PROPOSED RULE MAKING



and 284-43-5980.

Agency: Office of the Insurance Commissioner

CR-102 (June 2024) (Implements RCW 34.05.320)

Do NOT use for expedited rule making

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WSR 24-20-133

Insurance Commissioner Matter R 2024-05

,							
□ Original Notice □							
□ Supplemental Notice to WSR							
□ Continuance of WSR							
□ Preproposal State	ment of Inq	uiry was filed as WSR WS	24-12-	<u>075</u> ; or			
☐ Expedited Rule Ma	☐ Expedited Rule MakingProposed 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) Consolidated Health Care – Implementation of SSB 5300 (2023-24), SB 5821 (2023-24), ESHB 1957 (2023-24), and other related legislation and laws incorporated as consolidated health care rulemaking.							
Hearing location(s):		•					
Date:	Time:	Location: (be specific)		Comment:			
Thursday, November 7, 2024	9:00AM	Virtually via Zoom meetings please see this website for links and registration: https://www.insurance.wa.gunsolidated-health-care-r-20	the gov/co	Written comments are due to the OIC by close of business (5 PM PST) on Friday, November 8, 2024. Written comments can be emailed to RulesCoordinator@oic.wa.gov			
Date of intended ado	ption: Mond	lay, November 18, 2024.		e: This is NOT the effective date)			
Submit written comments to:			Assis	ance for persons with disabilities:			
Name Delika Steele, H	Health Policy	/ Analyst	Contact Katie Bennett				
Address PO Box 40260, Olympia, WA 98504-0260			Phone (360) 725-7013				
Email RulesCoordinat	or@oic.wa.c	<u>JOV</u>	Fax (360) 586-2023				
Fax 360-586-3109			TTY (360) 586-0241				
Other			Email Katie.Bennett@oic.wa.gov				
Beginning (date and time) 8 a.m. PST on October 2, 2024			Other				
By (date and time) Close of business 5 p.m., PST on Friday November 8, 2024			, ,	te) Thursday, November 7, 2024			
				changes in existing rules: The Insurance			
Commissioner is considering consolidated health care rulemaking due to the recent passage of insurance-related legislation and other changes in law. Multiple provisions of health care and insurance regulations in the Washington Administrative Code (WAC) may need to be updated by OIC to be consistent with the legislation passed and codified in the Revised Code of							
Washington (RCW) and recent federal law changes. These rules will facilitate implementation of the new laws by ensuring that all affected health care and insurance entities understand their legal rights and obligations under the enacted legislation.							
Reasons supporting proposal: This rulemaking may include but is not limited to clarifying prescription drug coverage for							
incasons supporting proposal. This rule making may include but is not limited to damying prescription drug coverage for							

behavioral health treatment; updating the definition of "established relationship" as applied to audio-only telemedicine services; and clarifying coverage and cost sharing requirements for preventive services. The rulemaking impacts the

following authorities: WAC 284-170-130, 284-43-0120, 284-43-0160, 284-43-5080, 284-43-5110, 284-43-5642, 284-43-5800,

Statutory authority for adoption: RCW 48.02.060; RCW 48.43.0961 (to effectuate Chapter 325, Laws of 2023); RCW 48.43.735 (to effectuate Chapter 215, Laws of 2024); and RCW 48.43.047 (to effectuate Chapter 314, Laws of 2024) Statute being implemented: Chapter 325, Laws of 2023; Chapter 215, Laws of 2024; and Chapter 314, Laws of 2024

Is rule necessary	because of a:					
Federal Law						
Federal Cou	☐ Yes ⊠ No					
State Court	Decision?		□ Yes ⋈ No			
If yes, CITATION:	Federal Rule: 89 FR 37522					
Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: None						
Name of proponent: (person or organization) Washington State Office of the Insurance Commissioner Type of proponent: □ Private. □ Public. ☒ Governmental.						
Name of agency	personnel responsible for:					
	Name	Office Location	Phone			
Drafting	Delika Steele	P.O. Box 40255, Olympia, WA 98504-0255	360-725-7260			
Implementation	Ned Gaines	P.O. Box 40255, Olympia, WA 98504-0255	360-725-7126			
Enforcement	Kim Tocco	P.O. Box 40255, Olympia, WA 98504-0255	360-725-7118			
	-	uired under <u>RCW 28A.305.135</u> ?	☐ Yes ☒ No			
If yes, insert stater	nent nere.					
The public may	obtain a copy of the school dist	rict fiscal impact statement by contacting:				
Name						
Address						
Phone						
Fax TTY						
Email						
Other						
	analysis required under RCW	34.05.328?				
	liminary cost-benefit analysis ma					
-	Simon Casson	ay so obtained by contacting.				
	PO Box 40260 Olympia, WA 9	98504				
	360-725-7038					
Fax 360)-586-3109					
TTY						
Email <u>si</u>	mon.casson@oic.wa.gov					
Other						
☐ No: Pleas	se 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						
This rule proposal, or portions of the proposal, may be exempt from requirements of the Regulatory Fairness Act (see						
<u>chapter 19.85 RCW</u>). For additional information on exemptions, consult the <u>exemption guide published by ORIA</u> . 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.						

	proposal, or portions of the proposal, is exempt u	nder <u>R</u>	CW 19.85.025(3). Check all that apply:			
	RCW 34.05.310 (4)(b)	\boxtimes	RCW 34.05.310 (4)(e)			
	(Internal government operations)		(Dictated by statute)			
\boxtimes	RCW 34.05.310 (4)(c)		RCW 34.05.310 (4)(f)			
	(Incorporation by reference)		(Set or adjust fees)			
\boxtimes	RCW 34.05.310 (4)(d)		RCW 34.05.310 (4)(g)			
	(Correct or clarify language)		((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 u	nder <u>R</u> 0	CW 19.85.025(4). (Does not affect small businesses).			
<u>(e)</u> .		_				
Explanation of how the above exemption(s) applies to the proposed rule: The proposed rule language either adopts or incorporates by reference without material change from the state statutes, is explicitly dictated by statute, or adds clarifying language without changing the underlying effect of the regulation.						
	70-130 Definitions					
	ed rule amendments align existing rules with the la 34.05.328(5)(b)(v), because proposed changes a		stablished by Chapter 215, Laws of 2024 and is exempt ted by statute without option.			
WAC 284-43	3-0120 Applicability and scope					
		out cha	inging the underlying effect of the regulation and is			
exempt und	er RCW 34.05.328(5)(b)(iv).					
WAC 284-4	3-0160 Definitions					
The propose	ed rule amendments align existing rules with the la		stablished by Chapter 325, Laws of 2023 and is exempt			
under RCW	34.05.328(5)(b)(v), because proposed changes a	re dicta	ted by statute without option.			
WAC 284-4	3-5080 Prescription drug benefit design					
		w as es	stablished by Chapter 325, Laws of 2023 and is exempt			
	under RCW 34.05.328(5)(b)(v), because proposed changes are dictated by statute without option.					
WAC 204 4	2 F440 Coot aboving for proportion drives					
	3-5110 Cost-sharing for prescription drugs	w as es	stablished by Chapter 325, Laws of 2023 and is exempt			
	34.05.328(5)(b)(v), because proposed changes at					
			,			
	3-5642 Essential health benefit categories		stabilished by Obantas 244. Laws of 2004 and is assessed			
			stablished by Chapter 314, Laws of 2024 and is exempt			
under RCW 34.05.328(5)(b)(iii), as it incorporates existing federal rule and state statute by reference.						
WAC 284-43-5800 Plan cost-sharing and benefit substitution and limitations						
The proposed rule amendments align existing rules with the law as established by Chapter 325, Laws of 2023 and is exempt						
under RCW 34.05.328(5)(b)(iii), as it incorporates existing statute by reference and RCW 34.05.328(5)(b)(v) because proposed changes are dictated by statute without option.						
proposed cr	langes are dictated by statute without option.					
WAC 284-4	3-5980 Notice requirement					
The proposed rule amendments align existing rules with ACA section 1557 final rule and is exempt under RCW						
34.05.328(5)(b)(iii), as it incorporates existing federal rule by reference.						
(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 rully exempt. (<i>Skip section 3.)</i> Exemptions identified above apply to all portions of the rule proposal: The rule proposal: Is partially exempt. (<i>Complete section 3.</i>) 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):						
	proposal: Is not exempt. (Complete section 3.) No					
(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:						

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations 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

	Signature:
Date: October 1, 2024	1 1 2 3 11
Name: Mike Kreidler	Mile Kreidle
Title: Insurance Commissioner	Vilous &

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

- WAC 284-43-0120 Applicability and scope. (1) This chapter shall apply to all health plans and all health carriers subject to the jurisdiction of the state of Washington except as otherwise expressly provided in this chapter. Health carriers are responsible for compliance with the provisions of this chapter ((and)). A carrier's obligation to comply with the provisions of this chapter is nondelegable. Carriers are responsible for the compliance of any person, health care benefit manager, or other organization acting on behalf of or at the direction of the carrier, or acting pursuant to carrier standards or requirements concerning the coverage of, payment for, or provision of health care services.
- (2) A carrier may not offer as a defense to a violation of any provision of this chapter that the violation arose from the act or omission of a participating provider or facility, network administrator, claims administrator, health care benefit manager, or other person acting on behalf of or at the direction of the carrier, or acting pursuant to carrier standards or requirements under a contract with the carrier rather than from the direct act or omission of the carrier. Nothing in this chapter shall be construed to permit the direct regulation of health care providers or facilities by the office of the insurance commissioner.

AMENDATORY SECTION (Amending WSR 23-24-034, filed 11/30/23, effective 1/1/24)

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

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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) "Behavioral health agency" means an agency licensed or certified under RCW 71.24.037.
- (4) "Clinical review criteria" means the written screens or screening procedures, decision rules, medical protocols, or clinical practice guidelines used by the carrier as an element in the evaluation of medical necessity and appropriateness of requested admissions, procedures, and services, including prescription drug benefits, under the auspices of the applicable plan. Clinical approval criteria has the same meaning as clinical review criteria.
- (5) "Covered health condition" means any disease, illness, injury or condition of health risk covered according to the terms of any health plan.
- (6) "Covered person" or "enrollee" means an individual covered by a health plan including a subscriber, policyholder, or beneficiary of a group plan.
- (7) "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.
- (8) "Emergency medical condition" has the meaning set forth in RCW 48.43.005.
- (9) "Emergency services" has the meaning set forth in RCW 48.43.005.
- (10) "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.
- (11) "Expedited prior authorization request" has the meaning set forth in RCW 48.43.830.
- (12) "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.
- (13) "Formulary" means a listing of drugs used within a health plan. A formulary must include drugs covered under an enrollee's medical benefit.
 - (14) "Grievance" has the meaning set forth in RCW 48.43.005.
 - (15) "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.
- (16) "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.
- (17) "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 mainte-

nance 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)).

- (18) "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.
- (19) "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.
 - (20) "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).

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- (21) "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.
- (22) "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.
- (23) "Mental health provider" means a health care provider or a health care facility authorized by state law to provide mental health services.
- (24) "Mental health services" means in-patient or out-patient treatment including, but not limited to, partial hospitalization, residential treatment, out-patient facility-based treatment, intensive outpatient treatment, emergency services, or prescription drugs to manage, stabilize or ameliorate the effects of a mental disorder listed in the most current version of the *Diagnostic and Statistical Manual of Mental Disorders (DSM)* published by the American Psychiatric Association, including diagnoses and treatment for substance use disorder.
- (25) "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.
- (26) "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.
- (27) "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.
- (28) "Pharmacy services" means the practice of pharmacy as defined in chapter $18.64\ \text{RCW}$ and includes any drugs or devices as defined in chapter $18.64\ \text{RCW}$.
- (29) "Predetermination request" means a voluntary request from an enrollee or provider or facility for a carrier or its designated or contracted representative to determine if a service is a benefit, in relation to the applicable plan.
- (30) "Preservice requirement" means any requirement that a carrier places on a provider or facility that may limit their ability to deliver a service that requires prior authorization. Examples include limits on the type of provider or facility delivering the service, a service that must be provided before a specific service will be authorized, site of care/place of service, and whether a provider administered medication needs to be obtained from a specialty pharmacy.
- (31) "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.

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- (32) "Preexisting condition" means any medical condition, illness, or injury that existed any time prior to the effective date of coverage.
- (33) "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.
- (34) "Prior authorization" means a mandatory process that a carrier or its designated or contracted representative requires a provider or facility to follow to determine if a service is a benefit and meets the requirements for medical necessity, clinical appropriateness, level of care, or effectiveness in relation to the applicable plan. Prior authorization occurs before the service is delivered. For purposes of WAC 284-43-2050 and 284-43-2060, any term used by a carrier or its designated or contracted representative to describe this process is prior authorization. For example, prior authorization has also been referred to as "prospective review," "preauthorization," or "precertification."
- (35) "Refill" means a second or subsequent filling of a previously issued prescription.
- (36) "Serious mental illness" means a mental disorder, as defined in the most recent edition of the *Diagnostic and Statistical Manual of Mental Disorders* published by the American Psychiatric Association, that results in serious functional impairment that substantially interferes with or limits one or more major life activities.
- (37) "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.
- $((\frac{36}{36}))$ "Small group plan" means a health plan issued to a small employer as defined under RCW 48.43.005 $((\frac{33}{36}))$ comprising from one to 50 eligible employees.
- $((\frac{37}{10}))$ <u>(39)</u> "Standard prior authorization request" has the meaning set forth in RCW 48.43.830.
- $((\frac{(38)}{)}))$ <u>(40)</u> "Step therapy protocol" means a drug utilization management prior authorization protocol or program that establishes the specific sequence in which prescription drugs are covered by a health carrier for a medical condition.
- $((\frac{39}{0}))$ <u>(41)</u> "Substance use disorder" means a substance-related or addictive disorder listed in the most current version of the *Diagnostic and Statistical Manual of Mental Disorders (DSM)* published by the American Psychiatric Association.
- ((40))) (42) "Substitute drug" means a prescription medication, drug or therapy that a carrier covers based on an exception request. When the exception request is based on therapeutic equivalence, a substitute drug means a therapeutically equivalent substance as defined in chapter 69.41 RCW.
- ((41))) (43) "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

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federal law but that may be rendered in connection with dispensing, or that may be used in disease prevention or disease management.

 $((\frac{42}{12}))$ (44) "Withdrawal management services" means 24 hour medically managed or medically monitored detoxification and assessment and treatment referral for adults or adolescents withdrawing from alcohol or drugs, which may include induction of medications for addiction recovery.

AMENDATORY SECTION (Amending WSR 22-23-070, filed 11/10/22, effective 12/11/22)

- 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) <u>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:</u>
- (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 ((3)) of this section.
- (((3))) (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

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the enrollee's condition, specific medical necessity criteria, patient safety, or other criteria that meet an accepted, medically applicable standard of care.

- $((\frac{4}{}))$) $\underline{(6)}$ 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.
- $((\frac{5}{}))$ <u>(7)</u> 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 (($\frac{1}{1}$) through ($\frac{1}{1}$)).

<u>AMENDATORY SECTION</u> (Amending WSR 17-03-087, filed 1/12/17, effective 2/12/17)

- 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 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) Except to the extent provided otherwise WAC 284-43-5080, 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 ba-

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sis 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) Except to the extent provided otherwise in WAC 284-43-5080, 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 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.

AMENDATORY SECTION (Amending WSR 20-24-040, filed 11/23/20, effective 12/24/20)

- WAC 284-43-5642 Essential health benefit categories. (1) A health benefit plan must cover "ambulatory patient services" in a manner substantially equal to the base-benchmark plan. For purposes of determining a plan's actuarial value, an issuer must classify as "ambulatory patient services" those medically necessary services delivered to enrollees in settings other than a hospital or skilled nursing facility, which are generally recognized and accepted for diagnostic or therapeutic purposes to treat illness or injury.
- (a) A health benefit plan must include the following services, which are specifically covered by the base-benchmark plan, and classify them as ambulatory patient services:
 - (i) Home and outpatient dialysis services;
- (ii) Hospice and home health care, including skilled nursing care as an alternative to hospitalization consistent with WAC 284-44-500, 284-46-500, and 284-96-500;
- (iii) Provider office visits and treatments, and associated supplies and services, including therapeutic injections and related supplies;
- (iv) Urgent care center visits, including provider services, facility costs and supplies;
- (v) Ambulatory surgical center professional services, including anesthesiology, professional surgical services, surgical supplies and facility costs;

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- (vi) Diagnostic procedures including colonoscopies, cardiovascular testing, pulmonary function studies and neurology/neuromuscular procedures; and
- (vii) Provider contraceptive services and supplies including, but not limited to, vasectomy, tubal ligation and insertion or extraction of FDA-approved contraceptive devices.
- (b) A health benefit plan may, but is not required to, include the following services as part of the EHB-benchmark package. The base-benchmark plan specifically excludes these services. If an issuer includes these benefits in a health plan, the issuer should not include the following benefits in establishing actuarial value for the ambulatory category:
- (i) Infertility treatment and reversal of voluntary sterilization;
 - (ii) Routine foot care for those that are not diabetic;
- (iii) Coverage of dental services following injury to sound natural teeth. However, health plans must cover oral surgery related to trauma and injury. Therefore, a plan may not exclude services or appliances necessary for or resulting from medical treatment if the service is either emergency in nature or requires extraction of teeth to prepare the jaw for radiation treatments of neoplastic disease;
- (iv) Private duty nursing for hospice care and home health care, to the extent consistent with state and federal law;
- (v) Adult dental care and orthodontia delivered by a dentist or in a dentist's office;
 - (vi) Nonskilled care and help with activities of daily living;
- (vii) Hearing care, routine hearing examinations, programs or treatment for hearing loss including, but not limited to, externally worn or surgically implanted hearing aids, and the surgery and services necessary to implant them. However, plans must cover cochlear implants and hearing screening tests that are required under the preventive services category, unless coverage for these services and devices are required as part of and classified to another essential health benefits category; and
 - (viii) Obesity or weight reduction or control other than:
 - (A) Covered nutritional counseling; and
- (B) Obesity-related services for which the U.S. Preventive Services Task Force for prevention and chronic care has issued A and B recommendations on or before the applicable plan year, which issuers must cover under subsection (9) of this section.
- (c) The base-benchmark plan's visit limitations on services in the ambulatory patient services category include:
- (i) Ten spinal manipulation services per calendar year without referral;
- (ii) Twelve acupuncture services per calendar year without referral;
- (iii) Fourteen days respite care on either an inpatient or outpatient basis for hospice patients, per lifetime; and
- (iv) One hundred thirty visits per calendar year for home health care.
- (d) State benefit requirements classified to the ambulatory patient services category are:
 - (i) Chiropractic care (RCW 48.44.310);
- (ii) TMJ disorder treatment (RCW 48.21.320, 48.44.460, and 48.46.530); and
- (iii) Diabetes-related care and supplies (RCW 48.20.391, 48.21.143, 48.44.315, and 48.46.272).

- (2) A health benefit plan must cover "emergency medical services" in a manner substantially equal to the base-benchmark plan. For purposes of determining a plan's actuarial value, an issuer must classify as emergency medical services the care and services related to an emergency medical condition.
- (a) A health benefit plan must include the following services which are specifically covered by the base-benchmark plan and classify them as emergency services:
- (i) Ambulance transportation to an emergency room and treatment provided as part of the ambulance service;
- (ii) Emergency room and department based services, supplies and treatment, including professional charges, facility costs, and outpatient charges for patient observation and medical screening exams required to stabilize a patient experiencing an emergency medical condition;
- (iii) Prescription medications associated with an emergency medical condition, including those purchased in a foreign country.
- (b) The base-benchmark plan does not specifically exclude services classified to the emergency medical services category.
- (c) The base-benchmark plan does not establish visit limitations on services in the emergency medical services category.
- (d) State benefit requirements classified to the emergency medical services category include services necessary to screen and stabilize a covered person (RCW 48.43.093).
- (3) A health benefit plan must cover "hospitalization" in a manner substantially equal to the base-benchmark plan. For purposes of determining a plan's actuarial value, an issuer must classify as hospitalization services the medically necessary services delivered in a hospital or skilled nursing setting including, but not limited to, professional services, facility fees, supplies, laboratory, therapy or other types of services delivered on an inpatient basis.
- (a) A health benefit plan must include the following services which are specifically covered by the base-benchmark plan and classify them as hospitalization services:
- (i) Hospital visits, facility costs, provider and staff services and treatments delivered during an inpatient hospital stay, including inpatient pharmacy services;
- (ii) Skilled nursing facility costs, including professional services and pharmacy services and prescriptions filled in the skilled nursing facility pharmacy;
- (iii) Transplant services, supplies and treatment for donors and recipients, including the transplant or donor facility fees performed in either a hospital setting or outpatient setting;
 - (iv) Dialysis services delivered in a hospital;
- (v) Artificial organ transplants based on an issuer's medical guidelines and manufacturer recommendations;
- (vi) Respite care services delivered on an inpatient basis in a hospital or skilled nursing facility;
- (vii) Inpatient hospitalization where mental illness is the primary diagnosis.
- (b) A health benefit plan may, but is not required to, include the following services as part of the EHB-benchmark package. The base-benchmark plan specifically excludes these services. If an issuer includes these benefits in a health plan, the issuer should not include the following benefits in establishing actuarial value for the hospitalization category:

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- (i) Cosmetic or reconstructive services and supplies except in the treatment of a congenital anomaly, to restore a physical bodily function lost as a result of injury or illness, or related to breast reconstruction following a medically necessary mastectomy;
 - (ii) The following types of surgery:
 - (A) Bariatric surgery and supplies;
- (B) Orthognathic surgery and supplies unless due to temporomandibular joint disorder or injury, sleep apnea or congenital anomaly.
 - (iii) Reversal of sterilizations; and
- (iv) Surgical procedures to correct refractive errors, astigmatism or reversals or revisions of surgical procedures which alter the refractive character of the eye.
- (c) The base-benchmark plan establishes specific limitations on services classified to the hospitalization category that conflict with state or federal law as of January 1, 2017. Health plans may not include the base-benchmark plan limitations listed below and must cover all services consistent with federal rules and guidance implementing 42 U.S.C. 18116, Sec. 1557, including those codified at 81 Fed. Reg. 31375 et seq. (2016), that were in effect on January 1, 2017, RCW 48.30.300, 48.43.0128, 48.43.072, 48.43.073, 49.60.040 and 49.60.178:
- (i) The base-benchmark plan allows a waiting period for transplant services;
- (ii) The base-benchmark plan excludes coverage for sexual reassignment treatment, surgery, or counseling services; and
- (iii) The base-benchmark plan excludes coverage for hospitalization where mental illness or a substance use disorder is the primary diagnosis.
- (d) The base-benchmark plan's visit limitations on services in the hospitalization category include:
- (i) Sixty inpatient days per calendar year for illness, injury or physical disability in a skilled nursing facility;
- (ii) Thirty inpatient rehabilitation service days per calendar year. For purposes of determining actuarial value, this benefit may be classified to the hospitalization category or to the rehabilitation services category, but not to both.
- (e) State benefit requirements classified to the hospitalization category are:
- (i) General anesthesia and facility charges for dental procedures for those who would be at risk if the service were performed elsewhere and without anesthesia (RCW 48.43.185);
- (ii) Reconstructive breast surgery resulting from a mastectomy that resulted from disease, illness or injury (RCW 48.20.395, 48.21.230, 48.44.330, and 48.46.280);
- (iii) Coverage for treatment of temporomandibular joint disorder (RCW 48.21.320, 48.44.460, and 48.46.530); and
- (iv) Coverage at a long-term care facility following hospitalization (RCW 48.43.125).
- (4) A health benefit plan must cover "maternity and newborn services" in a manner substantially equal to the base-benchmark plan. For purposes of determining a plan's actuarial value, an issuer must classify as maternity and newborn services the medically necessary care and services delivered to women during pregnancy and in relation to delivery and recovery from delivery and to newborn children.
- (a) A health benefit plan must cover the following services which are specifically covered by the base-benchmark plan and classify them as maternity and newborn services:
 - (i) In utero treatment for the fetus;

- (ii) Vaginal or cesarean childbirth delivery in a hospital or birthing center, including facility fees;
- (iii) Nursery services and supplies for newborns, including newly adopted children;
 - (iv) Infertility diagnosis;
- (v) Prenatal and postnatal care and services, including screening;
- (vi) Complications of pregnancy such as, but not limited to, fetal distress, gestational diabetes, and toxemia; and
- (vii) Termination of pregnancy coverage that is substantially equivalent to coverage for maternal care or services, as provided in RCW 48.43.073.
- (b) A health benefit plan may, but is not required to, include genetic testing of the child's father as part of the EHB-benchmark package. The base-benchmark plan specifically excludes this service. If an issuer covers this benefit, the issuer may not include this benefit in establishing actuarial value for the maternity and newborn category.
- (c) The base-benchmark plan's limitations on services in the maternity and newborn services category include coverage of home birth by a midwife or nurse midwife only for low risk pregnancy.
- (d) State benefit requirements classified to the maternity and newborn services category include:
- (i) Maternity services that include diagnosis of pregnancy, prenatal care, delivery, care for complications of pregnancy, physician services, and hospital services (RCW 48.43.041);
- (ii) Newborn coverage that is not less than the postnatal coverage for the mother, for no less than three weeks (RCW 48.43.115); and
- (iii) Prenatal diagnosis of congenital disorders by screening/diagnostic procedures if medically necessary (RCW 48.20.430, 48.21.244, 48.44.344, and 48.46.375).
- (5) A health benefit plan must cover "mental health and substance use disorder services, including behavioral health treatment" in a manner substantially equal to the base-benchmark plan. For purposes of determining a plan's actuarial value, an issuer must classify as mental health and substance use disorder services, including behavioral health treatment, the medically necessary care, treatment and services for mental health conditions and substance use disorders categorized in the most recent version of the *Diagnostic and Statistical Manual of Mental Disorders (DSM)* published by the American Psychiatric Association, including behavioral health treatment for those conditions.
- (a) A health benefit plan must include the following services, which are specifically covered by the base-benchmark plan, and classify them as mental health and substance use disorder services, including behavioral health treatment:
- (i) Inpatient, residential, and outpatient mental health and substance use disorder treatment, including diagnosis, partial hospital programs or inpatient services;
 - (ii) Chemical dependency detoxification;
 - (iii) Behavioral treatment for a DSM category diagnosis;
- (iv) Services provided by a licensed behavioral health provider for a covered diagnosis in a skilled nursing facility;
- (v) Prescription medication including medications prescribed during an inpatient and residential course of treatment;
- (vi) Acupuncture treatment visits without application of the visit limitation requirements, when provided for chemical dependency.

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- (b) A health benefit plan may, but is not required to, include court-ordered mental health treatment that is not medically necessary as part of the EHB-benchmark package. The base-benchmark plan specifically excludes this service. If an issuer includes this benefit in a health plan, the issuer may not include this benefit in establishing actuarial value for the category of mental health and substance use disorder services including behavioral health treatment.
- (c) The base-benchmark plan establishes specific limitations on services classified to the mental health and substance abuse disorder services category that conflict with state or federal law as of January 1, 2017. The state EHB-benchmark plan requirements for these services are: The base-benchmark plan does not provide coverage for mental health services and substance use disorder treatment delivered in a home health setting in parity with medical surgical benefits consistent with state and federal law. Health plans must cover mental health services and substance use disorder treatment that is delivered in parity with medical surgical benefits, consistent with state and federal law.
- (d) The base-benchmark plan's visit limitations on services in this category include court-ordered treatment only when medically necessary.
- (e) State benefit requirements classified to this category include:
- (i) Mental health services (RCW 48.20.580, 48.21.241, 48.44.341, and 48.46.285);
- (ii) Chemical dependency detoxification services (RCW 48.21.180, 48.44.240, 48.44.245, 48.46.350, and 48.46.355); and
- (iii) Services delivered pursuant to involuntary commitment proceedings (RCW 48.21.242, 48.44.342, and 48.46.292).
- (f) The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (Public Law 110-343) (MHPAEA) applies to a health benefit plan subject to this section. Coverage of mental health and substance use disorder services, along with any scope and duration limits imposed on the benefits, must comply with the MHPAEA, and all rules, regulations and guidance issued pursuant to Section 2726 of the federal Public Health Service Act (42 U.S.C. Sec. 300gg-26) including where state law is silent, or where federal law preempts state law.
- (6) A health benefit plan must cover "prescription drug services" in a manner substantially equal to the base-benchmark plan. For purposes of determining a plan's actuarial value, an issuer must classify as prescription drug services medically necessary prescribed drugs, medication and drug therapies.
- (a) A health benefit plan must include the following services, which are specifically covered by the base-benchmark plan, and classify them as prescription drug services:
- (i) Drugs and medications both generic and brand name, including self-administrable prescription medications, consistent with the requirements of (b) through (e) of this subsection;
- (ii) Prescribed medical supplies, including diabetic supplies that are not otherwise covered as durable medical equipment under the rehabilitative and habilitative services category, including test strips, glucagon emergency kits, insulin and insulin syringes;
- (iii) All FDA-approved contraceptive methods, and prescription-based sterilization procedures;
- (iv) Certain preventive medications including, but not limited to, aspirin, fluoride, and iron, and medications for tobacco use ces-

sation, according to, and as recommended by, the United States Preventive Services Task Force, when obtained with a prescription order; and

- (v) Medical foods to treat inborn errors of metabolism in accordance with RCW 48.44.440, 48.46.510, 48.20.520, 48.21.300, and 48.43.176.
- (b) A health benefit plan may, but is not required to, include the following services as part of the EHB-benchmark package. The base-benchmark plan specifically excludes these services for the prescription drug services category. If an issuer includes these services, the issuer may not include the following benefits in establishing actuarial value for the prescription drug services category:
- (i) Insulin pumps and their supplies, which are classified to and covered under the rehabilitation and habilitation services category; and
 - (ii) Weight loss drugs.
- (c) The base-benchmark plan's visit limitations on services in the prescription drug services category include:
- (i) Prescriptions for self-administrable injectable medication are limited to ((thirty)) 30 day supplies at a time, other than insulin, which may be offered with more than a ((thirty)) 30 day supply. This limitation is a floor, and an issuer may permit supplies greater than ((thirty)) 30 days as part of its health benefit plan;
- (ii) Teaching doses of self-administrable injectable medications are limited to three doses per medication per lifetime.
- (d) State benefit requirements classified to the prescription drug services category include:
- (i) Medical foods to treat inborn errors of metabolism (RCW 48.44.440, 48.46.510, 48.20.520, 48.21.300, and 48.43.176);
- (ii) Diabetes supplies ordered by the physician (RCW 48.44.315, 48.46.272, 48.20.391, and 48.21.143). Inclusion of this benefit requirement does not bar issuer variation in diabetic supply manufacturers under its drug formulary;
- (iii) Mental health prescription drugs to the extent not covered under the hospitalization or skilled nursing facility services, or mental health and substance use disorders categories (RCW 48.44.341, 48.46.291, 48.20.580, and 48.21.241);
- (iv) Reproductive health-related over-the-counter drugs, devices, and products approved by the federal Food and Drug Administration.
- (e) An issuer's formulary is part of the prescription drug services category. The formulary filed with the commissioner must be substantially equal to the base-benchmark plan formulary, both as to U.S. Pharmacopoeia therapeutic category and classes covered and number of drugs in each class. If the base-benchmark plan formulary does not cover at least one drug in a category or class, an issuer must include at least one drug in the uncovered category or class.
- (i) An issuer must file its formulary quarterly, following the filing instructions defined by the insurance commissioner in WAC 284-44A-040, 284-46A-050, and 284-58-025.
- (ii) An issuer's formulary does not have to be substantially equal to the base-benchmark plan formulary in terms of formulary placement.
- (iii) An issuer may include over-the-counter medications in its formulary for purposes of establishing quantitative limits and administering the benefit.
- (7) A health benefit plan must cover "rehabilitative and habilitative services" in a manner substantially equal to the base-benchmark plan.

- (a) For purposes of determining a plan's actuarial value, an issuer must classify as rehabilitative services the medically necessary services that help a person keep, restore or improve skills and function for daily living that have been lost or impaired because a person was sick, hurt or disabled.
- (b) A health benefit plan must include the following services, which are specifically covered by the base-benchmark plan, and classify them as rehabilitative services:
 - (i) Cochlear implants;
- (ii) Inpatient rehabilitation facilities and professional services delivered in those facilities;
- (iii) Outpatient physical therapy, occupational therapy and speech therapy for rehabilitative purposes;
- (iv) Braces, splints, prostheses, orthopedic appliances and orthotic devices, supplies or apparatus used to support, align or correct deformities or to improve the function of moving parts; and
- (v) Durable medical equipment and mobility enhancing equipment used to serve a medical purpose, including sales tax.
- (c) A health benefit plan may, but is not required to, include the following services as part of the EHB-benchmark package. The base-benchmark plan specifically excludes these services. If an issuer includes the following benefits in a health plan, the issuer may not include these benefits in establishing actuarial value for the rehabilitative and habilitative services category:
 - (i) Off-the-shelf shoe inserts and orthopedic shoes;
 - (ii) Exercise equipment for medically necessary conditions;
- (iii) Durable medical equipment that serves solely as a comfort or convenience item; and
 - (iv) Hearing aids other than cochlear implants.
- (d) For purposes of determining a plan's actuarial value, an issuer must classify as habilitative services the range of medically necessary health care services and health care devices designed to assist a person to keep, learn or improve skills and functioning for daily living. Examples include services for a child who isn't walking or talking at the expected age, or services to assist with keeping or learning skills and functioning within an individual's environment, or to compensate for a person's progressive physical, cognitive, and emotional illness. These services may include physical and occupational therapy, speech-language pathology and other services for people with disabilities in a variety of inpatient or outpatient settings.
- (i) As a minimum level of coverage, an issuer must establish limitations on habilitative services on parity with those for rehabilitative services. A health benefit plan may include such limitations only if the limitations take into account the unique needs of the individual and target measurable, and specific treatment goals appropriate for the person's age and physical and mental condition. When habilitative services are delivered to treat a mental health diagnosis categorized in the most recent version of the DSM, the mental health parity requirements apply and supersede any rehabilitative services parity limitations permitted by this subsection.
- (ii) A health benefit plan must not limit an enrollee's access to covered services on the basis that some, but not all, of the services in a plan of treatment are provided by a public or government program.
- (iii) An issuer may establish utilization review guidelines and practice guidelines for habilitative services that are recognized by the medical community as efficacious. The guidelines must not require a return to a prior level of function.

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- (iv) Habilitative health care devices may be limited to those that require FDA approval and a prescription to dispense the device.
- (v) Consistent with the standards in this subsection, speech therapy, occupational therapy, physical therapy, and aural therapy are habilitative services. Day habilitation services designed to provide training, structured activities and specialized assistance to adults, chore services to assist with basic needs, vocational or custodial services are not classified as habilitative services.
- (vi) An issuer must not exclude coverage for habilitative services received at a school-based health care center unless the habilitative services and devices are delivered pursuant to federal Individuals with Disabilities Education Act of 2004 (IDEA) requirements and included in an individual educational plan (IEP).
- (e) The base-benchmark plan's visit limitations on services in the rehabilitative and habilitative services category include:
- (i) Inpatient rehabilitation facilities and professional services delivered in those facilities are limited to ((thirty)) 30 service days per calendar year; and
- (ii) Outpatient physical therapy, occupational therapy and speech therapy are limited to ((twenty-five)) 25 outpatient visits per calendar year, on a combined basis, for rehabilitative purposes.
- (f) State benefit requirements classified to this category include:
 - (i) State sales tax for durable medical equipment; and
- (ii) Coverage of diabetic supplies and equipment (RCW 48.44.315, 48.46.272, 48.20.391, and 48.21.143).
- (g) An issuer must not classify services to the rehabilitative services category if the classification results in a limitation of coverage for therapy that is medically necessary for an enrollee's treatment for cancer, chronic pulmonary or respiratory disease, cardiac disease or other similar chronic conditions or diseases. For purposes of this subsection, an issuer must establish limitations on the number of visits and coverage of the rehabilitation therapy consistent with its medical necessity and utilization review guidelines for medical/surgical benefits. Examples of these are, but are not limited to, breast cancer rehabilitation therapy, respiratory therapy, and cardiac rehabilitation therapy. Such services may be classified to the ambulatory patient or hospitalization services categories for purposes of determining actuarial value.
- (8) A health plan must cover "laboratory services" in a manner substantially equal to the base-benchmark plan. For purposes of determining actuarial value, an issuer must classify as laboratory services the medically necessary laboratory services and testing, including those performed by a licensed provider to determine differential diagnoses, conditions, outcomes and treatment, and including blood and blood services, storage and procurement, and ultrasound, X-ray, MRI, CAT scan and PET scans.
- (a) A health benefit plan must include the following services, which are specifically covered by the base-benchmark plan, and classify them as laboratory services:
- (i) Laboratory services, supplies and tests, including genetic testing;
- (ii) Radiology services, including X-ray, MRI, CAT scan, PET scan, and ultrasound imaging; and
- (iii) Blood, blood products, and blood storage, including the services and supplies of a blood bank.

- (b) A health benefit plan may, but is not required to, include the following services as part of the EHB-benchmark package. The base-benchmark plan specifically excludes procurement and storage of personal blood supplies provided by a member of the enrollee's family when this service is not medically indicated. If an issuer includes this benefit in a health plan, the issuer may not include this benefit in establishing the health plan's actuarial value.
- (9) A health plan must cover "preventive and wellness services, including chronic disease management" in a manner substantially equal to the base-benchmark plan. For purposes of determining a plan's actuarial value, an issuer must classify as preventive and wellness services, including chronic disease management, the services that identify or prevent the onset or worsening of disease or disease conditions, illness or injury, often asymptomatic; services that assist in the multidisciplinary management and treatment of chronic diseases; and services of particular preventative or early identification of disease or illness of value to specific populations, such as women, children and seniors.
- (a) If a plan does not have in its network a provider who can perform the particular service, then the plan must cover the item or service when performed by an out-of-network provider and must not impose cost-sharing with respect to the item or service. In addition, a health plan must not limit sex-specific recommended preventive services based on an individual's sex assigned at birth, gender identity or recorded gender. If a provider determines that a sex-specific recommended preventive service is medically appropriate for an individual, and the individual otherwise satisfies the coverage requirements, the plan must provide coverage without cost-sharing.
- (b) A health benefit plan must include the following services as preventive and wellness services, including chronic disease management:
- (i) Immunizations recommended by the Centers for Disease Control's Advisory Committee on Immunization Practices;
- (ii) (A) Screening and tests for which the U.S. Preventive Services Task Force (($\frac{\text{for Prevention and Chronic Care have}}{\text{on or before the applicable plan year.}}$
- (B) To the extent not specified in ((a)) the relevant recommendation or guideline, federal rules and guidance related to preventive services in effect on January 8, 2024, and in chapter 284-43 WAC, a plan may ((rely on the relevant evidence base and)) use reasonable medical management techniques((, based on necessity or appropriateness,)) to determine the frequency, method, treatment, or setting for the provision of ((a recommended preventive health)) an item or service described in RCW 48.43.047;
- (iii) Services, tests and screening contained in the U.S. Health Resources and Services Administration ("HRSA") Bright Futures guidelines as set forth by the American Academy of Pediatricians; and
- (iv) Services, tests, screening and supplies recommended in the HRSA women's preventive and wellness services guidelines:
- (A) If the plan covers children under the age of ((nineteen)) 19, or covers dependent children age ((nineteen)) 19 or over who are on the plan pursuant to RCW 48.44.200, 48.44.210, or 48.46.320, the plan must provide the child with the full range of recommended preventive services suggested under HRSA guidelines for the child's age group without cost-sharing. Services provided in this regard may be combined in one visit as medically appropriate or may be spread over more than

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one visit, without incurring cost-sharing, as medically appropriate; and

- (B) A plan may use reasonable medical management techniques to determine the frequency, method, treatment or setting for ((a recommended preventive service)) an item or service described in RCW 48.43.047, including providing multiple prevention and screening services at a single visit or across multiple visits. Medical management techniques may not be used that limit enrollee choice in accessing the full range of contraceptive drugs, devices, or other products approved by the federal Food and Drug Administration.
- (v) Chronic disease management services, which typically include, but are not limited to, a treatment plan with regular monitoring, co-ordination of care between multiple providers and settings, medication management, evidence-based care, measuring care quality and outcomes, and support for patient self-management through education or tools; and
 - (vi) Wellness services.
- (c) The base-benchmark plan establishes specific limitations on services classified to the preventive services category that conflict with state or federal law as of January 1, 2017, and should not be included in essential health benefit plans.

Specifically, the base-benchmark plan excludes coverage for obesity or weight control other than covered nutritional counseling. Health plans must cover certain obesity-related services that are listed as A or B recommendations by the U.S. Preventive Services Task Force, consistent with ((42~U.S.C.~300gg-13~(a)~(1))) RCW 48.43.047 and 45 C.F.R. 147.130 (a)(1)(i).

- (d) The base-benchmark plan does not establish visit limitations on services in this category. In accordance with Sec. 2713 of the Public Health Service Act (PHS Act) and its implementing regulations relating to coverage of preventive services, the base-benchmark plan does not impose cost-sharing requirements with respect to the preventive services listed under (b)(i) through (iv) of this subsection that are provided in-network.
 - (e) State benefit requirements classified in this category are:
 - (i) Colorectal cancer screening as set forth in RCW 48.43.043;
- (ii) Mammogram services, both diagnostic and screening (RCW 48.21.225, 48.44.325, and 48.46.275); and
- (iii) Prostate cancer screening (RCW 48.20.392, 48.21.227, 48.44.327, and 48.46.277).
- (10) Some state benefit requirements are limited to those receiving pediatric services, but are classified to other categories for purposes of determining actuarial value.
 - (a) These benefits include:
- (i) Neurodevelopmental therapy, consisting of physical, occupational and speech therapy and maintenance to restore or improve function based on developmental delay, which cannot be combined with rehabilitative services for the same condition (RCW 48.44.450, 48.46.520, and 48.21.310). This state benefit requirement may be classified to ambulatory patient services or mental health and substance abuse disorder including behavioral health categories; and
- order including behavioral health categories; and
 (ii) Treatment of congenital anomalies in newborn and dependent children (RCW 48.20.430, 48.21.155, 48.44.212, and 48.46.250). This state benefit requirement may be classified to hospitalization, ambulatory patient services or maternity and newborn categories.
- (b) The base-benchmark plan contains limitations or scope restrictions that conflict with state or federal law as of January 1,

- 2017. Specifically, the plan covers outpatient neurodevelopmental therapy services only for persons age six and under. Health plans must cover medically necessary neurodevelopmental therapy for any DSM diagnosis without blanket exclusions.
- (11) Issuers must know and apply relevant guidance, clarifications and expectations issued by federal governmental agencies regarding essential health benefits. Such clarifications may include, but are not limited to, Affordable Care Act implementation and frequently asked questions jointly issued by the U.S. Department of Health and Human Services, the U.S. Department of Labor and the U.S. Department of the Treasury.
- (12) Each category of essential health benefits must at a minimum cover services required by current state law and be consistent with federal rules and guidance implementing 42 U.S.C. 18116, Sec. 1557, including those codified at 81 Fed. Reg. 31375 et seq. (2016), that were in effect on January 1, 2017.
- (13) This section applies to health plans that have an effective date of January 1, 2020, or later.

AMENDATORY SECTION (Amending WSR 16-14-106, filed 7/6/16, effective 8/6/16)

- WAC 284-43-5800 Plan cost-sharing and benefit substitutions and limitations. (1) A health benefit plan must not apply cost-sharing requirements to Native Americans purchasing a health benefit plan through the exchange, whose incomes are at or below ((three hundred)) 300 percent of federal poverty level.
- (2) A small group health benefit plan that includes the essential health benefits package may not impose annual cost-sharing or deductibles that exceed the maximum annual amounts that apply to high deductible plans linked to health savings accounts, as set forth in the most recent version of IRS Publication 969, pursuant to Section 106 (c)(2) of the Internal Revenue Code of 1986, and Section 1302 (c)(2) of PPACA.
- (3) An issuer may use reasonable medical management techniques to control costs, including promoting the use of appropriate, high value preventive services, providers and settings. An issuer's policies must permit waiver of an otherwise applicable copayment for a service that is tied to one setting but not the preferred high-value setting, if the enrollee's provider determines that it would be medically inappropriate to have the service provided in the lower-value setting. An issuer may still apply applicable in-network requirements.
- (4) (a) An issuer may not require cost-sharing for preventive services as defined in RCW 48.43.047, delivered by network providers ((, specifically related to those with an A or B rating in the most recent recommendations of the United States Preventive Services Task Force, women's preventive health care services recommended by the U.S. Health Resources and Services Administration (HRSA) and HRSA Bright Futures guideline designated pediatric services)). If a health plan offered by an issuer does not have in its network a provider who can provide an item or service described in RCW 48.43.047, the plan must cover the item or service when performed by an out-of-network provider and may not impose cost sharing with respect to the item or service.

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- $\underline{\text{(b)}}$ An issuer must post on its website a list of the specific preventive and wellness services mandated by PPACA $\underline{\text{or RCW }48.43.047}$ that it covers.
- (5) If an issuer establishes cost-sharing levels, structures or tiers for specific essential health benefit categories, the cost-sharing levels, structures or tiers must not be discriminatory. "Cost-sharing" has the same meaning as set forth in RCW 48.43.005 and WAC $284-43-0160((\frac{(8)}{1}))$.
- (a) An issuer must not apply cost-sharing or coverage limitations differently to enrollees with chronic disease or complex underlying medical conditions than to other enrollees, unless the difference provides the enrollee with access to care and treatment commensurate with the enrollee's specific medical needs, without imposing a surcharge or other additional cost to the enrollee beyond normal cost-sharing requirements under the plan.
- (b) An issuer must not establish a different cost-sharing structure for a specific benefit or tier for a benefit than is applied to the plan in general if the sole type of enrollee who would access that benefit or benefit tier is one with a chronic illness or medical condition.
- (6) For health plans that include prescription drug coverage issued or renewed on or after January 1, 2025, a health carrier or its health benefit manager may not increase an enrollee's cost-sharing obligation mid-plan year for a prescription drug refill of an antipsychotic, antidepressant, antiepileptic, or other drug prescribed to the enrollee to treat a serious mental illness, if the enrollee is medically stable on the drug, and a participating provider continues to prescribe the drug.

AMENDATORY SECTION (Amending WSR 20-24-040, filed 11/23/20, effective 12/24/20)

- WAC 284-43-5980 Notice requirement. (1) An issuer offering a plan shall take appropriate initial and continuing steps to notify enrollees, applicants, and members of the public of the following:
- (a) The issuer does not discriminate on the basis of race, color, national origin, disability, age, sex, gender identity, or sexual orientation in its benefits and services;
- (b) The issuer provides appropriate auxiliary aids and services, including qualified interpreters for individuals with disabilities and information in alternate formats, free of charge and in a timely manner, when such aids and services are necessary to ensure an equal opportunity to participate to individuals with disabilities;
- (c) The issuer provides language assistance services, including translated documents and oral interpretation, free of charge and in a timely manner, when such services are necessary to provide meaningful access to individuals with limited-English proficiency;
- (d) How to obtain the aids and services in (b) and (c) of this subsection;
- (e) An identification of, and contact information for, the employee responsible for compliance with RCW 48.43.0128 and WAC 284-43-5935 through 284-43-5980;

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- (f) How to file a grievance with the issuer related to the issuer's compliance with RCW 48.43.0128 and WAC 284-43-5935 through 284-43-5980; and
- (g) How to file a complaint with the commissioner related to the issuer's compliance with RCW 48.43.0128 and WAC 284-43-5935 through this section or with the federal Department of Health and Human Services, Office of Civil Rights related to the issuer's compliance with 42 U.S.C. Sec. 18119 (Sec. 1557 of the Affordable Care Act).
 - (2) An issuer offering a plan shall:
- (a) As described in subsection (7) of this section, post a notice that conveys the information in subsection (1) (a) through (g) of this section; and
- (b) As described in subsection (8) of this section, if applicable, post a nondiscrimination statement that conveys the information in subsection (1) (a) of this section.
- (3) To ((satisfy)) aid in compliance with the requirements of this section, issuers may use the sample notices published at ((81 Fed. Reg. 31472 through 31473 (May 18, 2016) that convey:
- (a) The information in subsection (1) (a) through (g) of this section; and
- (b) The information in subsection (1)(a) of this section)) https://www.hhs.gov/civil-rights/for-providers/resources-covered-enti-ties/index.html.

For use beginning January 1, 2022, the notice referenced in (($\frac{(a)}{of}$)) this subsection must be modified to identify the office of the insurance commissioner as the designated entity to file a complaint regarding compliance with RCW 48.43.0128 and WAC 284-43-5935 through 284-43-5980 and the federal Department of Health and Human Services, Office of Civil Rights as the designated entity to file a complaint regarding compliance related to the issuer's compliance with 42 U.S.C. Sec. 18119 (Sec. 1557 of the Affordable Care Act). (($\frac{U}{U}$) ($\frac{U}{U}$) that date, issuers may continue to use the sample notice published at 81 Fed. Reg. 31472 through 31473 (May 18, 2016).))

- (4) Except to the extent provided otherwise in subsection (5) of this section, each issuer shall:
- (a) As described in subsection (7)(a) of this section, post taglines in at least the top ($(\frac{\text{fifteen}}{\text{field}})$) $\frac{15}{\text{languages}}$ spoken by individuals with limited-English proficiency in Washington state; and
- (b) As described in subsection (8)(b) of this section, if applicable, post taglines in at least the top two languages spoken by individuals with limited-English proficiency in Washington state.
- (5) Plans deemed by the commissioner to have a short-term limited purpose or duration that are offered in Washington state must come into compliance with the language assistance notice and tagline requirements in this section on or before April 1, 2021.
- (6) To satisfy the requirements of this section, issuers may use taglines provided by the federal Department of Health and Human Services pursuant to 45 C.F.R. 92.8, as in effect on January 1, 2017.
- (7)(a) Each issuer shall post the notice required by subsection (1) of this section and the taglines required by subsection (4)(a) of this section in a conspicuously visible font size:
- (i) In significant publications and significant communications targeted to enrollees, applicants, and members of the public, except for significant publications and significant communications that are small-sized, such as postcards and tri-fold brochures;
- (ii) In conspicuous physical locations where the issuer interacts with the public; and

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- (iii) In a conspicuous location on the issuer's website accessible from the home page of the issuer's website.
- (b) An issuer may also post the notice and taglines in additional publications and communications.
- (8) Each issuer shall post, in a conspicuously visible font size, in significant publications and significant communications that are small-sized, such as postcards and tri-fold brochures:
- (a) The nondiscrimination statement required by subsection (1)(a) of this section; and
 - (b) The taglines required by subsection (4)(b) of this section.
- (9) An issuer may combine the content of the notice required in subsection (1) of this section with the content of other notices if the combined notice clearly informs individuals of their rights under RCW 48.43.0128 and WAC 284-43-5935 through 284-43-5980 and 42 U.S.C. Sec. 18119 (Sec. 1557 of the Affordable Care Act).

- WAC 284-170-130 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) "Allowed amount" has the meaning set forth in RCW 48.43.005.
- (3)(a) "Audio-only telemedicine" means the delivery of health care services through the use of audio-only technology, permitting real-time communication between the patient at the originating site and the provider, for the purpose of diagnosis, consultation, or treatment.
 - (b) "Audio-only telemedicine" does not include:
- (i) The use of facsimile, email, or text messages, unless the use of text-like messaging is necessary to ensure effective communication with individuals who have a hearing, speech, or other disability; or
- (ii) The delivery of health care services that are customarily delivered by audio-only technology and customarily not billed as separate services by the provider, such as the sharing of laboratory results.
- (4) "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.
- (5) "Clinical review criteria" means the written screens, or screening procedures, decision rules, medical protocols, or clinical practice guidelines used by the carrier as an element in the evaluation of medical necessity and appropriateness of requested admissions, procedures, and services, including prescription drug benefits, under the auspices of the applicable health plan. Clinical approval criteria has the same meaning as clinical review criteria.
- (6) "Covered health condition" means any disease, illness, injury or condition of health risk covered according to the terms of any health plan.

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- (7) "Covered person" or "enrollee" means an individual covered by a health plan including a subscriber, policyholder, or beneficiary of a group plan.
- (8) "Disciplining authority" has the meaning set forth in RCW 18.130.020.
 - (9) "Distant site" has the meaning set forth in RCW 48.43.735.
- (10) "Emergency medical condition" has the meaning set forth in RCW 48.43.005.
- (11) "Emergency services" has the meaning set forth in RCW 48.43.005.
- (12) "Enrollee point-of-service cost-sharing" or "cost-sharing" has the meaning set forth in RCW 48.43.005.
- (13) "Established relationship" means the provider providing audio-only telemedicine has access to sufficient health records to ensure safe, effective, and appropriate care services and:
- (a) ((For health care services included in the essential health benefits category of mental health and substance use disorder services, including behavioral health treatment:
- $\frac{(i)}{(i)}$) The covered person has had, within the past three years, at least one in-person appointment, or at least one real-time interactive appointment using both audio and video technology, with:
 - $((\frac{A}{A}))$ (i) The provider providing audio-only telemedicine;
- $((\frac{(B)}{(B)}))$ (ii) A provider employed at the same medical group, at the same clinic, or by the same integrated delivery system operated by a carrier licensed under chapter 48.44 or 48.46 RCW as the provider providing audio-only telemedicine; or
- $((\frac{C}{C}))$ (iii) A locum tenens or other provider who is the designated back up or substitute provider for the provider providing audionly telemedicine who is on leave and is not associated with an established medical group, clinic, or integrated delivery system operated by a carrier licensed under chapter 48.44 or 48.46 RCW; or
- $((\frac{(ii)}{(ii)}))$ The covered person was referred to the provider providing audio-only telemedicine by another provider who has:
- $((\frac{A}{A}))$ <u>(i)</u> Had, within the past three years, at least one inperson appointment, or at least one real-time interactive appointment using both audio and video technology, with the covered person; and
- $((\frac{B}{B}))$ (ii) Provided relevant medical information to the provider providing audio-only telemedicine.
- $((\frac{C}{C}))$ (iii) A referral includes circumstances in which the provider who has had at least one in-person appointment, or at least one real-time interactive appointment using both audio and video technology, with the covered person participates in the audio-only telemedicine encounter with the provider to whom the covered person has been referred.
 - (((b) For any other health care service:
- (i) The covered person has had, within the past two years, at least one in-person appointment, or, until July 1, 2024, at least one real-time interactive appointment using both audio and video technology, with:
 - (A) The provider providing audio-only telemedicine; or
- (B) A provider employed at the same medical group, at the same clinic, or by the same integrated delivery system operated by a carrier licensed under chapter 48.44 or 48.46 RCW as the provider providing audio-only telemedicine; or
- (C) A locum tenens or other provider who is the designated back up or substitute provider for the provider providing audio-only telemedicine who is on leave and is not associated with an established

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medical group, clinic, or integrated delivery system operated by a carrier licensed under chapter 48.44 or 48.46 RCW; or

- (ii) The covered person was referred to the provider providing audio-only telemedicine by another provider who has:
- (A) Had, within the past two years, at least one in-person appointment or, until July 1, 2024, at least one real-time interactive appointment using both audio and video technology, with the covered person; and
- (B) Provided relevant medical information to the provider providing audio-only telemedicine.
- (C) A referral includes circumstances in which the provider who has had at least one in-person appointment, or, until July 1, 2024, at least one real-time interactive appointment using both audio and video technology, with the covered person participating in the audio-only telemedicine encounter with the provider to whom the covered person has been referred.)
- (14) "Expedited prior authorization request" has the meaning set forth in RCW 48.43.830.
- (15) "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.
- (16) "Formulary" means a listing of drugs used within a health plan.
 - (17) "Grievance" has the meaning set forth in RCW 48.43.005.
 - (18) "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.
- (19) "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.
- (20) "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)).
- (21) "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;

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- (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.
 - (22) "Hospital" has the meaning set forth in RCW 48.43.735.
 - (23) "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. Sec. 1661;
- (b) An Indian tribe, as defined in the Indian Health Care Improvement Act, Section 4(14), 25 U.S.C. Sec. 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. Sec. 450 et seq.;
- (c) A tribal organization, as defined in the Indian Health Care Improvement Act, Section 4(26), 25 U.S.C. Sec. 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. Sec. 450 et seq.;
- (d) An Indian tribe, as defined in the Indian Health Care Improvement Act, Section 4(14), 25 U.S.C. Sec. 1603(14), or tribal organization, as defined in the Indian Health Care Improvement Act, Section 4(26), 25 U.S.C. Sec. 1603(26), that operates a health program with funding provided in whole or part pursuant to 25 U.S.C. Sec. 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. Sec. 1603(29).
- (24) "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.
- (25) "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.
- (26) "Mental health provider" means a health care provider or a health care facility authorized by state law to provide mental health services.
- (27) "Mental health services" means in-patient or out-patient treatment including, but not limited to, partial hospitalization, residential treatment, out-patient facility-based treatment, intensive outpatient treatment, emergency services, or prescription drugs to manage, stabilize, or ameliorate the effects of a mental disorder listed in the most current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM) published by the American Psychiatric Association, including diagnoses and treatment for substance use disorder.

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- (28) "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.
- (29) "Originating site" means the physical location of a patient receiving health care services through telemedicine, and includes those sites described in WAC 284-170-433.
- (30) "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.
- (31) "Participating provider" and "participating facility" mean 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.
- (32) "Patient consent" means a voluntary and informed decision by a patient, following an explanation by the provider or auxiliary personnel under the general supervision of the provider presented in a manner understandable to the patient that is free of undue influence, fraud or duress, to consent to a provider billing the patient or the patient's health plan for an audio-only telemedicine service under RCW 48.43.735 or WAC 284-170-433.
- (33) "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.
- (34) "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.
- (35) "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.
- (36) "Preexisting condition" means any medical condition, illness, or injury that existed any time prior to the effective date of coverage.
- (37) "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.
- (38) "Real time communication" means synchronous and live communication between a provider and a patient. It does not include delayed or recorded messages, such as email, facsimile or voicemail.
- (39) "Same amount of compensation" means providers are reimbursed by a carrier using the same allowed amount for telemedicine services as they would if the service had been provided in-person unless negotiation has been undertaken under RCW 48.43.735 or WAC

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- $284-170-433((\frac{(2)}{(2)}))$. Where consumer cost-sharing applies to telemedicine services, the consumer's payment combined with the carrier's payment must be the same amount of compensation, or allowed amount, as the carrier would pay the provider if the telemedicine service had been provided in person. Where an alternative payment methodology other than fee-for-service payment would apply to an in-person service, "same amount of compensation" means providers are reimbursed by a carrier using the same alternative payment methodology that would be used for the same service if provided in-person, unless negotiation has been undertaken under RCW 48.43.735 or WAC $284-170-433((\frac{(2)}{(2)}))$.
- (40) "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.
- (41) "Small group plan" means a health plan issued to a small employer as defined under RCW $48.43.005((\frac{34}{100}))$ comprising from one to 50 eligible employees.
- (42) "Standard prior authorization request" has the meaning set forth in RCW 48.43.830.
- (43) "Store and forward technology" has the meaning set forth in RCW 48.43.735.
- (44) "Substance use disorder services" means in-patient or outpatient treatment including, but not limited to, partial hospitalization, residential treatment, or out-patient facility-based treatment, intensive outpatient treatment, emergency services, or prescription drugs to manage, stabilize, or ameliorate the effects of a substance use disorder listed in the most current version of the *Diagnostic and Statistical Manual of Mental Disorders* (DSM) published by the American Psychiatric Association, including diagnoses and treatment for substance use disorder.
- (45) "Substitute drug" means a prescription medication, drug or therapy that a carrier covers based on an exception request. When the exception request is based on therapeutic equivalence, a substitute drug means a therapeutically equivalent substance as defined in chapter 69.41 RCW.
- (46) "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.
- (47) "Telemedicine" means the delivery of health care services through the use of interactive audio and video technology or audio-only technology, permitting real-time communication between the patient at the originating site and the provider, for the purpose of diagnosis, consultation, or treatment. For purposes of this chapter, "telemedicine" does not include facsimile, email, or text messaging, unless the use of text-like messaging is necessary to ensure effective communication with individuals who have a hearing, speech, or other disability.

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