PROPOSED RULE MAKING

CR-102 (June 2012)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

Agency: Office of the Insurance Commissioner

☒ **Preproposal Statement of Inquiry was filed as WSR 16-12-082**
☐ **Expedited Rule Making--Proposed notice was filed as WSR _____; or**
☐ **Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1).**

☒ **Original Notice**
☐ **Supplemental Notice to WSR _____**
☐ **Continuance of WSR _____**

Title of rule and other identifying information: Prescription drug benefit disclosures

Insurance Commissioner Matter No. R 2016-16

Hearing location(s):
Office of the Insurance Commissioner
5000 Capitol Blvd
Tumwater, WA

Date: Nov. 22, 2016 Time: 3:00 p.m.

Date of intended adoption: Nov 23, 2016
(Note: This is **NOT** the **effective** date)

Submit written comments to:
Name: Jim Freeburg
Address: PO Box 40258
Olympia, WA 98504
e-mail rulescoordinator@oic.wa.gov
Fax: 360-586-3109 by (date) Nov. 22, 2016

Assistance for persons with disabilities:
Contact: Lorie Villaflores by , Nov 18, 2016

TTY (360) 586-0241 or (360) 725-7087

Purpose of the proposal and its anticipated effects, including any changes in existing rules: The rule clarifies the prescription drug benefit disclosure requirements for health carriers to make them easier to understand. The rule also clarifies that drugs covered under the medical benefit are included within the definition of the formulary.

Reasons supporting proposal:
Additional clarity is needed so that consumers are fully aware of their prescription drug benefits and the rights available to them regarding those benefits.

Statutory authority for adoption: RCW 48.02.060, RCW 48.43.510

Statute being implemented: RCW 48.43.510

Is rule necessary because of a:

Federal Law?	☐ Yes	☒ No
Federal Court Decision?	☐ Yes	☒ No
State Court Decision?	☐ Yes	☒ No

If yes, CITATION:

DATE
October 18, 2016

NAME (type or print)
Mike Kreidler

SIGNATURE

Mike Kreidler

TITLE
Insurance Commissioner

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: October 18, 2016
TIME: 4:28 PM

WSR 16-21-091

(COMPLETE REVERSE SIDE)

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:
None

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

☐ Private
☐ Public
☒ Governmental

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting.....	Jim Freeburg	PO Box 40255, Olympia WA 98504	(360) 725-7170
Implementation....	Molly Nollette	PO Box 40255, Olympia WA 98504	(360) 725-7117
Enforcement.....	AnnaLisa Gellerman	PO Box 40255, Olympia WA 98504	(360) 725-7037

Has a small business economic impact statement been prepared under chapter 19.85 RCW or has a school district fiscal impact statement been prepared under section 1, chapter 210, Laws of 2012?

☐ Yes. Attach copy of small business economic impact statement or school district fiscal impact statement.

A copy of the statement may be obtained by contacting:
Name:
Address:

phone ( ) _____
fax ( )_____
e-mail _____

☒ No. Explain why no statement was prepared.

The health insurance issuers that must comply with the rule are not small businesses, pursuant to chapter 19.85 RCW. In addition, the requirements embodied in these proposed rules do not represent any significant increase in regulatory standards from that which is currently in place.

Is a cost-benefit analysis required under RCW 34.05.328?

☐ Yes A preliminary cost-benefit analysis may be obtained by contacting:
Name: Jim Freeburg
Address: PO Box 40255, Olympia WA 98504

phone (360) 725-7170_____
fax ( )_____
e-mail jimf@oic.wa.gov

☒ No: Please explain:

This proposed rule (R2016-16) primarily eliminates former WAC section 284-43-5040 and reincorporates its provisions in WAC 284-43-5170. The new amendments to WAC 284-43-5170 represent non-substantive changes and clarifications from those originally found in WAC 284-43-5040. The one other rule change proposed in this rulemaking is an amendment to WAC 284-43-0160 (11). It adds a clarifying requirement that “a formulary must include drugs covered under an enrollee’s medical benefit”. This seemingly new requirement also is non-substantive; it essentially restates the obvious implication found in several related WAC sections—notably WAC 284-43-5642 (6) (f), WAC 284-43-5170 (2), WAC 284-43-1020 (5), and WAC 284-43-1100 (3) (and similar provisions elsewhere).

Because this proposed rule fits under the definition provided in RCW 34.05.328 (5)(b)(iv), it does not require a cost benefit analysis.

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

WAC 284-43-0160 Definitions. Except as defined in other subchapters and unless the context requires otherwise, the following definitions shall apply throughout this chapter.

(1) "Adverse determination" has the same meaning as the definition of adverse benefit determination in RCW 48.43.005, and includes:

(a) The determination includes any decision by a health carrier's designee utilization review organization that a request for a benefit under the health carrier's health benefit plan does not meet the health carrier's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness or is determined to be experimental or investigational and the requested benefit is therefore denied, reduced, or terminated or payment is not provided or made, in whole or in part for the benefit;

(b) The denial, reduction, termination, or failure to provide or make payment, in whole or in part, for a benefit based on a determination by a health carrier or its designee utilization review organization of a covered person's eligibility to participate in the health carrier's health benefit plan;

(c) Any prospective review or retrospective review determination that denies, reduces, or terminates or fails to provide or make payment in whole or in part for a benefit;

(d) A rescission of coverage determination; or

(e) A carrier's denial of an application for coverage.

(2) "Authorization" or "certification" means a determination by the carrier that an admission, extension of stay, or other health care service has been reviewed and, based on the information provided, meets the clinical requirements for medical necessity, appropriateness, level of care, or effectiveness in relation to the applicable health plan.

(3) "Clinical review criteria" means the written screens, decision rules, medical protocols, or guidelines used by the carrier as an element in the evaluation of medical necessity and appropriateness of requested admissions, procedures, and services under the auspices of the applicable health plan.

(4) "Covered health condition" means any disease, illness, injury or condition of health risk covered according to the terms of any health plan.

(5) "Covered person" or "enrollee" means an individual covered by a health plan including a subscriber, policyholder, or beneficiary of a group plan.

(6) "Emergency fill" means a limited dispensed amount of medication that allows time for the processing of a preauthorization request. Emergency fill only applies to those circumstances where a patient presents at a contracted pharmacy with an immediate therapeutic need for a prescribed medication that requires a prior authorization.

(7) "Emergency medical condition" means the emergent and acute onset of a symptom or symptoms, including severe pain, that would lead a prudent layperson acting reasonably to believe that a health condition exists that requires immediate medical attention, if failure to provide medical attention would result in serious impairment to bodily functions or serious dysfunction of a bodily organ or part, or would place the person's health in serious jeopardy.

(8) "Emergency services" has the meaning set forth in RCW 48.43.005.

(9) "Enrollee point-of-service cost-sharing" or "cost-sharing" means amounts paid to health carriers directly providing services, health care providers, or health care facilities by enrollees and may include copayments, coinsurance, or deductibles.

(10) "Facility" means an institution providing health care services, including but not limited to hospitals and other licensed inpatient centers, ambulatory surgical or treatment centers, skilled nursing centers, residential treatment centers, diagnostic, laboratory, and imaging centers, and rehabilitation and other therapeutic settings, and as defined in RCW 48.43.005.

(11) "Formulary" means a listing of drugs used within a health plan. A formulary must include drugs covered under an enrollee's medical benefit.

(12) "Grievance" has the meaning set forth in RCW 48.43.005.

(13) "Health care provider" or "provider" means:

(a) A person regulated under Title 18 RCW or chapter 70.127 RCW, to practice health or health-related services or otherwise practicing health care services in this state consistent with state law; or

(b) An employee or agent of a person described in (a) of this subsection, acting in the course and scope of his or her employment.

(14) "Health care service" or "health service" means that service offered or provided by health care facilities and health care providers relating to the prevention, cure, or treatment of illness, injury, or disease.

(15) "Health carrier" or "carrier" means a disability insurance company regulated under chapter 48.20 or 48.21 RCW, a health care service contractor as defined in RCW 48.44.010, and a health maintenance organization as defined in RCW 48.46.020, and includes "issuers" as that term is used in the Patient Protection and Affordable Care Act (P.L. 111-148, as amended (2010)).

(16) "Health plan" or "plan" means any individual or group policy, contract, or agreement offered by a health carrier to provide, arrange, reimburse, or pay for health care service except the following:

(a) Long-term care insurance governed by chapter 48.84 RCW;

(b) Medicare supplemental health insurance governed by chapter 48.66 RCW;

(c) Limited health care service offered by limited health care service contractors in accordance with RCW 48.44.035;

(d) Disability income;

(e) Coverage incidental to a property/casualty liability insurance policy such as automobile personal injury protection coverage and homeowner guest medical;

(f) Workers' compensation coverage;

(g) Accident only coverage;

(h) Specified disease and hospital confinement indemnity when marketed solely as a supplement to a health plan;

(i) Employer-sponsored self-funded health plans;

(j) Dental only and vision only coverage; and

(k) Plans deemed by the insurance commissioner to have a short-term limited purpose or duration, or to be a student-only plan that is guaranteed renewable while the covered person is enrolled as a regular full-time undergraduate or graduate student at an accredited higher education institution, after a written request for such classification by the carrier and subsequent written approval by the insurance commissioner.

(17) "Immediate therapeutic needs" means those needs where passage of time without treatment would result in imminent emergency care, hospital admission or might seriously jeopardize the life or health of the patient or others in contact with the patient.

(18) "Indian health care provider" means:

(a) The Indian Health Service, an agency operated by the U.S. Department of Health and Human Services established by the Indian Health Care Improvement Act, Section 601, 25 U.S.C. §1661;

(b) An Indian tribe, as defined in the Indian Health Care Improvement Act, Section 4(14), 25 U.S.C. §1603(14), that operates a health program under a contract or compact to carry out programs of the Indian Health Service pursuant to the Indian Self-Determination and Education Assistance Act (ISDEAA), 25 U.S.C. §450 et seq.;

(c) A tribal organization, as defined in the Indian Health Care Improvement Act, Section 4(26), 25 U.S.C. §1603(26), that operates a health program under a contract or compact to carry out programs of the Indian Health Service pursuant to the ISDEAA, 25 U.S.C. §450 et seq.;

(d) An Indian tribe, as defined in the Indian Health Care Improvement Act, Section 4(14), 25 U.S.C. §1603(14), or tribal organization, as defined in the Indian Health Care Improvement Act, Section 4(26), 25 U.S.C. §1603(26), that operates a health program with funding provided in whole or part pursuant to 25 U.S.C. §47 (commonly known as the Buy Indian Act); or

(e) An urban Indian organization that operates a health program with funds in whole or part provided by Indian Health Service under a grant or contract awarded pursuant to Title V of the Indian Health Care Improvement Act, Section 4(29), 25 U.S.C. §1603(29).

(19) "Managed care plan" means a health plan that coordinates the provision of covered health care services to a covered person through the use of a primary care provider and a network.

(20) "Medically necessary" or "medical necessity" in regard to mental health services and pharmacy services is a carrier determination as to whether a health service is a covered benefit because the service is consistent with generally recognized standards within a relevant health profession.

(21) "Mental health provider" means a health care provider or a health care facility authorized by state law to provide mental health services.

(22) "Mental health services" means in-patient or out-patient treatment, partial hospitalization or out-patient treatment to manage or ameliorate the effects of a mental disorder listed in the *Diagnostic and Statistical Manual (DSM) IV* published by the American Psychiatric Association, excluding diagnoses and treatments for substance abuse, 291.0 through 292.9 and 303.0 through 305.9.

(23) "Network" means the group of participating providers and facilities providing health care services to a particular health plan or line of business (individual, small, or large group). A health plan network for issuers offering more than one health plan may be smaller in number than the total number of participating providers and facilities for all plans offered by the carrier.

(24) "Out-patient therapeutic visit" or "out-patient visit" means a clinical treatment session with a mental health provider of a duration consistent with relevant professional standards used by the carrier to determine medical necessity for the particular service being rendered, as defined in *Physicians Current Procedural Terminology,* published by the American Medical Association.

(25) "Participating provider" and "participating facility" means a facility or provider who, under a contract with the health carrier or with the carrier's contractor or subcontractor, has agreed to provide health care services to covered persons with an expectation of receiving payment, other than coinsurance, copayments, or deductibles, from the health carrier rather than from the covered person.

(26) "Person" means an individual, a corporation, a partnership, an association, a joint venture, a joint stock company, a trust, an unincorporated organization, any similar entity, or any combination of the foregoing.

(27) "Pharmacy services" means the practice of pharmacy as defined in chapter 18.64 RCW and includes any drugs or devices as defined in chapter 18.64 RCW.

(28) "Primary care provider" means a participating provider who supervises, coordinates, or provides initial care or continuing care to a covered person, and who may be required by the health carrier to initiate a referral for specialty care and maintain supervision of health care services rendered to the covered person.

(29) "Preexisting condition" means any medical condition, illness, or injury that existed any time prior to the effective date of coverage.

(30) "Premium" means all sums charged, received, or deposited by a health carrier as consideration for a health plan or the continuance of a health plan. Any assessment or any "membership," "policy," "contract," "service," or similar fee or charge made by a health carrier in consideration for a health plan is deemed part of the premium. "Premium" shall not include amounts paid as enrollee point-of-service cost-sharing.

(31) "Service area" means the geographic area or areas where a specific product is issued, accepts members or enrollees, and covers provided services. A service area must be defined by the county or counties included unless, for good cause, the commissioner permits limitation of a service area by zip code. Good cause includes geographic barriers within a service area, or other conditions that make offering coverage throughout an entire county unreasonable.

(32) "Small group plan" means a health plan issued to a small employer as defined under RCW 48.43.005(33) comprising from one to fifty eligible employees.

(33) "Substitute drug" means a therapeutically equivalent substance as defined in chapter 69.41 RCW.

(34) "Supplementary pharmacy services" or "other pharmacy services" means pharmacy services involving the provision of drug therapy management and other services not required under state and federal law but that may be rendered in connection with dispensing, or that may be used in disease prevention or disease management.

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

WAC 284-43-5170 Prescription drug benefit disclosures. (1) A carrier must include the following information in the certificate of coverage issued for a health benefit plan, policy or agreement that includes a prescription drug benefit((÷)) in addition to those required elsewhere in Titles 48 RCW and 284 WAC. The commissioner may

disapprove any contract issued on or after January 1, 2018, if the requirements of this subsection are not met.

(a) A clear statement explaining that the health benefit plan((~~, policy or agreement may cover brand name drugs or medication under the circumstances set forth in WAC [284-43-5080] [284-43-817] or [284-43-5100] [284-43-818], including, if a formulary is part of the benefit design, brand name drugs or other medication not in the formulary~~)) uses the following in its coverage of drugs (as applicable):

(i) Exclusion of certain brand name or other medications from its formulary;

(ii) Therapeutic drug substitution;

(iii) Incentives for use of generic drugs (such as step-therapy protocols);

(iv) Prior authorization requirements;

(v) Mid-plan year formulary changes; or

(vi) Other limits of its prescription drug benefit.

(b) A clear explanation of the substitution process required under WAC 284-43-5080 that the enrollee or their provider must use to seek coverage of a prescription drug or medication that is not in the formulary or is not the carrier's preferred drug or medication for the covered medical condition.

(c) A clear statement explaining that consumers may be eligible to receive an emergency fill for prescription drugs under the circumstances described in WAC 284-170-470. The disclosure must include the process for consumers to obtain an emergency fill, and cost-sharing requirements, if any, for an emergency fill.

(d) The process for developing coverage standards and formularies, including the principal criteria by which drugs are selected for inclusion, exclusion, restriction or limitation.

(e) The process of changing formularies and coverage standards, including changes in the use of substitute drugs. If the plan has provisions for "grandfathering" certain ongoing prescriptions or other coverage exceptions, these practices must be disclosed.

(f) The disclosure must state whether drugs may move between tiers during a plan year and whether this may affect cost-sharing.

(g) Any medication management, disease management, or other pharmacy-related services reimbursed by the plan in addition to those required under state and federal law in connection with dispensing drugs, such as disease management services for migraine, diabetes, smoking cessation, asthma, or lipid management.

(h) The general categories of drugs excluded from coverage must be disclosed. Such categories may include items such as appetite suppressants, dental prescriptions, cosmetic agents or most over-the-counter medications. This subsection does not require that any particular category of coverage for drugs or pharmacy services should be excluded, reduced, or limited by a health plan.

(2) When a carrier eliminates a previously covered drug from its formulary, or establishes new limitations on coverage of the drug or medication, at a minimum a carrier must ensure that prior notice of the change will be provided as soon as is practicable, to enrollees who filled a prescription for the drug within the prior three months.

(a) Provided the enrollee agrees to receive electronic notice and such agreement has not been withdrawn, either electronic mail notice, or written notice by first class mail at the last known address of the enrollee, are acceptable methods of notice.

(b) If neither of these notice methods is available because the carrier lacks contact information for enrollees, a carrier may post

notice on its web site or at another location that may be appropriate, so long as the posting is done in a manner that is reasonably calculated to reach and be noticed by affected enrollees.

(3) A carrier and health plan may use provider and enrollee education to promote the use of therapeutically equivalent generic drugs. The materials must not mislead an enrollee about the difference between biosimilar or bioequivalent, and therapeutically equivalent, generic medications.

(4) A carrier must include the following statement in the certificate of coverage issued for a health benefit plan, policy, or agreement that includes a prescription drug benefit, and provide current contact information as prompted below:

YOUR PRESCRIPTION DRUG RIGHTS

You have the right to safe and effective pharmacy services. You also have the right to know what drugs are covered by your plan and the limits that apply. If you have a question or concern about your prescription drug benefits, please contact us (the health carrier) at (health carrier's contact phone number) or visit (health carrier's web site). If you would like to know more about your rights, or if you have concerns about your plan, you may contact the Washington state office of insurance commissioner at 1-800-562-6900 or www.insurance.wa.gov. If you have a concern about the pharmacists or pharmacies serving you, please contact the Washington state department of health at 360-236-4700, www.doh.wa.gov, or HSQACSC@doh.wa.gov.

REPEALER

The following section of the Washington Administrative Code is repealed:

WAC 284-43-5040 Coverage for pharmacy services.