RULE-MAKING ORDER

CR-103P (May 2009)
(Implements RCW 34.05.360)

Agency: Office of the Insurance Commissioner

Permanent Rule Only

Effective date of rule:
Permanent Rules
☒ **31 days after filing.**
☐ **Other (specify)** _____ **(If less than 31 days after filing, a specific finding under RCW 34.05.380(3) is required and should be stated below)**

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?
☐ **Yes** ☒ **No** **If Yes, explain:**

Purpose: To align state law with federal law, changes are necessary to add specificity regarding the substitution process for a consumer to request a non-formulary drug. The rule adds specific timeframes for carrier's to process a consumer's request. Consumers need predictability when a non-formulary drug is necessary for their condition.

Insurance Commissioner Matter No. R 2016-22

Citation of existing rules affected by this order:
Repealed:
Amended: WAC 284-43-5080, WAC 284-43-5110
Suspended:

Statutory authority for adoption: RCW 48.02.060, RCW 48.18.140, RCW 48.43.510

Other authority:

PERMANENT RULE (Including Expedited Rule Making)
Adopted under notice filed as WSR **16-22-092** on November 2, 2016.
Describe any changes other than editing from proposed to adopted version: None

If a preliminary cost-benefit analysis was prepared under RCW 34.05.328, a final cost-benefit analysis is available by contacting:

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Date adopted: January 12, 2017

NAME (TYPE OR PRINT)
Mike Kreidler

SIGNATURE
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TITLE
Insurance Commissioner

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: January 12, 2017
TIME: 4:16 PM

WSR 17-03-087

(COMPLETE REVERSE SIDE)

Note: If any category is left blank, it will be calculated as zero. No descriptive text.

Count by whole WAC sections only, from the WAC number through the history note. A section may be counted in more than one category.

The number of sections adopted in order to comply with:

Federal statute:	New		Amended		Repealed	
Federal rules or standards:	New		Amended	2	Repealed	
Recently enacted state statutes:	New		Amended		Repealed	

The number of sections adopted at the request of a nongovernmental entity:

	New		Amended		Repealed	

The number of sections adopted in the agency's own initiative:

	New		Amended		Repealed	

The number of sections adopted in order to clarify, streamline, or reform agency procedures:

	New		Amended		Repealed	

The number of sections adopted using:

Negotiated rule making:	New		Amended		Repealed	
Pilot rule making:	New		Amended		Repealed	
Other alternative rule making:	New		Amended	2	Repealed	

AMENDATORY SECTION (Amending WSR 16-01-081, filed 12/14/15, effective 12/14/15)

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 must establish a process that a provider and enrollee (or their designee) may use to request a substitution for a ((~~covered~~)) prescribed therapy, drug or medication that is not on the formulary.

(a) The process must not unreasonably restrict an enrollee's access to nonformulary or alternate medications for refractory conditions. Used in this context, "refractory" means "not responsive to treatment."

(b) ((~~A carrier's substitution process must not result in delay in treating an enrollee's emergency fill or urgent care needs, or expedited requests for authorization.~~)) For an individual or small group plan, a carrier must make its determination on a standard exception and notify the enrollee or the enrollee's designee and the prescribing provider (or other prescriber, as appropriate) of its coverage determination no later than seventy-two hours following receipt of the request. A carrier that grants a standard exception request must provide coverage of the nonformulary drug for the duration of the prescription, including refills.

(c) For an individual or small group plan, a carrier must have a process for an enrollee, the enrollee's designee, or the enrollee's prescribing provider (or other prescriber) to request an expedited review based on exigent circumstances. For purposes of this section, "exigent circumstances" exist when an enrollee is experiencing a health condition that may seriously jeopardize the enrollee's life, health, or ability to regain maximum function or when an enrollee is undergoing a current course of treatment using a nonformulary drug.

(i) A carrier must make its coverage determination on an expedited review request based on exigent circumstances and notify the enrollee or the enrollee's designees and the prescribing provider (or other prescriber) of its coverage determination no later than twenty-four hours following receipt of the request.

(ii) A carrier that grants an exception based on exigent circumstances must provide coverage of the nonformulary drug for the duration of the exigency.

(d) Subject to the terms and conditions of the policy that otherwise limit or exclude coverage, the carrier must permit substitution of a covered generic drug or formulary drug if:

(i) An enrollee does not tolerate the covered generic or formulary drug; or

(ii) An enrollee's provider determines that the covered generic or formulary drug is not therapeutically efficacious for an enrollee. A carrier may require the provider to submit specific clinical documentation as part of the substitution request; or

(iii) The provider determines that a dosage is required for clinically efficacious treatment that differs from a carrier's formulary dosage limitation for the covered drug. A carrier may require the provider to submit specific clinical documentation as part of the substitution request and must review that documentation prior to making a decision.

(4) 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.

(a) Neither the substitution process criteria nor the type or volume of documentation required to support a substitution request may be unreasonably burdensome to the enrollee or their provider.

(b) The substitution process must be administered consistently, and include a documented consultation with the prescribing provider prior to denial of a substitution request.

(5) Use of a carrier's substitution process is not a grievance or appeal pursuant to RCW 48.43.530 and 48.43.535. Denial of a substitution request is an adverse benefit determination, and an enrollee, their representative provider or facility, or representative may request review of that decision using the carrier's appeal or adverse benefit determination review process.

(6) In an individual or small group plan, if the carrier denies a request for a standard exception or for an expedited exception, the carrier must have a process for the enrollee, the enrollee's designee, or the enrollee's prescribing provider (or other prescriber) to request that the original exception request and subsequent denial of such request be reviewed by an independent review organization.

(a) A carrier must determine whether or not to grant an external exception request review and notify the enrollee or the enrollee's designee and the prescribing provider (or other prescriber, as appropriate) of its decision no later than seventy-two hours following its receipt of the request, if the original request was a standard exception request, and no later than twenty-four hours following its receipt of the request, if the original request was an expedited exception request.

(b) If a standard exception request is granted after an external review, the health plan must provide coverage of the nonformulary drug for the duration of the prescription. If an expedited exception request is granted after an external review, the health plan must provide coverage of the nonformulary drug for the duration of the exigency. If such an exigency ceases, any drug previously covered under such exigency may only be reauthorized through the standard exception request process.

AMENDATORY SECTION (Amending WSR 16-19-086, filed 9/20/16, effective 10/21/16)

WAC 284-43-5110 Cost-sharing for prescription drugs. (1) A carrier and health plan unreasonably restrict the treatment of patients if an ancillary charge, in addition to the plan's normal copayment or coinsurance requirements, is imposed for a drug that is covered because of one of the circumstances set forth in either WAC ((~~[284-43-5080] [284-43-817] or [284-43-5100] [284-43-818]~~)) 284-43-5080 or 284-43-5100. An ancillary charge means any payment required by a carrier that is in addition to or excess of cost-sharing explained in the policy or contract form as approved by the commissioner. Cost-sharing means amounts paid directly to a provider or pharmacy by an enrollee for services received under the health benefit plan, and includes copayment, coinsurance, or deductible amounts.

(2) When an enrollee requests a brand name drug from the formulary in lieu of a therapeutically equivalent generic drug or a drug from a higher tier within a tiered formulary, and there is not a documented clinical basis for the substitution, a carrier may require the enrollee to pay for the difference in price between the drug that the formulary would have required, and the covered drug, in addition to the copayment. This charge must reflect the actual cost difference.

(3) When a carrier approves a substitution drug, whether or not the drug is in the carrier's formulary, the enrollee's cost-sharing for the substitution drug must be adjusted to reflect any discount agreements or other pricing adjustments for the drug that are available to a carrier. Any charge to the enrollee for a substitution drug must not increase the carrier's underwriting gain for the plan beyond the gain contribution calculated for the original formulary drug that is replaced by the substitution.

(4) If a carrier uses a tiered formulary in its prescription drug benefit design, and a substitute drug that is in the formulary is required based on one of the circumstances in either WAC ((~~[284-43-5080] [284-43-817] or [284-43-5100] [284-43-818]~~)) 284-43-5080 or 284-43-5100, the enrollee's cost sharing may be based on the tier in which the carrier has placed the substitute drug.

(5) If a carrier requires cost-sharing for enrollees receiving an emergency fill as defined in WAC 284-170-470, then issuers must disclose that information to enrollees within their policy forms.

(6) For individual and small group plans, if a substitution is granted, the carrier must treat the drug as an essential health benefit, including by counting any cost-sharing towards the plan's annual limitation on cost-sharing and towards any deductible.