 360-725-7041; Implementation: Molly Nollette, 5000 Capitol Boulevard S.E., Tumwater, WA 98501, 360-725-7117; and Enforcement: Charles Malone, 5000 Capitol Boulevard S.E., Tumwater, WA 98501, 360-725-7050.

A school district fiscal impact statement is not required under RCW 28A.305.135.

A cost-benefit analysis is required under RCW 34.05.328. A preliminary cost-benefit analysis may be obtained by contacting Simon Casson, P.O. Box 40260, Olympia, WA 98504, phone 360-725-7038, fax 360-586-3109, email Simon.Casson@OIC.wa.gov.

This rule proposal, or portions of the proposal, is exempt from requirements of the Regulatory Fairness Act because the proposal:

Is exempt under RCW 19.85.025(4).

Explanation of exemptions: SSB 5610 Cost sharing for prescription drugs was passed to address consumer complaints about the incon-

sistency 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 rule making 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.

Chapter 19.85 RCW 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."

¹ RCW 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>.

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 office of the insurance commissioner (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 RCW 19.85.020(3).

OIC determines that this rule is exempt from SBEIS requirements.

Scope of exemption for rule proposal:

Is fully exempt.

August 23, 2022

Mike Kreidler

Insurance Commissioner

OTS-3915.3

AMENDATORY SECTION (Amending WSR 20-24-105, filed 12/1/20, effective 1/1/21)

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 ther-

apeutic 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).

[Statutory Authority: RCW 48.02.060, 48.43.400, 48.43.410, and 48.43.420. WSR 20-24-105, § 284-43-5080, filed 12/1/20, effective 1/1/21. Statutory Authority: RCW 48.02.060, 48.18.140, and 48.43.510. WSR 17-03-087 (Matter No. R 2016-22), § 284-43-5080, filed 1/12/17,

effective 2/12/17. WSR 16-01-081, recodified as § 284-43-5080, filed 12/14/15, effective 12/14/15. Statutory Authority: RCW 48.02.060, 48.02.062, 48.18.140, 48.43.525, 48.44.050, 48.44.440(2), 48.44.460(2), 48.46.200, and 48.46.510. WSR 12-21-019 (Matter No. R 2012-03), § 284-43-817, filed 10/8/12, effective 11/8/12.]