WAC 284-43-130 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) "Authorization" or "certification" means a determination by the carrier that an admission, extension of stay, or other health care service has been reviewed and, based on the information provided, meets the clinical requirements for medical necessity, appropriateness, level of care, or effectiveness in relation to the applicable health plan.

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

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

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

(6) “Emergency fill” means a limited dispensed amount of medication that allows time for the processing of a pre-authorization 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. An issuer’s emergency fill policy is only applicable when:

(a) An issuer has around the clock availability to respond to phone calls from a dispensing pharmacy, but the health plan cannot reach the prescriber for full consultation; or

(b) The dispensing pharmacy cannot reach the issuer’s prior authorization department by phone as it is outside of that department’s business hours.

((~~(6)~~))(7) "Emergency medical condition" means the emergent and acute onset of a symptom or symptoms, including severe pain, that would lead a prudent layperson acting reasonably to believe that a health condition exists that requires immediate medical attention, if failure to provide medical attention would result in serious impair-

ment to bodily functions or serious dysfunction of a bodily organ or part, or would place the person's health in serious jeopardy.

((~~(7)~~)) (8) "Emergency services" has the meaning set forth in RCW 48.43.005.

((~~(8)~~)) (9) "Enrollee point-of-service cost-sharing" or "cost-sharing" means amounts paid to health carriers directly providing services, health care providers, or health care facilities by enrollees and may include copayments, coinsurance, or deductibles.

((~~(9)~~)) (10) "Facility" means an institution providing health care services, including but not limited to hospitals and other licensed inpatient centers, ambulatory surgical or treatment centers, skilled nursing centers, residential treatment centers, diagnostic, laboratory, and imaging centers, and rehabilitation and other therapeutic settings, and as defined in RCW 48.43.005.

((~~(10)~~)) (11) "Formulary" means a listing of drugs used within a health plan.

((~~(11)~~)) (12) "Grievance" has the meaning set forth in RCW 48.43.005.

((~~(12)~~)) (13) "Health care provider" or "provider" means:

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

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

((~~(13)~~)) (14) "Health care service" or "health service" means that service offered or provided by health care facilities and health care providers relating to the prevention, cure, or treatment of illness, injury, or disease.

((~~(14)~~)) (15) "Health carrier" or "carrier" means a disability insurance company regulated under chapter 48.20 or 48.21 RCW, a health care service contractor as defined in RCW 48.44.010, and a health maintenance organization as defined in RCW 48.46.020, and includes "issuers" as that term is used in the Patient Protection and Affordable Care Act (P.L. 111-148, as amended (2010)).

((~~(15)~~)) (16) "Health plan" or "plan" means any individual or group policy, contract, or agreement offered by a health carrier to provide, arrange, reimburse, or pay for health care service except the following:

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

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

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

(d) Disability income;

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

(f) Workers' compensation coverage;

(g) Accident only coverage;

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

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

(j) Dental only and vision only coverage; and

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

((~~(16)~~)) (17) "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).

((~~(17)~~)) (18) "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.

((~~(18)~~)) (19) "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.

((~~(19)~~)) (20) "Mental health provider" means a health care provider or a health care facility authorized by state law to provide mental health services.

((~~(20)~~)) (21) "Mental health services" means in-patient or out-patient treatment, partial hospitalization or out-patient treatment to manage or ameliorate the effects of a mental disorder listed in the *Diagnostic and Statistical Manual (DSM) IV* published by the American Psychiatric Association, excluding diagnoses and treatments for substance abuse, 291.0 through 292.9 and 303.0 through 305.9.

((~~(21)~~)) (22) "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.

((~~(22)~~)) (23) "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.

((~~(23)~~)) (24) "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.

((~~(24)~~)) (25) "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.

((~~(25)~~)) (26) "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.

((~~(26)~~)) (27) "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.

((~~(27)~~)) (28) "Preexisting condition" means any medical condition, illness, or injury that existed any time prior to the effective date of coverage.

((~~(28)~~)) (29) "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.

((~~(29)~~)) (30) "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.

((~~(30)~~)) (31) "Small group plan" means a health plan issued to a small employer as defined under RCW 48.43.005(33) comprising from one to fifty eligible employees.

((~~(31)~~)) (32) "Substitute drug" means a therapeutically equivalent substance as defined in chapter 69.41 RCW.

((~~(32)~~)) (33) "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.

NEW SECTION

WAC 284-43-325 Pharmacy claims – Rejections, notifications and disclosures. Issuers must provide to submitting pharmacies sufficient

information in order to facilitate the processing of prior authorization requests. This includes instances where insufficient information has been submitted by a provider for an issuer to make a decision on a prior authorization request.

(1) For purposes of this section “claim rejection” is an administrative step in the claim process where a claim is neither paid nor denied, but is held awaiting a defined action from the pharmacist, prescriber or member.

(2) An issuer must notify the submitting pharmacy of a claim rejection electronically and make available to the pharmacy, utilizing the National Council for Prescription Drug Programs (NCPDP) Telecommunications standard transaction, all required data elements, as well as the following information, to the extent supported by the transaction:

(a) Rejection reasons such as prior authorization, Quantity Level Limit, and exclusion;

(b) Other medications to consider that would not require a pre-authorization (if applicable);

(c) Other medications to consider that would require a pre-authorization (if applicable);

(d) Instructions for further processing of claim or for more specific contact information which may include a reference to a specific location on a web site;

(e) Contact phone number of a person or department to contact who can provide additional information.

(3) Every issuer must notify its participating pharmacies of its claim process in its contracts;

(4) Every issuer must be responsible for ensuring that any person acting on behalf of or at the direction of the issuer or acting pursuant to carrier standards or requirements complies with these transaction standards.

(5) In every provider agreement, the issuer must disclose if the provider or pharmacy has the right to make a prior authorization request.

(6) The prior authorization determination must be transmitted to the requesting party and must include the following

(a) Information about whether a request was approved.

(b) If the request was made by the pharmacy, notification will additionally be made to the prescriber.

(7) In every provider agreement, every issuer will state that an issuer will authorize an emergency fill by the dispensing pharmacist

and approve the claim payment. In addition, the issuer's emergency fill policy must include the following:

(a) The inclusionary and exclusionary list of medications provided for emergency fill by issuers. This list must be posted online on the issuer's website and a common website dedicated to administrative simplification and available to the public, such as OneHealthPort.

(b) The authorized amount of the emergency fill will be no more than the prescribed amount up to a seven day supply or the minimum packaging size available at the time the emergency fill is dispensed.

(c) An emergency fill medication does not necessarily constitute a covered health service. Determination as to whether this is a covered health service under the patient benefit will be made as part of the prior authorization processing.

(8) Pharmacies and issuers are not required to comply with these contract provisions if the failure to comply is occasioned by any act of God, bankruptcy, act of a governmental authority responding to an act of God or other emergency, or the result of a strike, lockout, or other labor dispute.

WAC 284-43-410 Health care services ((U))utilization review—Generally. (1) These definitions apply to this section:

(a) "Concurrent care review request" means any request for an extension of a previously authorized inpatient stay or a previously authorized ongoing outpatient service, e.g., physical therapy, home health, etc.

(b) "Immediate review request" means any request for approval of an intervention, care or treatment where passage of time without treatment would, in the judgment of the provider, result in an imminent emergency room visit or hospital admission and deterioration of the patient's health status. Examples of situations that do not qualify under an immediate review request include, but are not limited to, situations where:

(i) The requested service was prescheduled, was not an emergency when scheduled, and there has been no change in the patient's condition;

(ii) The requested service is experimental or in a clinical trial;

(iii) The request is for the convenience of the patient's schedule or physician's schedule; and

(iv) The results of the requested service are not likely to lead to an immediate change in the patient's treatment.

(c) "Nonurgent preservice review request" means any request for approval of care or treatment where the request is made in advance of the patient obtaining medical care or services and is not an urgent care request.

(d) "Postservice review request" means any request for approval of care or treatment that has already been received by the patient.

(e) "Urgent care review request" means any request for approval of care or treatment where the passage of time could seriously jeopardize the life or health of the patient, seriously jeopardize the patient's ability to regain maximum function, or, in the opinion of a physician with knowledge of the patient's medical condition, would subject the patient to severe pain that cannot be adequately managed without the care or treatment that is the subject of the request.

(2) Each ((~~carrier~~)) issuer must maintain a documented utilization review program description and written clinical review criteria based on reasonable medical evidence. The program must include a method for reviewing and updating criteria. ((~~Carriers~~)) Issuers must make clinical review criteria available upon request to participating providers. ((~~A carrier~~)) an issuer need not use medical evidence or

standards in its utilization review of religious nonmedical treatment or religious nonmedical nursing care.

(3) The utilization review program must meet accepted national certification standards such as those used by the National Committee for Quality Assurance except as otherwise required by this chapter and must have staff who are properly qualified, trained, supervised, and supported by explicit written clinical review criteria and review procedures.

(4) Each ((~~carrier~~)) issuer when conducting utilization review must:

(a) Accept information from any reasonably reliable source that will assist in the certification process;

(b) Collect only the information necessary to certify the admission, procedure or treatment, length of stay, or frequency or duration of services;

(c) Not routinely require providers or facilities to numerically code diagnoses or procedures to be considered for certification, but may request such codes, if available;

(d) Not routinely request copies of medical records on all patients reviewed;

(e) Require only the section(s) of the medical record during prospective review or concurrent review necessary in that specific case to certify medical necessity or appropriateness of the admission or extension of stay, frequency or duration of service;

(f) For prospective and concurrent review, base review determinations solely on the medical information obtained by the ((~~carrier~~)) issuer at the time of the review determination;

(g) For retrospective review, base review determinations solely on the medical information available to the attending physician or order provider at the time the health service was provided;

(h) Not retrospectively deny coverage for emergency and nonemergency care that had prior authorization under the plan's written policies at the time the care was rendered unless the prior authorization was based upon a material misrepresentation by the provider;

(i) Not retrospectively deny coverage or payment for care based upon standards or protocols not communicated to the provider or facility within a sufficient time period for the provider or facility to modify care in accordance with such standard or protocol; and

(j) Reverse its certification determination only when information provided to the ((~~carrier~~)) issuer is materially different from that

which was reasonably available at the time of the original determination.

(5) Each ((~~carrier~~)) issuer must reimburse reasonable costs of medical record duplication for reviews.

(6) Each ((~~carrier~~)) issuer must have written procedures to assure that reviews and second opinions are conducted in a timely manner.

(a) Review time frames must be appropriate to the severity of the patient condition and the urgency of the need for treatment, as documented in the review request.

(b) If the review request from the provider is not accompanied by all necessary information, the ((~~carrier~~)) issuer must tell the provider what additional information is needed and the deadline for its submission. Upon the sooner of the receipt of all necessary information or the expiration of the deadline for providing information, the time frames for ((~~carrier~~)) issuer review determination and notification must be no less favorable than federal Department of Labor standards, as follows:

(i) For immediate request situations, within one business day when the lack of treatment may result in an emergency visit or emergency admission;

(ii) For concurrent review requests that are also urgent care review requests, as soon as possible, taking into account the medical exigencies, and no later than twenty-four hours, provided that the request is made at least twenty-four hours prior to the expiration of previously approved period of time or number of treatments;

(iii) For urgent care review requests within forty-eight hours;

(iv) For nonurgent preservice review requests, including nonurgent concurrent review requests, within five calendar days; or

(v) For postservice review requests, within thirty calendar days.

(c) Notification of the determination must be provided as follows:

(i) Information about whether a request was approved or denied must be made available to the attending physician, ordering provider, facility, and covered person. ((~~Carrier~~)) Issuers must at a minimum make the information available on their web site or from their call center.

(ii) Whenever there is an adverse determination the ((~~carrier~~)) issuer must notify the ordering provider or facility and the covered person. The ((~~carrier~~)) issuer must inform the parties in advance whether it will provide notification by phone, mail, fax, or other means. For an adverse determination involving an urgent care review

request, the ((~~carrier~~)) issuer may initially provide notice by phone, provided that a written or electronic notification meeting United States Department of Labor standards is furnished within seventy-two hours of the oral notification.

(d) As appropriate to the type of request, notification must include the number of extended days, the next anticipated review point, the new total number of days or services approved, and the date of admission or onset of services.

(e) The frequency of reviews for the extension of initial determinations must be based on the severity or complexity of the patient's condition or on necessary treatment and discharge planning activity.

(7) No ((~~carrier~~)) issuer may penalize or threaten a provider or facility with a reduction in future payment or termination of participating provider or participating facility status because the provider or facility disputes the ((~~carrier's~~)) issuer's determination with respect to coverage or payment for health care service.

NEW SECTION

WAC 284-43-420 Drug utilization review—Generally. (1) These definitions apply to this section only:

(a) “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.

(b) "Nonurgent review request" means any request for approval of care or treatment where the request is made in advance of the patient obtaining medical care or services, or a renewal of a previously approved request, and is not an urgent care request.

(c) "Urgent care review request" means any request for approval of care or treatment where the passage of time could seriously jeopardize the life or health of the patient, seriously jeopardize the patient's ability to regain maximum function, or, in the opinion of a provider with knowledge of the patient's medical condition, would subject the patient to severe pain that cannot be adequately managed without the care or treatment that is the subject of the request.

(2) Each issuer must maintain a documented drug utilization review program. The program must include a method for reviewing and updating criteria. Issuers must make drug review criteria available upon request to a participating provider.

(3) The utilization review program must meet accepted national certification standards such as those used by the National Committee for Quality Assurance except as otherwise required by this chapter.

(4) The utilization review program must have staff who are properly qualified, trained, supervised, and supported by explicit written clinical review criteria and review procedures.

(5) Each issuer must have written procedures to assure that reviews are conducted in a timely manner.

(a) If the review request from a provider is not accompanied by all necessary information, the issuer must tell the provider what additional information is needed and the deadline for its submission. Upon the sooner of the receipt of all necessary information or the expiration of the deadline for providing information, the time frames for issuer determination and notification must be no less favorable than federal Department of Labor standards, and are as follows:

(i) For urgent care review requests:

(A) Must approve the request within 48 hours if the information provided is sufficient to approve the claim and include the authorization number in its approval;

(B) Must deny the request within 48 hours if the requested service is not medically necessary and the information provided is sufficient to deny the claim; or

(C) Within 24 hours, if the information provided is not sufficient to approve or deny the claim, the issuer must request that the provider submits additional information to make the prior authorization determination.

(I) The issuer must give the provider 48 hours to submit the requested information;

(II) The issuer must then approve or deny the request within 48 hours of the receipt of the requested additional information and include the authorization number in its approval;

(ii) For nonurgent care review requests:

(A) Must approve the request within five calendar days if the information is sufficient to approve the claim and include the authorization number in its approval;

(B) Must deny the request within five calendar days if the requested service is not medically necessary and the information provided is sufficient to deny the claim; or

(C) Within five calendar days, if the information provided is not sufficient to approve or deny the claim, the issuer must

request that the provider submits additional information to make the prior authorization determination:

(I) The issuer must give the provider five calendar days to submit the requested additional information;

(II) The issuer must then approve or deny the request within four calendar days of the receipt of the additional information and include the authorization number in its approval.

(b) Notification of the prior authorization determination must be provided as follows:

(i) Information about whether a request was approved must be made available to the provider.

(ii) Whenever there is an adverse determination resulting in a denial the issuer must notify the requesting provider by one or more of the following methods; phone, fax and/or secure electronic notification, and the covered person in writing or via secure electronic notification. Status information will be communicated to the billing pharmacy, via electronic transaction, upon the issuer’s receipt of a claim after the request has been denied. The issuer must transmit these notifications within the timeframes specified in subsections (5)(a)(i) and (5)(a)(ii) of this section in compliance with United States Department of Labor standards.

(6) No issuer may penalize or threaten a pharmacist or pharmacy with a reduction in future payment or termination of participating provider or participating facility status because the pharmacist or pharmacy disputes the issuer's determination with respect to coverage or payment for pharmacy service.

WAC 284-43-818 Formulary changes. ((~~A carrier~~)) An issuer is not required to use a formulary as part of its prescription drug benefit design. If a formulary is used, ((~~a carrier~~)) an issuer must, at a minimum, comply with these requirements when a formulary change occurs.

(1) In addition to the requirements set forth in WAC 284-30-450, ((~~a carrier~~)) an issuer must not exclude or remove a medication from its formulary if the medication is the sole prescription medication option available to treat a disease or condition for which the health benefit plan, policy or agreement otherwise provides coverage, unless the medication or drug is removed because the drug or medication becomes available over-the-counter, is proven to be medically ineffacious, or for documented medical risk to patient health.

(2) If a drug is removed from ((~~a carrier's~~)) an issuer's formulary for a reason other than withdrawal of the drug from the market,

availability of the drug over-the-counter, or the issue of black box warnings by the Federal Drug Administration, ((~~a carrier~~)) an issuer must continue to cover a drug that is removed from the ((~~carrier's~~)) issuer's formulary for the time period required for an enrollee who is taking the medication at the time of the formulary change to use ((~~a carrier's~~)) an issuer's substitution process to request continuation of coverage for the removed medication, and receive a decision through that process, unless patient safety requires swifter replacement.

(3) Formularies and related pre-authorization information must be posted on ((~~a carrier~~)) an issuer or ((~~carrier's~~)) issuer's contracted pharmacy benefit manager web site and must be current. Unless the removal is done on an immediate or emergency basis or because a generic equivalent becomes available without prior notice, formulary changes must be posted thirty days before the effective date of the change. In the case of an emergency removal, the change must be posted as soon as practicable, without unreasonable delay.(4) An issuer must make current formulary information electronically available for loading into e-prescribing applications/electronic health records utilizing the National Council for Prescription Drug Programs (NCPDP) formulary and benefit standard transaction. Issuers must include all required data

elements as well as the following information, to the extent supported by the transaction:

(i) Tier level;

(ii) Contract exclusions;

(iii) Quantity limits;

(iv) Pre-authorization required;

(v) Preferred/step therapy.