**WAC 284-43-5080 Prescription drug benefit design.** (1) Except as provided in subsection (2) of this section, 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) Beginning January 1, 2025, a carrier or its health care benefit manager may not require the substitution of a nonpreferred drug with a preferred drug in a given therapeutic class, or increase an enrollee's cost-sharing obligation mid-plan year for the drug, if:

(a) The prescription is for a refill of an antipsychotic, antidepressant, antiepileptic, or other drug prescribed to the enrollee to treat a serious mental illness;

(b) The enrollee is medically stable on the drug; and

(c) A participating provider continues to prescribe the drug.

(3) Nothing in subsection (2) of this section prohibits:

(a) A carrier from requiring generic substitution during the current plan year;

(b) A carrier from adding new drugs to its formulary during the current plan year;

(c) A carrier from removing a drug from its formulary for reasons of patient safety concerns, drug recall or removal from the market, or medical evidence indicating no therapeutic effect of the drug; or

(d) A participating provider from prescribing a different drug that is covered by the plan and medically appropriate for the enrollee.

(4) Except to the extent provided otherwise in subsection (2) of this section, 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 (5) of this section.

(5) Except to the extent provided otherwise in subsection (2) of this section, 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.

(6) 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.

(7) 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.

[Statutory Authority: RCW 48.02.060, 48.43.0961, 2023 c 325, 48.43.735, 2024 c 215, 48.43.047, 2024 c 314, and 89 F.R. 37522. WSR 24-24-067 (Matter R 2024-05), s 284-43-5080, filed 11/27/24, effective 12/28/24. Statutory Authority: 2022 c 228 § 1(3). WSR 22-23-070 (Matter R 2022-05), § 284-43-5080, filed 11/10/22, effective 12/11/22. 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.]