Chapter 182-530 WAC
PRESCRIPTION DRUGS (OUTPATIENT)

WAC

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WAC 182-530-1000 Outpatient drug program—General. (1) The purpose of the outpatient drug program is to reimburse providers for outpatient drugs, vitamins, minerals, devices, and drug-related supplies according to department rules and subject to the limitations and requirements in this chapter.

(2) The department reimburses for outpatient drugs, vitamins, minerals, devices, and pharmaceutical supplies that are:

(a) Covered. Refer to WAC 388-530-2000 for covered drugs, vitamins, minerals, devices, and drug-related supplies and to WAC 388-530-2100 for noncovered drugs and drug-related supplies;

(b) Prescribed by a provider with prescriptive authority (see exceptions for family planning and emergency contraception for women eighteen years of age and older in WAC 388-530-2000 (1)(b), and over-the-counter (OTC) drugs to promote smoking cessation in WAC 388-530-2000 (1)(g);

(c) Within the scope of an eligible client's medical assistance program;

(d) Medically necessary as defined in WAC 388-500-0005 and determined according to the process found in WAC 388-501-0165; and

(e) Authorized, as required within this chapter;

(f) Billed according to WAC 388-502-0150 and 388-502-0160; and

(g) Billed according to the requirements of this chapter.

(3) Coverage determinations for the department are made by the department's pharmacists or medical consultants in accordance with applicable federal law. The department's determination may include consultation with the drug use review (DUR) board.

(4) The department may not reimburse for prescriptions written by health care practitioners whose application for a core provider agreement (CPA) has been denied, or whose CPA has been terminated.

(5) The department may not reimburse for prescriptions written by non-CPA health care practitioners who do not have a current core provider agreement with the department when the department determines there is a potential danger to the client's health and/or safety.

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WAC 182-530-1050 Definitions. In addition to the definitions and abbreviations found in chapter 182-500 WAC, Medical definitions, the following definitions apply to this chapter.

"Active ingredient" - The chemical component of a drug responsible for a drug's prescribed/intended therapeutic

effect. The medicaid agency or its designee limits coverage of active ingredients to those with an eleven-digit national drug code (NDC) and those specifically authorized by the agency or its designee.

"Actual acquisition cost (AAC)" - The net cost a provider paid for a drug, device, or drug-related supply marketed in the package size purchased. The AAC includes discounts, rebates, charge backs and other adjustments to the price of the drug, device or drug-related supply, but excludes dispensing fees.

"Administer" - Includes the direct application of a prescription drug or device by injection, insertion, inhalation, ingestion, or any other means, to the body of a patient by a practitioner, or at the direction of the practitioner.

"Appointing authority" - For the evidence-based prescription drug program of the participating agencies in the state-operated health care programs, the following persons acting jointly: The director of the health care authority (HCA), the secretary of the department of social and health services (DSHS), and the director of the department of labor and industries (L&I).

"Automated authorization" - Adjudication of claims using submitted NCPDP data elements or claims history to verify that the medicaid agency's or its designee's authorization requirements have been satisfied without the need for the medicaid agency or its designee to request additional clinical information.

"Automated maximum allowable cost (AMAC)" - The rate established by the medicaid agency or its designee for a multiple-source drug that is not on the maximum allowable cost (MAC) list and that is designated by two or more products at least one of which must be under a federal drug rebate contract.

"Average manufacturer price (AMP)" - The average price paid to a manufacturer by wholesalers for drugs distributed to retail pharmacies.

"Average sales price (ASP)" - The weighted average of all nonfederal sales to wholesalers net of charge backs, discounts, rebates, and other benefits tied to the purchase of the drug product, whether it is paid to the wholesaler or the retailer.

"Average wholesale price (AWP)" - The average price of a drug product that is calculated from wholesale list prices nationwide at a point in time and reported to the medicaid agency or its designee by the agency's drug file contractor.

"Combination drug" - A commercially available drug including two or more active ingredients.

"Compendia of drug information" includes the following:

(1) The American Hospital Formulary Service Drug Information;

(2) The United States Pharmacopeia Drug Information; and

(3) DRUGDEX Information System.

"Compounding" - The act of combining two or more active ingredients or adjusting therapeutic strengths in the preparation of a prescription.

"Deliver or delivery" - The transfer of a drug or device from one person to another.

"Dispense as written (DAW)" - An instruction to the pharmacist forbidding substitution of a generic drug or a therapeutically equivalent product for the specific drug product prescribed.

"Dispensing fee" - The fee the medicaid agency or its designee sets to pay pharmacy providers for dispensing agency-covered prescriptions. The fee is the agency's maximum reimbursement for expenses involved in the practice of pharmacy and is in addition to the agency's reimbursement for the costs of covered ingredients.

"Drug evaluation matrix" - The criteria-based scoring sheet used to objectively and consistently evaluate the food and drug administration (FDA) approved drugs to determine drug coverage status.

"Drug file" - A list of drug products, pricing and other information provided to the medicaid agency or its designee and maintained by a drug file contractor.

"Drug file contractor" - An entity which has been contracted to provide regularly updated information on drugs, devices, and drug-related supplies at specified intervals, for the purpose of pharmaceutical claim adjudication. Information is provided specific to individual national drug codes, including product pricing.

"Drug rebates" - Reimbursements provided by pharmaceutical manufacturers to state medicaid programs under the terms of the manufacturers' agreements with the Department of Health and Human Services (DHHS).

"Drug-related supplies" - Nondrug items necessary for the administration, delivery, or monitoring of a drug or drug regimen.

"Drug use review (DUR)" - A review of covered outpatient drug use that assures prescriptions are appropriate, medically necessary, and not likely to result in adverse medical outcomes.

"Effectiveness" - The extent to which a given intervention is likely to produce beneficial results for which it is intended in ordinary circumstances.

"Efficacy" - The extent to which a given intervention is likely to produce beneficial effects in the context of the research study.

"Emergency kit" - A set of limited pharmaceuticals furnished to a nursing facility by the pharmacy that provides prescription dispensing services to that facility. Each kit is specifically set up to meet the emergency needs of each nursing facility's client population and is for use during those hours when pharmacy services are unavailable.

"Endorsing practitioner" - A practitioner who has reviewed the Washington preferred drug list (PDL) and has enrolled with the health care authority (HCA), agreeing to allow therapeutic interchange (substitution) of a preferred drug for any nonpreferred drug in a given therapeutic class on the Washington PDL.

"Estimated acquisition cost (EAC)" - The medicaid agency's estimate of the price providers generally and currently pay for a drug marketed or sold by a particular manufacturer or labeler.

"Evidence-based" and **"evidenced-based medicine (EBM)" -** The application of a set of principles and a method for the review of well-designed studies and objective clinical data to determine the level of evidence that proves to the greatest extent possible, that a health care service is safe, effective and beneficial when making population-based coverage policies or individual medical necessity decisions.

"Evidence-based practice center" - A research organization that has been designated by the Agency for Healthcare Research and Quality (AHRQ) of the U.S. government to conduct systematic reviews of all the evidence to produce evidence tables and technology assessments to guide health care decisions.

"Federal upper limit (FUL)" - The maximum allowable reimbursement set by the Centers for Medicare and Medicaid Services (CMS) for a multiple-source drug.

"Formulary" - All drugs covered under WAC 182-530-2000 and not removed from the formulary by the DUR board (see WAC 182-530-2200).

"Formulary drug" - A drug covered under WAC 182-530-2000 and not removed from the formulary by the DUR board with respect to the treatment of a specific disease or condition for an identified population (see WAC 182-530-2200).

"Four brand name prescriptions per calendar month limit" - The maximum number of paid prescription claims for brand name drugs that the medicaid agency or its designee allows for each client in a calendar month without a complete review of the client's drug profile.

"Generic drug" - A nonproprietary drug that is required to meet the same bioequivalency tests as the original brand name drug.

"Inactive ingredient" - A drug component that remains chemically unchanged during compounding but serves as the:

(1) Necessary vehicle for the delivery of the therapeutic effect; or

(2) Agent for the intended method or rate of absorption for the drug's active therapeutic agent.

"Ingredient cost" - The portion of a prescription's cost attributable to the covered drug ingredients or chemical components.

"Innovator multiple source drug" - As set forth in Section 1927 (k)(7)(A)(ii) of the Social Security Act, includes all covered outpatient drugs approved under a new drug application (NDA), product license approval (PLA), establishment license approval (ELA), or antibiotic drug approval (ADA). A covered outpatient drug marketed by a cross-licensed producer or distributor under the approved new drug application will be included as an innovator multiple source drug when the drug product meets this definition.

"Less than effective drug" or **"DESI" -** A drug for which:

(1) Effective approval of the drug application has been withdrawn by the Food and Drug Administration (FDA) for safety or efficacy reasons as a result of the drug efficacy study implementation (DESI) review; or

(2) The secretary of the Department of Health and Human Services (DHHS) has issued a notice of an opportunity for a hearing under section 505(e) of the federal Food, Drug, and Cosmetic Act on a proposed order of the secretary to withdraw approval of an application for such drug under such section because the secretary has determined the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling.

"Long-term therapy" - A drug regimen a client receives or will receive continuously through and beyond ninety days.

"Maximum allowable cost (MAC)" - The maximum amount that the medicaid agency or its designee reimburses for a drug, device, or drug-related supply.

"Medically accepted indication" - Any use for a covered outpatient drug:

(1) Which is approved under the federal Food, Drug, and Cosmetic Act; or

(2) The use of which is supported by one or more citations included or approved for inclusion in any of the compendia of drug information, as defined in this chapter.

"Modified unit dose delivery system" (also known as blister packs or "bingo/punch cards") - A method in which each patient's medication is delivered to a nursing facility:

(1) In individually sealed, single dose packages or "blisters"; and

(2) In quantities for one month's supply, unless the prescriber specifies a shorter period of therapy.

"Multiple-source drug" - A drug marketed or sold by:

(1) Two or more manufacturers or labelers; or

(2) The same manufacturer or labeler:

(a) Under two or more different proprietary names; or

(b) Under a proprietary name and a generic name.

"National drug code (NDC)" - The eleven-digit number the FDA and manufacturer or labeler assigns to a pharmaceutical product and attaches to the product container at the time of packaging. The NDC is composed of digits in 5-4-2 groupings. The first five digits comprise the labeler code assigned to the manufacturer by the Food and Drug Administration (FDA). The second grouping of four digits is assigned by the manufacturer to describe the ingredients, dose form, and strength. The last grouping of two digits describes the package size.

"Noncontract drugs" - Are drugs manufactured or distributed by manufacturers/labelers who have not signed a drug rebate agreement with the federal Department of Health and Human Services.

"Nonformulary drug" - A drug:

(a) Removed from the formulary by the DUR board with respect to treatment of a specific disease or condition for an identified population (see WAC 182-530-2200);

(b) Prescribed for the treatment of the specific disease or condition identified in (a) of this definition nonformulary drug;

(c) Prescribed for a client in the identified population in (a) of this definition nonformulary drug; and

(d) Included on the agency's nonformulary list with a written explanation of the basis for the drug's removal from the formulary.

"Nonformulary justification" or **"NFJ" -** See WAC 182-530-2300.

"Nonformulary list" - The agency's list of nonformulary drugs and the reasons for removal from the formulary by the DUR board.

"Nonpreferred drug" - A drug that has not been selected as a preferred drug within the therapeutic class(es) of drugs on the preferred drug list.

"Obsolete NDC" - A national drug code replaced or discontinued by the manufacturer or labeler.

"Over-the-counter (OTC) drugs" - Drugs that do not require a prescription before they can be sold or dispensed.

"Peer reviewed medical literature" - A research study, report, or findings regarding the specific use of a drug that has been submitted to one or more professional journals, reviewed by experts with appropriate credentials, and subsequently published by a reputable professional journal. A clinical drug study used as the basis for the publication must be a double blind, randomized, placebo or active control study.

"Pharmacist" - A person licensed in the practice of pharmacy by the state in which the prescription is filled.

"Pharmacy" - Every location licensed by the state board of pharmacy in the state where the practice of pharmacy is conducted.

"Pharmacy and therapeutic (P&T) committee" - The independent Washington state committee created by RCW 41.05.021 (1)(a)(iii) and 70.14.050. At the election of the medicaid agency or its designee, the committee may serve as the drug use review board provided for in WAC 182-530-4000.

"Point-of-sale (POS)" - A pharmacy claims processing system capable of receiving and adjudicating claims online.

"Practice of pharmacy" - The practice of and responsibility for:

(1) Accurately interpreting prescription orders;

(2) Compounding drugs;

(3) Dispensing, labeling, administering, and distributing of drugs and devices;

(4) Providing drug information to the client that includes, but is not limited to, the advising of therapeutic values, hazards, and the uses of drugs and devices;

(5) Monitoring of drug therapy and use;

(6) Proper and safe storage of drugs and devices;

(7) Documenting and maintaining records;

(8) Initiating or modifying drug therapy in accordance with written guidelines or protocols previously established and approved for a pharmacist's practice by a practitioner authorized to prescribe drugs; and

(9) Participating in drug use reviews and drug product selection.

"Practitioner" - An individual who has met the professional and legal requirements necessary to provide a health care service, such as a physician, nurse, dentist, physical therapist, pharmacist or other person authorized by state law as a practitioner.

"Preferred drug" - Drug(s) of choice within a selected therapeutic class that are selected based on clinical evidence of safety, efficacy, and effectiveness.

"Preferred drug list (PDL)" - The medicaid agency's list of drugs of choice within selected therapeutic drug classes.

"Prescriber" - A physician, osteopathic physician/surgeon, dentist, nurse, physician assistant, optometrist, pharmacist, or other person authorized by law or rule to prescribe drugs. See WAC 246-863-100 for pharmacists' prescriptive authority.

"Prescription" - An order for drugs or devices issued by a practitioner authorized by state law or rule to prescribe drugs or devices, in the course of the practitioner's professional practice, for a legitimate medical purpose.

"Prescription drugs" - Drugs required by any applicable federal or state law or regulation to be dispensed by prescription only or that are restricted to use by practitioners only.

"Prospective drug use review (Pro-DUR)" - A process in which a request for a drug product for a particular client is screened, before the product is dispensed, for potential drug therapy problems.

"Reconstitution" - The process of returning a single active ingredient, previously altered for preservation and storage, to its approximate original state. Reconstitution is not compounding.

"Retrospective drug use review (Retro-DUR)" - The process in which drug utilization is reviewed on an ongoing periodic basis to identify patterns of fraud, abuse, gross overuse, or inappropriate or not medically necessary care.

"Risk/benefit ratio" - The result of assessing the side effects of a drug or drug regimen compared to the positive therapeutic outcome of therapy.

"Single source drug" - A drug produced or distributed under an original new drug application approved by the Food and Drug Administration (FDA).

"Substitute" - To replace a prescribed drug, with the prescriber's authorization, with:

(1) An equivalent generic drug product of the identical base or salt as the specific drug product prescribed; or

(2) A therapeutically equivalent drug other than the identical base or salt.

"Systematic review" - A specific and reproducible method to identify, select, and appraise all the studies that meet minimum quality standards and are relevant to a particular question. The results of the studies are then analyzed and summarized into evidence tables to be used to guide evidence-based decisions.

"Terminated NDC" - An eleven-digit national drug code (NDC) that is discontinued by the manufacturer for any reason. The NDC may be terminated immediately due to health or safety issues or it may be phased out based on the product's shelf life.

"Therapeutic alternative" - A drug product that contains a different chemical structure than the drug prescribed, but is in the same pharmacologic or therapeutic class and can be expected to have a similar therapeutic effect and adverse reaction profile when administered to patients in a therapeutically equivalent dosage.

"Therapeutic class" - A group of drugs used for the treatment, remediation, or cure of a specific disorder or disease.

"Therapeutic interchange" - To dispense a therapeutic alternative to the prescribed drug when an endorsing practitioner who has indicated that substitution is permitted, prescribes the drug. See therapeutic interchange program (TIP).

"Therapeutic interchange program (TIP)" - The process developed by participating state agencies under RCW 69.41.190 and 70.14.050, to allow prescribers to endorse a Washington preferred drug list, and in most cases, requires pharmacists to automatically substitute a preferred, equivalent drug from the list.

"Therapeutically equivalent" - Drug products that contain different chemical structures but have the same efficacy and safety when administered to an individual, as determined by:

(1) Information from the Food and Drug Administration (FDA);

(2) Published and peer-reviewed scientific data;

(3) Randomized controlled clinical trials; or

(4) Other scientific evidence.

"Tiered dispensing fee system" - A system of paying pharmacies different dispensing fee rates, based on the individual pharmacy's total annual prescription volume and/or the drug delivery system used.

"True unit dose delivery" - A method in which each patient's medication is delivered to the nursing facility in quantities sufficient only for the day's required dosage.

"Unit dose drug delivery" - True unit dose or modified unit dose delivery systems.

"Usual and customary charge" - The fee that the provider typically charges the general public for the product or service.

"Washington preferred drug list (Washington PDL)" - The list of drugs selected by the appointing authority to be used by applicable state agencies as the basis for purchase of drugs in state-operated health care programs.

"Wholesale acquisition cost" - The price paid by a wholesaler for drugs purchased from a manufacturer.

[Statutory Authority: RCW 41.05.021 and section 1927 of the Social Security Act. 12-18-062, § 182-530-1050, filed 8/31/12, effective 10/1/12. 11-14-075, recodified as § 182-530-1050, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.700, 2008 c 245. 08-21-107, § 388-530-1050, filed 10/16/08, effective 11/16/08. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. 07-20-049, § 388-530-1050, filed 9/26/07, effective 11/1/07. Statutory Authority: RCW 74.08.090, 70.14.050, 69.41.150, 69.41.190, chapter 41.05 RCW. 05-02-044, § 388-530-1050, filed 12/30/04, effective 1/30/05. Statutory Authority: RCW 74.09.080, 74.04.050 and 42 C.F.R. Subpart K, subsection 162.1102. 02-17-023, § 388-530-1050, filed 8/9/02, effective 9/9/02. Statutory Authority: RCW 74.08.090, 74.04.050. 01-24-066, § 388-530-1050, filed 11/30/01, effective 1/2/02; 01-01-028, § 388-530-1050, filed 12/7/00, effective 1/7/01. Statutory Authority: RCW 74.08.090. 96-21-031, § 388-530-1050, filed 10/9/96, effective 11/9/96.]

WAC 182-530-1075 Requirements—Use of tamper-resistant prescription pads. (1) The department requires providers to use tamper-resistant prescription pads or paper for written outpatient prescriptions, including over-the-counter drugs, for medical assistance clients.

(2) This requirement applies to all outpatient prescription drugs including:

(a) Prescriptions when medicaid is primary or secondary payer (including medicare Part D prescriptions).

(b) Signed hardcopy prescriptions given to a client, whether handwritten or computer-generated.

(3) This requirement does not apply to:

(a) Prescriptions paid for by Washington's healthy options (HO) program or other department contracted managed care organizations.

(b) Prescription drugs that are part of the per diem or bundled rate and not reimbursed separately in designated institutional or clinical settings, such as a nursing facility, ICF/MR, dental office, hospice, or radiology. For example, a morphine prescription used to control a hospice client's cancer pain is covered under the hospice per diem rate and therefore the tamper-resistant prescription requirement is not required.

(c) Telephone, fax or electronic prescriptions.

(d) Refill prescriptions, if the original written prescriptions were presented at a pharmacy before April 1, 2008.

(e) Prescriber or clinic drug samples given directly to the client.

(f) An institutional setting, as defined in WAC 388-500-0005, where the prescriber writes the order into the medical records and the orders go directly to the pharmacy.

(4) Effective April 1, 2008, the tamper-resistant prescription pads and paper must meet at least one of the following industry recognized characteristics:

(a) One or more features designed to prevent unauthorized copying of a completed or blank prescription form;

(b) One or more features designed to prevent the erasure or modification of information written on the prescription by the prescriber; or

(c) One or more features designed to prevent the use of counterfeit prescription forms.

(5) Effective October 1, 2008, the tamper-resistant prescription pads and paper must contain all of the three characteristics in subsection (4) of this section.

(6) If the written prescription is not on tamper-resistant paper, the pharmacy may provide the prescription on an emergency basis. The pharmacy must verify the prescription with the prescriber by telephone, fax, or electronic communication, or by physical receipt of a tamper-resistant written prescription within seventy-two hours of filling the prescription.

(7) Federal controlled substance laws on controlled substances apply when prescribing or dispensing schedule II drugs.

(8) Record retention requirements (WAC 388-502-0020) remain in effect. Additional documentation is required as follows:

(a) Documentation by the pharmacy of verbal confirmation of a noncompliant written prescription.

(b) Documentation by the pharmacy of verbal confirmation about the authenticity of the tamper-resistant prescription.

(9) To submit a claim for a medicaid client retroactively certified for medicaid, the following applies:

(a) The prescription must meet the tamper-resistant compliance requirement.

(b) Refills that occur after the date on which the client is determined to be eligible require a new, tamper-resistant prescription in compliance with this WAC.

(c) If the original order is not compliant with subsection (4) of this section, the pharmacy must obtain a verbal, faxed, or email confirmation of the prescription from the prescriber.

(d) The pharmacy must reimburse the client in accordance with WAC 388-502-0160.

(10) The pharmacy accepting a prescription transfer from another pharmacy must confirm the authenticity of the prescription by telephone or facsimile from the transferring pharmacy.

[11-14-075, recodified as § 182-530-1075, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.08.090, 74.04.050, 74.04.057, 74.09.500 and Section 1903(i) of the Social Security Act (42 U.S.C. Section 1936b (i)(23)); Section 7002(b), U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act, 2007 (Pub.L. 110-28). 08-07-048, § 388-530-1075, filed 3/14/08, effective 4/14/08.]

COVERAGE

WAC 182-530-2000 Covered—Outpatient drugs, devices, and drug-related supplies. (1) The department covers:

(a) Outpatient drugs, including over-the-counter drugs, as defined in WAC 388-530-1050, subject to the limitations and requirements in this chapter, when:

(i) The drug is approved by the Food and Drug Administration (FDA);

(ii) The drug is for a medically accepted indication as defined in WAC 388-530-1050;

(iii) The drug is not excluded from coverage under WAC 388-530-2100;

(iv) The manufacturer has a signed drug rebate agreement with the federal Department of Health and Human Services (DHHS). Exceptions to the drug rebate requirement are described in WAC 388-530-7500 which describes the drug rebate program; and

(v) Prescribed by a provider with prescriptive authority (see exceptions for family planning and emergency contraception for women eighteen years of age and older in WAC 388-530-2000 (1)(b), and over-the-counter (OTC) drugs to promote smoking cessation in WAC 388-530-2000 (1)(g).

(b) Family planning drugs, devices, and drug-related supplies per chapter 388-532 WAC and as follows:

(i) Over-the-counter (OTC) family planning drugs, devices, and drug-related supplies without a prescription when the department determines it necessary for client access and safety.

(ii) Family planning drugs that do not meet the federal drug rebate requirement in WAC 388-530-7500 on a case-by-case basis; and

(iii) Contraceptive patches, contraceptive rings, and oral contraceptives, only when dispensed in at least a three-month supply, unless otherwise directed by the prescriber. There is no required minimum for how many cycles of emergency contraception may be dispensed.

(c) Prescription vitamins and mineral products, only as follows:

(i) When prescribed for clinically documented deficiencies;

(ii) Prenatal vitamins, when prescribed and dispensed to pregnant women; or

(iii) Fluoride prescribed for clients under the age of twenty-one.

(d) OTC drugs, vitamins, and minerals when determined by the department to be the least costly therapeutic alternative for a medically accepted indication. The department will maintain and publish a list of the covered OTC drugs available to clients which have been determined to be the least costly therapeutic alternatives for medically accepted indications. Subsection (1)(d) does not apply to products prescribed for the treatment of cough or cold symptoms. See WAC 388-530-2000 (1)(i) and 388-530-2100 (1)(b)(v) for coverage of products prescribed for the treatment of cough and cold symptoms.

(e) Drug-related devices and drug-related supplies as an outpatient pharmacy benefit when:

(i) Prescribed by a provider with prescribing authority;

(ii) Essential for the administration of a covered drug;

(iii) Not excluded from coverage under WAC 388-530-2100; and

(iv) Determined by the department, that a product covered under chapter 388-543 WAC Durable medical equipment and supplies should be available at retail pharmacies.

(f) Preservatives, flavoring and/or coloring agents, only when used as a suspending agent in a compound.

(g) Over-the-counter (OTC) drugs, without a prescription, to promote smoking cessation only for clients who are eighteen years of age or older and participating in a department-approved smoking cessation program. Limitation extensions as described in WAC 388-501-0169 are prohibited for the age and counseling requirements in this section.

(h) Prescription drugs to promote smoking cessation only for clients who are eighteen years of age or older and participating in a department-approved smoking cessation program. Limitation extensions as described in WAC 388-501-0169 are prohibited for the age and counseling requirements in this section.

(i) For the treatment of cough and cold symptoms:

(i) Only the following generic, single ingredient formulations:

(A) Guaifenesin 100 mg/5 ml liquid or syrup;

(B) Dextromethorphan 15 mg/5 ml liquid or syrup;

(C) Pseudoephedrine 30 mg or 60 mg tablets;

(D) Saline nasal spray 0.65%; and

(ii) Generic combination product dextromethorphan-guaifenesin 10-100 mg/5 ml syrup, including sugar-free formulations.

(2) The department does not reimburse for any drug, device, or drug-related supply not meeting the coverage requirements under this section.

[11-14-075, recodified as § 182-530-2000, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.04.050, 74.08.090, SSA § 1927 (42 U.S.C. 1396r-8(d)(2)(D)), and 2009 c 564 § 1109. 09-22-005, § 388-530-2000, filed 10/22/09, effective 11/22/09. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. 09-05-007, § 388-530-2000, filed 2/5/09, effective 3/8/09. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.700, 2008 c 245. 08-21-107, § 388-530-2000, filed 10/16/08, effective 11/16/08. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. 07-20-049, § 388-530-2000, filed 9/26/07, effective 11/1/07.]

WAC 182-530-2100 Noncovered—Outpatient drugs and pharmaceutical supplies. (1) The medicaid agency does not cover:

(a) A drug that is:

(i) Not approved by the Food and Drug Administration (FDA); or

(ii) Prescribed for a nonmedically accepted indication, including diagnosis, dose, or dosage schedule that is not evidenced-based.

(b) A drug prescribed:

(i) For weight loss or gain;

(ii) For infertility, frigidity, impotency;

(iii) For sexual or erectile dysfunction;

(iv) For cosmetic purposes or hair growth; or

(v) For treatment of cough or cold symptoms, except as listed in WAC 182-530-2000 (1)(i).

(c) Drugs used to treat sexual or erectile dysfunction, in accordance with section 1927 (d)(2)(K) of the Social Security Act, unless such drugs are used to treat a condition other than

sexual or erectile dysfunction, and these uses have been approved by the Food and Drug Administration.

(d) Drugs listed in the federal register as "less-than-effective" ("DESI" drugs) or which are identical, similar, or related to such drugs.

(e) Outpatient drugs for which the manufacturer requires as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or manufacturer's designee.

(f) A product:

(i) With an obsolete national drug code (NDC) for more than two years;

(ii) With a terminated NDC;

(iii) Whose shelf life has expired; or

(iv) Which does not have an eleven-digit NDC.

(g) Over-the-counter (OTC) drugs, vitamins, and minerals, except as allowed under WAC 182-530-2000 (1)(i).

(h) Any drug regularly supplied by other public agencies as an integral part of program activity (e.g., immunization vaccines for children).

(i) Free pharmaceutical samples.

(j) Over-the-counter or prescription drugs to promote smoking cessation unless the client is eighteen years old or older and participating in a medicaid agency-approved cessation program.

(k) A nonformulary drug except as allowed by WAC 182-530-2300(4).

(2) A noncovered drug can be requested:

(a) As described in WAC 182-530-2300 for a nonformulary drug; or

(b) As described in WAC 182-501-0160 for all other noncovered drugs.

(3) If a noncovered drug is prescribed through the early and periodic screening, diagnosis, and treatment (EPSDT) process, an authorization request may be submitted indicating that the request is EPSDT related, and the request will be evaluated according to the process in WAC 182-501-0165. (See WAC 182-534-0100 for EPSDT rules).

[Statutory Authority: RCW 41.05.021 and section 1927 of the Social Security Act. 12-18-062, § 182-530-2100, filed 8/31/12, effective 10/1/12. 11-14-075, recodified as § 182-530-2100, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.04.050, 74.08.090, SSA § 1927 (42 U.S.C. 1396r-8(d)(2)(D)), and 2009 c 564 § 1109. 09-22-005, § 388-530-2100, filed 10/22/09, effective 11/22/09. Statutory Authority: RCW 74.04.050, 74.08.-090, 74.09.530, and 74.09.700. 09-05-007, § 388-530-2100, filed 2/5/09, effective 3/8/09. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.-700, 2008 c 245. 08-21-107, § 388-530-2100, filed 10/16/08, effective 11/16/08. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. 07-20-049, § 388-530-2100, filed 9/26/07, effective 11/1/07.]

WAC 182-530-2200 How the medicaid agency develops and maintains the formulary. The medicaid agency maintains a formulary developed by the state's drug use review (DUR) board (see WAC 182-530-4000) for the purpose of providing clients access to clinically appropriate, cost-effective pharmaceutical options to treat their medical conditions.

(1) The formulary includes all drugs covered under WAC 182-530-2000 and not removed from the formulary by the DUR board according to the process described in subsection (2) of this section.

(2) The agency periodically presents drugs labeled by the food and drug administration (FDA) for treatment of a specific disease or condition for an identified population, or which have a medically accepted indication for the treatment of the specific disease or condition to the DUR board for review. The following categories of drugs cannot be presented by the agency to the DUR board for review:

(a) Antiretroviral drugs used to treat HIV/AIDS;

(b) Anticancer medication used to kill or slow the growth of cancerous cells;

(c) Antihemophilic drugs;

(d) Insulin or other drugs to lower blood glucose;

(e) Immunosuppressive drugs;

(f) Drugs in therapeutic classes included in the Washington preferred drug list.

(3) If a drug is found by the DUR board to have no significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome for treatment of a specific disease or condition for an identified population over other drugs on the formulary, the drug may be removed from the formulary for treatment of the specific disease or condition for the identified population, provided that the DUR board's written explanation of the basis for removal is made available to the public.

(4) At the DUR board's discretion, nonformulary drugs may be added back to the formulary.

(5) At the DUR board's discretion, a drug removed from the formulary for a specified indication or subpopulation will remain covered for clients already stable on the medication at the time the drug is removed from the formulary.

(6) The agency maintains a nonformulary list on a publicly accessible internet site detailing the:

(a) Nonformulary drugs;

(b) Specific disease or condition for an identified population for which the drug is nonformulary; and

(c) DUR board's written explanation of the basis for the drug's removal from the formulary.

(7) Formulary drugs may be subject to authorization requirements and other restrictions detailed in this chapter.

(8) The agency covers nonformulary drugs for specific clients for the treatment of a specific disease or condition according to the nonformulary justification process defined in WAC 182-530-2300.

(9) If a dispensing pharmacist makes a professional judgment that the client's need for a nonformulary drug is an emergency, the pharmacist may dispense a nonformulary drug without approval through the nonformulary justification (NFJ) process defined in WAC 182-530-2300. The agency will reimburse for the dispensed medication if justification for the emergency is provided to the agency within seventy-two hours of the date of dispense, excluding weekends and Washington state holidays.

(10) The nonformulary status of a drug does not constitute a denial of service.

[Statutory Authority: RCW 41.05.021 and section 1927 of the Social Security Act. 12-18-062, § 182-530-2200, filed 8/31/12, effective 10/1/12.]

WAC 182-530-2300 The medicaid agency's nonformulary justification process. A client's prescriber or the client with the assistance of the prescriber may request the agency cover a nonformulary drug for the specific client for

the treatment of a specific disease or condition. This process is called a nonformulary justification (NFJ).

(1) The medicaid agency only reviews a request for a noncovered service as an NFJ when:

(a) The NFJ is submitted by the prescriber on the form provided by the agency;

(b) The drug is a nonformulary drug; and

(c) The NFJ conforms with the agency's minimum requirements in current published billing instructions, numbered memoranda, provider notices, and any additional requirements in the Washington Administrative Code (WAC) and/or Revised Code of Washington (RCW).

(2) The agency approves, on a case-by-case basis, an NFJ when the agency determines the drug is medically necessary as defined in WAC 182-500-0070. The process the agency uses to assess whether a nonformulary drug is medically necessary is based on evaluation of submitted client-specific information and documentation establishing:

(a) The client's clinical condition is different from the majority of individuals with the same or similar diagnosis whose treatment needs are met within the scope of covered services;

(b) Medical treatment, items of service, and all formulary drugs covered under the client's medical assistance program and which, under accepted standards of medical practice, are indicated as appropriate for the treatment of the illness or condition, have been found to be:

(i) Medically ineffective in the treatment of the client's condition after an adequate trial at the maximum dose approved by the FDA; or

(ii) Medically inappropriate for that specific client.

(c) The requested nonformulary drug can be reasonably expected to successfully treat or improve the client's function and the condition the nonformulary drug is prescribed to treat when other treatments, items of service, and all formulary outpatient drugs covered under the client's medical assistance program have proven to be medically ineffective or inappropriate for the client.

(3)(a) When the agency receives a request for an NFJ, the agency acknowledges receipt within:

(i) Twenty-four hours if the NFJ is received during normal state business hours; or

(ii) Twenty-four hours of opening for business on the next business day if the NFJ is received outside normal state business hours.

(b) Within five business days the agency:

(i) Approves the NFJ if the requested nonformulary drug is medically necessary according to subsection (2) of this section; or

(ii) Denies the NFJ if the requested nonformulary drug is not medically necessary according to subsection (2) of this section; and

(iii) Sends written notification to the client and a facsimile to the client's prescriber of the agency's determination.

(c) The agency's pharmacists or medical consultants have final authority of approval or denial of the NFJ.

(4) Nonformulary drugs which meet all other conditions of coverage with the exception of their nonformulary status are covered services for the specific client for the treatment of a specific disease or condition when approved under subsection (3) of this section.

(5) A client has the right to request an administrative hearing on NFJ denials.

(6) Drugs determined to be noncovered according to WAC 182-530-2100 (1)(a) through (j) will be reviewed according to the exception to rule (ETR) process in WAC 182-501-0160.

[Statutory Authority: RCW 41.05.021 and section 1927 of the Social Security Act. 12-18-062, § 182-530-2300, filed 8/31/12, effective 10/1/12.]

AUTHORIZATION

WAC 182-530-3000 When the department requires authorization. Pharmacies must obtain authorization for covered drugs, devices, or drug-related supplies in order to receive reimbursement as described in this section.

(1) The department's pharmacists and medical consultants:

(a) Have determined that authorization for the drug, device, or drug-related supply is required, as described in WAC 388-530-3100; or

(b) Have not yet reviewed the manufacturer's dossier of drug information submitted in the Academy of Managed Care Pharmacy (AMCP) format.

(2) The drug, device, or drug-related supply is in the therapeutic drug class on the Washington preferred drug list and the product is one of the following:

(a) Nonpreferred as described in WAC 388-530-4100; and

(i) The prescriber is a nonendorsing practitioner; or

(ii) The drug is designated as exempt from the therapeutic interchange program per WAC 388-530-4100(6) or 388-530-4150 (2)(c);

(b) Preferred for a special population or specific indication and has been prescribed by a nonendorsing practitioner under conditions for which the drug, device, or drug-related supply is not preferred; or

(c) Determined to require authorization for safety.

(3) For the purpose of promoting safety, efficacy, and effectiveness of drug therapy, the department identifies clients or groups of clients who would benefit from further clinical review.

(4) The department designates the prescriber(s) as requiring authorization because the prescriber(s) is under department review or is sanctioned for substandard quality of care.

(5) Utilization data indicate there are health and safety concerns or the potential for misuse and abuse. Examples of utilization concerns include:

(a) Multiple prescriptions filled of the same drug in the same calendar month;

(b) Prescriptions filled earlier than necessary for optimal therapeutic response;

(c) Therapeutic duplication;

(d) Therapeutic contraindication;

(e) Excessive dosing, excessive duration of therapy, or subtherapeutic dosing as determined by FDA labeling or the compendia of drug information; and

(f) Number of prescriptions filled per month in total or by therapeutic drug class.

(6) The pharmacy requests reimbursement in excess of the maximum allowable cost and the drug has been prescribed with instructions to dispense as written.

[11-14-075, recodified as § 182-530-3000, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.700, 2008 c 245. 08-21-107, § 388-530-3000, filed 10/16/08, effective 11/16/08. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. 07-20-049, § 388-530-3000, filed 9/26/07, effective 11/1/07.]

WAC 182-530-3100 How the department determines when a drug requires authorization. (1) The department's pharmacists and medical consultants evaluate new covered drugs, new covered indications, or new dosages approved by the Food and Drug Administration (FDA) to determine the drug authorization requirement.

(a) The clinical team uses a drug evaluation matrix to evaluate and score the benefit/risk assessment and cost comparisons of drugs to similar existing drugs based on quality evidence contained in compendia of drug information and peer-reviewed medical literature.

(b) In performing this evaluation the clinical team may consult with other department clinical staff, financial experts, and program managers. The department may also consult with an evidence-based practice center, the drug use review (DUR) board, and/or medical experts in this evaluation.

(c) Information reviewed in the drug evaluation matrix includes, but is not limited to, the following:

(i) The drug, device, or drug-related supply's benefit/risk ratio;

(ii) Potential for clinical misuse;

(iii) Potential for client misuse/abuse;

(iv) Narrow therapeutic indication;

(v) Safety concerns;

(vi) Availability of less costly therapeutic alternatives; and

(vii) Product cost and outcome data demonstrating the drug, device, or drug-related supply's cost effectiveness.

(d) Based on the clinical team's evaluation and the drug evaluation matrix score, the department may determine that the drug, device, or drug-related supply:

(i) Requires authorization;

(ii) Requires authorization to exceed department established limitations; or

(iii) Does not require authorization.

(2) Drugs in therapeutic classes on the Washington preferred drug list are not subject to determination of authorization requirements through the drug evaluation matrix. Authorization requirements are determined by their preferred status according to WAC 388-530-4100.

(3) The department periodically reviews existing drugs, devices, or drug-related supplies and reassigns authorization requirements as necessary according to the same provisions as outlined above for new drugs, devices, or pharmaceutical supplies.

(4) For any drug, device, or drug-related supply with limitations or requiring authorization, the department may elect to apply automated authorization criteria according to WAC 388-530-3200.

[11-14-075, recodified as § 182-530-3100, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. 07-20-049, § 388-530-3100, filed 9/26/07, effective 11/1/07.]

WAC 182-530-3200 The department's authorization process. (1) The department may establish automated ways for pharmacies to meet authorization requirements for specified drugs, devices, and drug-related supplies, or circumstances as listed in WAC 388-530-3000(4) including, but are not limited to:

(a) Use of expedited authorization codes as published in the department's prescription drug program billing instructions and numbered memoranda;

(b) Use of specified values in national council of prescription drug programs (NCPDP) claim fields;

(c) Use of diagnosis codes; and

(d) Evidence of previous therapy within the department's claim history.

(2) When the automated requirements in subsection (1) of this section do not apply or cannot be satisfied, the pharmacy provider must request authorization from the department before dispensing. The pharmacy provider must:

(a) Ensure the request states the medical diagnosis and includes medical justification for the drug, device, drug-related supply, or circumstance as listed in WAC 388-530-3000(4); and

(b) Keep documentation on file of the prescriber's medical justification that is communicated to the pharmacy by the prescriber at the time the prescription is filled. The records must be retained for the period specified in WAC 388-502-0020(5).

(3) When the department receives the request for authorization:

(a) The department acknowledges receipt:

(i) Within twenty-four hours if the request is received during normal state business hours; or

(ii) Within twenty-four hours of opening for business on the next business day if received outside of normal state business hours.

(b) The department reviews all evidence submitted and takes one of the following actions within fifteen business days:

(i) Approves the request;

(ii) Denies the request if the requested service is not medically necessary; or

(iii) Requests the prescriber submit additional justifying information.

(A) The prescriber must submit the additional information within ten days of the department's request.

(B) The department approves or denies the request within five business days of the receipt of the additional information.

(C) If the prescriber fails to provide the additional information within ten days, the department will deny the requested service. The department sends a copy of the request to the client at the time of denial.

(4) The department's authorization may be based on, but not limited to:

(a) Requirements under this chapter and WAC 388-501-0165;

(b) Client safety;

(c) Appropriateness of drug therapy;

(d) Quantity and duration of therapy;

(e) Client age, gender, pregnancy status, or other demographics; and

(f) The least costly therapeutically equivalent alternative.

(5) The department evaluates request for authorization of covered drugs, devices, and drug-related supplies that exceed limitations in this chapter on a case-by-case basis in conjunction with subsection (4) of this section and WAC 388-501-0169.

(6) If a provider needs authorization to dispense a covered drug outside of normal state business hours, the provider may dispense the drug without authorization only in an emergency. The department must receive justification from the provider within seventy-two hours of the fill date, excluding weekends and Washington state holidays, to be paid for the emergency fill.

(7) The department may remove authorization requirements under WAC 388-530-3000 for, but not limited to, the following:

(a) Prescriptions written by specific practitioners based on consistent high quality of care; or

(b) Prescriptions filled at specific pharmacies and billed to the department at the pharmacies' lower acquisition cost.

(8) Authorization requirements in WAC 388-530-3000 are not a denial of service.

(9) Rejection of a claim due to the authorization requirements listed in WAC 388-530-3000 is not a denial of service.

(10) When a claim requires authorization, the pharmacy provider must request authorization from the department. If the pharmacist fails to request authorization as required, the department does not consider this a denial of service.

(11) Denials that result as part of the authorization process will be issued by the department in writing.

(12) The department's authorization:

(a) Is a decision of medical appropriateness; and

(b) Does not guarantee payment.

[11-14-075, recodified as § 182-530-3200, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.08.090. 11-11-014, § 388-530-3200, filed 5/9/11, effective 6/9/11. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.700, 2008 c 245. 08-21-107, § 388-530-3200, filed 10/16/08, effective 11/16/08. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. 07-20-049, § 388-530-3200, filed 9/26/07, effective 11/1/07.]

QUALITY OF CARE

WAC 182-530-4000 Drug use review (DUR) board. In accordance with 42 C.F.R. 456.716, the department establishes a drug use review (DUR) board.

(1) The DUR board:

(a) Includes health professionals who are actively practicing and licensed in the state of Washington and who have recognized knowledge and expertise in one or more of the following:

(i) The clinically appropriate prescribing of outpatient drugs;

(ii) The clinically appropriate dispensing and monitoring of outpatient drugs;

(iii) Drug use review, evaluation, and intervention; and

(iv) Medical quality assurance.

(b) Is made up of at least one-third but not more than fifty-one percent physicians, and at least one-third pharmacists.

(2) The department may appoint members of the pharmacy and therapeutics committee established by the health care authority (HCA) under chapter 182-50 WAC or other qualified individuals to serve as members of the DUR board.

(3) The DUR board meets periodically to:

(a) Advise the department on drug use review activities;

(b) Review provider and patient profiles;

(c) Review scientific literature to establish evidence-based guidelines for the appropriate use of drugs, including the appropriate indications and dosing;

(d) Recommend adoption of standards and treatment guidelines for drug therapy;

(e) Recommend interventions targeted toward correcting drug therapy problems; and

(f) Produce an annual report.

(4) The department has the authority to accept or reject the recommendations of the DUR board in accordance with 42 C.F.R. 456.716(c).

[11-14-075, recodified as § 182-530-4000, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. 07-20-049, § 388-530-4000, filed 9/26/07, effective 11/1/07.]

WAC 182-530-4050 Drug use and claims review. (1) The department's drug use review (DUR) consists of:

(a) A prospective drug use review (Pro-DUR) that requires all pharmacy providers to:

(i) Obtain patient histories of allergies, idiosyncrasies, or chronic condition(s) which may relate to drug utilization;

(ii) Screen for potential drug therapy problems; and

(iii) Counsel the patient in accordance with existing state pharmacy laws and federal regulations.

(b) A retrospective drug use review (Retro-DUR), in which the department provides for the ongoing periodic examination of claims data and other records in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and individuals receiving benefits.

(2) The department reviews a periodic sampling of claims to determine if drugs are appropriately dispensed and billed. If a review of the sample finds that a provider is inappropriately dispensing or billing for drugs, the department may implement corrective action that includes, but is not limited to:

(a) Educating the provider regarding the problem practice(s);

(b) Requiring the provider to maintain specific documentation in addition to the normal documentation requirements regarding the provider's dispensing or billing actions;

(c) Recouping the payment for the drug(s); and/or

(d) Terminating the provider's core provider agreement (CPA).

[11-14-075, recodified as § 182-530-4050, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. 07-20-049, § 388-530-4050, filed 9/26/07, effective 11/1/07.]

WAC 182-530-4100 Washington preferred drug list (PDL). Under RCW 69.41.190 and 70.14.050, the department and other state agencies cooperate in developing and maintaining the Washington preferred drug list.

(1) Washington state contracts with evidence-based practice center(s) for systematic reviews of drug(s).

(2) The pharmacy and therapeutics (P&T) committee reviews and evaluates the safety, efficacy, and outcomes of

prescribed drugs, using evidence-based information provided by the evidence-based practice center(s).

(3) The P&T committee makes recommendations to state agencies as to which drug(s) to include on the Washington PDL under chapter 182-50 WAC.

(4) The appointing authority makes the final selection of drugs included on the Washington PDL.

(5) Drugs in a drug class on the Washington PDL that have been studied by the evidence-based practice center(s) and reviewed by the P&T committee and which have not been selected as preferred are considered nonpreferred drugs and are subject to the therapeutic interchange program (TIP) and dispense as written (DAW) rules under WAC 388-530-4150.

(6) Drugs in a drug class on the Washington PDL that have not been studied by the evidence-based practice center(s) and have not been reviewed by the P&T committee will be treated as nonpreferred drugs not subject to the dispense as written (DAW) or the therapeutic interchange program (TIP).

(7) A nonpreferred drug which the department determines as covered is considered for authorization after the client has:

(a) Tried and failed or is intolerant to at least one preferred drug; and

(b) Met department established criteria for the nonpreferred drug.

(8) Drugs in a drug class on the Washington PDL may be designated as preferred drugs for special populations or specific indications.

(9) Drugs in a drug class on the Washington PDL may require authorization for safety.

(10) Combination drugs that have been studied by the evidence-based practice center and have been reviewed by the P&T committee may be included in the Washington PDL.

(11) When a brand name drug has been reviewed by the P&T committee, the department may immediately designate an available, less expensive, equally effective, generic equivalent as a preferred drug. For the purpose of this chapter, generic equivalent drugs are those identified in the FDA's approved drug products with therapeutic equivalence evaluations (orange book).

(12) The dispensing of a brand name drug in a drug class on the Washington PDL as a client's first course of treatment within that therapeutic class may be subject to restrictions under WAC 388-530-4125 and WAC 388-530-4150(10).

[11-14-075, recodified as § 182-530-4100, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.04.050, 74.09.700, 74.08.090, 2009 c 575. 10-06-011, § 388-530-4100, filed 2/19/10, effective 3/22/10. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.700, 2008 c 245. 08-21-107, § 388-530-4100, filed 10/16/08, effective 11/16/08. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. 07-20-049, § 388-530-4100, filed 9/26/07, effective 11/1/07.]

WAC 182-530-4125 Generics first for a client's first course of treatment. The department uses point-of-sale (POS) claim messaging to communicate to pharmacies to use a preferred generic drug for the client's first course of treatment in specific drug classes.

(1) The department may require preferred generic drug(s) on the Washington preferred drug list (PDL) be used before any brand name drugs for a client's first course of treatment within that therapeutic class of drugs, when:

(a) There is a less expensive, equally effective therapeutic alternative generic product available to treat the condition; and

(b) The drug use review (DUR) board established under WAC 388-530-4000 has reviewed the drug class and recommended to the department that the drug class is appropriate to require generic drugs as a client's first course of treatment.

(2) For drug classes selected by the department which meet the criteria of subsection (1) of this section, only preferred generic drugs are covered for a client's first course of treatment, except as identified in subsection (3) of this section.

(3) Endorsing practitioners' prescriptions written "Dispense as written (DAW)" for preferred and nonpreferred brand name drugs and nonpreferred generics in the specific drug classes on the Washington PDL reviewed by the DUR board will be subject to authorization to establish medical necessity as defined in WAC 388-500-0005.

[11-14-075, recodified as § 182-530-4125, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.04.050, 74.09.700, 74.08.090, 2009 c 575. 10-06-011, § 388-530-4125, filed 2/19/10, effective 3/22/10.]

WAC 182-530-4150 Therapeutic interchange program (TIP). This section contains the department's rules for the endorsing practitioner therapeutic interchange program (TIP). TIP is established under RCW 69.41.190 and 70.14.-050. The statutes require state-operated prescription drug programs to allow physicians and other prescribers to endorse a Washington preferred drug list (PDL) and, in most cases, requires pharmacists to automatically substitute a preferred, equivalent drug from the list.

(1) The therapeutic interchange program (TIP) applies only to drugs:

(a) Within therapeutic classes on the Washington PDL;

(b) Studied by the evidence-based practice center(s);

(c) Reviewed by the pharmacy and therapeutics (P&T) committee; and

(d) Prescribed by an endorsing practitioner.

(2) TIP does not apply:

(a) When the P&T committee determines that TIP does not apply to the therapeutic class on the PDL; or

(b) To a drug prescribed by a nonendorsing practitioner.

(3) A practitioner who wishes to become an endorsing practitioner must specifically enroll with the health care authority (HCA) as an endorsing practitioner under the provisions of chapter 182-50 WAC and RCW 69.41.190(2).

(4) When an endorsing practitioner writes a prescription for a client for a nonpreferred drug, or for a preferred drug for a special population or indication other than the client's population or indication, and indicates that substitution is permitted, the pharmacist must:

(a) Dispense a preferred drug in that therapeutic class in place of the nonpreferred drug; and

(b) Notify the endorsing practitioner of the specific drug and dose dispensed.

(5) With the exception of subsection (7) and (10) of this section, when an endorsing practitioner determines that a nonpreferred drug is medically necessary, all of the following apply:

(a) The practitioner must indicate that the prescription is to be dispensed as written (DAW);

(b) The pharmacist dispenses the nonpreferred drug as prescribed; and

(c) The department does not require prior authorization to dispense the nonpreferred drug in place of a preferred drug except when the drug requires authorization for safety.

(6) In the event the following therapeutic drug classes are on the Washington PDL, pharmacists will not substitute a preferred drug for a nonpreferred drug in these therapeutic drug classes when the endorsing practitioner prescribes a refill (including the renewal of a previous prescription or adjustments in dosage):

(a) Antipsychotic;

(b) Antidepressant;

(c) Antiepileptic;

(d) Chemotherapy;

(e) Antiretroviral;

(f) Immunosuppressive; or

(g) Immunomodulator/antiviral treatment for hepatitis C for which an established, fixed duration of therapy is prescribed for at least twenty-four weeks but no more than forty-eight weeks.

(7) The department may impose nonendorsing status on an endorsing practitioner only under the following circumstances:

(a) The department runs three quarterly reports demonstrating that, within any therapeutic class of drugs on the Washington PDL, the endorsing practitioner's frequency of prescribing DAW varies from the prescribing patterns of the endorsing practitioner's department-designated peer grouping with a ninety-five percent confidence interval; and

(b) The medical director has:

(i) Delivered by mail to the endorsing practitioner the quarterly reports described in subsection (7)(a) of this section which demonstrate the endorsing practitioner's variance in prescribing patterns; and

(ii) Provided the endorsing practitioner an opportunity to explain the variation in prescribing patterns as medically necessary as defined under WAC 388-500-0005; or

(iii) Provided the endorsing practitioner two calendar quarters to change his or her prescribing patterns to align with those of the department-designated peer groupings.

(8) While the endorsing practitioner is engaged in the activities described in subsection (7)(b)(ii) or (7)(b)(iii) of this section, his or her endorsing practitioner status is maintained.

(9) The nonendorsing status restrictions imposed under this section will remain in effect until the quarterly reports demonstrate that the endorsing practitioner's prescribing patterns no longer vary in comparison to his or her department designated peer-grouping over a period of four calendar quarters, with a ninety-five percent confidence interval.

(10) Except as otherwise provided in subsection (11) of this section, for a client's first course of treatment within a therapeutic class of drugs, the endorsing practitioner's option to write DAW does not apply when:

(a) There is a less expensive, equally effective therapeutic alternative generic product available to treat the condition; and

(b) The drug use review (DUR) board established under WAC 388-530-4000 has reviewed the drug class and recommended to the department that the drug class is appropriate to require generic drugs as a client's first course of treatment.

(11) In accordance with WAC 388-530-4125(3) and WAC 388-501-0165, the department will request and review the endorsing practitioner's medical justification for preferred and nonpreferred brand name drugs and nonpreferred generic drugs for the client's first course of treatment.

[11-14-075, recodified as § 182-530-4150, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.04.050, 74.09.700, 74.08.090, 2009 c 575. 10-06-011, § 388-530-4150, filed 2/19/10, effective 3/22/10. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.700, 2008 c 245. 08-21-107, § 388-530-4150, filed 10/16/08, effective 11/16/08. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. 07-20-049, § 388-530-4150, filed 9/26/07, effective 11/1/07.]

BILLING

WAC 182-530-5000 Billing requirements—Pharmacy claim payment. (1) When billing the department for pharmacy services, providers must:

(a) Use the appropriate department claim form or electronic billing specifications;

(b) Include the actual eleven-digit national drug code (NDC) number of the product dispensed from a rebate eligible manufacturer;

(c) Bill the department using metric decimal quantities which is the National Council for Prescription Drug Programs (NCPDP) billing unit standard;

(d) Meet the general provider documentation and record retention requirements in WAC 388-502-0020; and

(e) Maintain proof of delivery receipts.

(i) When a provider delivers an item directly to the client or the client's authorized representative, the provider must be able to furnish proof of delivery including signature, client's name and a detailed description of the item(s) delivered.

(ii) When a provider mails an item to the client, the provider must be able to furnish proof of delivery including a mail log.

(iii) When a provider uses a delivery/shipping service to deliver items, the provider must be able to furnish proof of delivery and it must:

(A) Include the delivery service tracking slip with the client's name or a reference to the client's package(s); the delivery service package identification number; and the delivery address.

(B) Include the supplier's shipping invoice, with the client's name; the shipping service package identification number; and a detailed description(s).

(iv) Make proof of delivery receipts available to the department, upon request.

(2) When billing drugs under the expedited authorization process, providers must insert the authorization number which includes the corresponding criteria code(s) in the appropriate data field on the drug claim.

(3) Pharmacy services for clients on restriction under WAC 388-501-0135 must be prescribed by the client's primary care provider and are paid only to the client's primary pharmacy, except in cases of:

(a) Emergency;

(b) Family planning services; or

(c) Services properly referred from the client's assigned pharmacy or physician/ARNP.

[11-14-075, recodified as § 182-530-5000, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. 07-20-049, § 388-530-5000, filed 9/26/07, effective 11/1/07.]

WAC 182-530-5050 Billing requirements—Point-of-sale (POS) system/prospective drug use review (Pro-DUR). (1) Pharmacy claims for drugs and other products listed in the department's drug file and billed to the department by national drug code (NDC) are adjudicated by the department's point-of-sale (POS) system. Claims must be submitted for payment using the billing unit standard identified in WAC 388-530-5000.

(2) All pharmacy drug claims processed through the POS system undergo a system-facilitated prospective drug use review (Pro-DUR) screening as a complement to the Pro-DUR screening required of pharmacists.

(3) If the POS system identifies a potential drug therapy problem during Pro-DUR screening, a message will alert the pharmacy provider indicating the type of potential problem. The alerts regarding possible drug therapy problems include, but are not limited to:

(a) Therapeutic duplication;

(b) Duration of therapy exceeds the recommended maximum period;

(c) Drug-to-drug interaction;

(d) Drug disease precaution;

(e) High dose;

(f) Ingredient duplication;

(g) Drug-to-client age conflict;

(h) Drug-to-client gender conflict; or

(i) Refill too soon.

(4) The department provides pharmacy providers with a list of codes from which to choose in overriding POS system alert messages. These codes come from the National Council for Prescription Drug Programs (NCPDP).

(5) The dispensing pharmacist evaluates the potential drug therapy conflict and enters applicable NCPDP codes representing their professional interaction.

(a) If the resolution to the conflict satisfies department requirements, the claim will be processed accordingly.

(b) If the resolution to the conflict does not satisfy department requirements, the department requires prior authorization. This includes all claims for which an alert message is triggered in the POS system and an NCPDP override code is not appropriate.

(6) The department requires providers to retain documentation of the justification for the use of payment system override codes as described in subsections (4) and (5) of this section. The department requires the documentation be retained for the same period as that described in WAC 388-502-0020.

(7) POS/Pro-DUR screening is not applicable to pharmacy claims included in the managed care capitated rate.

[11-14-075, recodified as § 182-530-5050, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. 07-20-049, § 388-530-5050, filed 9/26/07, effective 11/1/07.]

WAC 182-530-5100 Billing requirements—Unit dose. (1) To be eligible for a unit dose dispensing fee from the department, a pharmacy must:

(a) Notify the department in writing of its intent to provide unit dose service;

(b) Identify the nursing facility(ies) to be served;

(c) Indicate the approximate date unit dose service to the facility(ies) will commence; and

(d) Follow department requirements for unit dose payment.

(2) Under a unit dose delivery system, a pharmacy must bill only for the number of drug units actually used by the medical assistance client in the nursing facility, except as provided in subsections (3), (4), and (5) of this section. It is the unit dose pharmacy provider's responsibility to coordinate with nursing facilities to ensure that the unused drugs the pharmacy dispensed to clients are returned to the pharmacy for credit.

(3) The pharmacy must submit an adjustment form or claims reversal of the charge to the department for the cost of all unused drugs returned to the pharmacy from the nursing facility on or before the sixtieth day following the date the drug was dispensed, except as provided in subsection (5) of this section. Such adjustment must conform to the nursing facility's monthly log as described in subsection (7) of this section.

(4) The department pays a unit dose provider a dispensing fee when a provider-packaged unit dose prescription is returned, in its entirety, to the pharmacy. A dispensing fee is not paid if the returned prescription is for a drug with a manufacturer-designated unit dose national drug code (NDC). In addition to the dispensing fee paid under this subsection, the provider may bill the department one unit of the tablet or capsule but must credit the department for the remainder of the ingredient costs for the returned prescription.

(5) Unit dose providers do not have to credit the department for federally designated schedule two drugs which are returned to the pharmacy. These returned drugs must be disposed of according to federal regulations.

(6) Pharmacies must not charge clients or the department a fee for repackaging a client's bulk medications in unit dose form. The costs of repackaging are the responsibility of the nursing facility when the repackaging is done:

(a) To conform with a nursing facility's drug delivery system; or

(b) For the nursing facility's convenience.

(7) The pharmacy must maintain detailed records of medications dispensed under unit dose delivery systems. The pharmacy must keep a monthly log for each nursing facility served, including but not limited to the following information:

(a) Facility name and address;

(b) Client's name and patient identification code (PIC);

(c) Drug name/strength;

(d) National drug code (NDC);

(e) Quantity and date dispensed;

(f) Quantity and date returned;

(g) Value of returned drugs or amount credited;

(h) Explanation for no credit given or nonreusable returns; and

(i) Prescription number.

(8) Upon the department's request, the pharmacy must submit copies of the logs referred to in subsection (7) of this section.

(9) When the pharmacy submits the completed annual prescription volume survey to the department, it must include an updated list of all nursing facilities currently served under unit dose systems.

[11-14-075, recodified as § 182-530-5100, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. 07-20-049, § 388-530-5100, filed 9/26/07, effective 11/1/07.]

MAIL-ORDER SERVICES

WAC 182-530-6000 Mail-order services. The department provides a contracted mail-order pharmacy service for client use. The mail-order contractor is selected as a result of a competitive procurement process.

(1) The contracted mail-order pharmacy service is available as an option to all medical assistance clients, subject to the:

(a) Scope of the client's medical care program;

(b) Availability of services from the contracted mail-order provider; and

(c) Special terms and conditions described in subsection (2) and (3) of this section.

(2) The mail-order prescription service may not dispense medication in a quantity greater than authorized by the prescriber. (See RCW 18.64.360(5), Nonresident pharmacies.)

(3) Prescribed medications may be filled by the mail-order pharmacy service within the following restrictions:

(a) Drugs available from mail-order in no more than a ninety day supply include:

(i) Preferred drugs (see WAC 388-530-4100);

(ii) Generic drugs; and

(iii) Drugs that do not have authorization requirements (see WAC 388-530-3000 through 388-530-3200).

(b) Drugs available in no more than a thirty-four-day supply:

(i) Controlled substances (schedules II through V); and

(ii) Drugs having authorization requirements (see WAC 388-530-3000).

(c) Other pharmacy restrictions (chapter 388-530 WAC, Pharmacy services) continue to apply.

(4) The contracted mail-order pharmacy services are reimbursed at levels lower than those established for the regular outpatient pharmacy services.

[11-14-075, recodified as § 182-530-6000, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. 07-20-049, § 388-530-6000, filed 9/26/07, effective 11/1/07.]

REIMBURSEMENT

WAC 182-530-7000 Reimbursement. (1) The agency's total reimbursement for a prescription drug must not exceed the lowest of:

(a) Estimated acquisition cost (EAC) plus a dispensing fee;

(b) Maximum allowable cost (MAC) plus a dispensing fee;

(c) Federal upper limit (FUL) plus a dispensing fee;

(d) Actual acquisition cost (AAC) plus a dispensing fee for drugs purchased under section 340B of the Public Health Service (PHS) Act;

(e) Automated maximum allowable cost (AMAC) plus a dispensing fee; or

(f) The provider's usual and customary charge to the nonmedicaid population.

(2) The agency selects the sources for pricing information used to set EAC and MAC.

(3) The agency may solicit assistance from pharmacy providers, pharmacy benefit managers (PBM), other government agencies, actuaries, and/or other consultants when establishing EAC and/or MAC.

(4) The agency reimburses a pharmacy for the least costly dosage form of a drug within the same route of administration, unless the prescriber has designated a medically necessary specific dosage form or the agency has selected the more expensive dosage form as a preferred drug.

(5) If the pharmacy provider offers a discount, rebate, promotion or other incentive which directly relates to the reduction of the price of a prescription to the individual nonmedicaid customer, the provider must similarly reduce its charge to the agency for the prescription.

(6) If the pharmacy provider gives an otherwise covered product for free to the general public, the pharmacy must not submit a claim to the agency.

(7) The agency does not reimburse for:

(a) Prescriptions written on presigned prescription blanks filled out by nursing facility operators or pharmacists;

(b) Prescriptions without the date of the original order;

(c) Drugs used to replace those taken from a nursing facility emergency kit;

(d) Drugs used to replace a physician's stock supply;

(e) Outpatient drugs, biological products, insulin, supplies, appliances, and equipment included in other reimbursement methods including, but not limited to:

(i) Diagnosis-related group (DRG);

(ii) Ratio of costs-to-charges (RCC);

(iii) Nursing facility daily rates;

(iv) Managed care capitation rates;

(v) Block grants; or

(vi) Drugs prescribed for clients who are on the agency's hospice program when the drugs are related to the client's terminal illness and related condition.

(f) Hemophilia and von Willebrand related products shipped to clients for administration in the home unless the products are provided through a qualified hemophilia treatment center of excellence (COE) as defined in WAC 182-531-1625.

[Statutory Authority: RCW 41.05.021. 12-16-061, § 182-530-7000, filed 7/30/12, effective 11/1/12. 11-14-075, recodified as § 182-530-7000, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. 07-20-049, § 388-530-7000, filed 9/26/07, effective 11/1/07.]

WAC 182-530-7050 Reimbursement—Dispensing fee determination. (1) Subject to the provisions of WAC 388-530-7000 and the exceptions permitted in WAC 388-530-2000, the department pays a dispensing fee for each covered, prescribed drug.

(2) The department does not pay a dispensing fee for nondrug items, devices, or drug-related supplies.

(3) The department adjusts the dispensing fee by considering factors including, but not limited to:

(a) Legislative appropriations for vendor rates;

(b) Input from provider and/or advocacy groups;

(c) Input from state-employed or contracted actuaries; and

(d) Dispensing fees paid by other third-party payers, including, but not limited to, health care plans and other states' medicaid agencies.

(4) The department uses a tiered dispensing fee system which pays higher volume pharmacies at a lower fee and lower volume pharmacies at a higher fee.

(5) The department uses total annual prescription volume (both medicaid and nonmedicaid) reported to the department to determine each pharmacy's dispensing fee tier.

(a) A pharmacy which fills more than thirty-five thousand prescriptions annually is a high-volume pharmacy. The department considers hospital-based pharmacies that serve both inpatient and outpatient clients as high-volume pharmacies.

(b) A pharmacy which fills between fifteen thousand one and thirty-five thousand prescriptions annually is a mid-volume pharmacy.

(c) A pharmacy which fills fifteen thousand or fewer prescriptions annually is a low-volume pharmacy.

(6) The department determines a pharmacy's annual total prescription volume as follows:

(a) The department sends out a prescription volume survey form to pharmacy providers during the first quarter of the calendar year;

(b) Pharmacies return completed prescription volume surveys to the department each year. Pharmacy providers not responding to the survey by the specified date are assigned to the high volume category;

(c) Pharmacies must include all prescriptions dispensed from the same physical location in the pharmacy's total prescription count;

(d) The department considers prescriptions dispensed to nursing facility clients as outpatient prescriptions; and

(e) Assignment to a new dispensing fee tier is effective on the first of the month, following the date specified by the department.

(7) A pharmacy may request a change in dispensing fee tier during the interval between the annual prescription volume surveys. The pharmacy must substantiate such a request with documentation showing that the pharmacy's most recent six-month dispensing data, annualized, would qualify the pharmacy for the new tier. If the department receives the documentation by the twentieth of the month, assignment to a new dispensing fee tier is effective on the first of the following month.

(8) The department grants general dispensing fee rate increases only when authorized by the legislature. Amounts authorized for dispensing fee increases may be distributed nonuniformly (e.g., tiered dispensing fee based upon volume).

(9) The department may pay true unit dose pharmacies at a different rate for unit dose dispensing.

[11-14-075, recodified as § 182-530-7050, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. 07-20-049, § 388-530-7050, filed 9/26/07, effective 11/1/07.]

WAC 182-530-7100 Reimbursement—Pharmaceutical supplies. (1) The department reimburses for selected pharmaceutical supplies through the pharmacy point-of-sale (POS) system when it is necessary for client access and safety.

(2) The department bases reimbursement of pharmaceutical items or supplies that are not payable through the POS on department-published fee schedules.

(3) The department uses any or all of the following methodologies to set the maximum allowable reimbursement rate for drugs, devices, and drug-related supplies:

(a) A pharmacy provider's acquisition cost. Upon review of the claim, the department may require an invoice which must show the name of the item, the manufacturer, the product description, the quantity, and the current cost including any free goods associated with the invoice;

(b) Medicare's reimbursement rate for the item; or

(c) A specified discount off the item's list price or manufacturer's suggested retail price (MSRP).

(4) The department does not pay a dispensing fee for nondrug items, devices, or drug-related supplies. See WAC 388-530-7050.

[11-14-075, recodified as § 182-530-7100, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. 07-20-049, § 388-530-7100, filed 9/26/07, effective 11/1/07.]

WAC 182-530-7150 Reimbursement—Compounded prescriptions. (1) The department does not consider reconstitution to be compounding.

(2) The department covers a drug ingredient used for a compounded prescription only when the manufacturer has a signed rebate agreement with the federal Department of Health and Human Services (DHHS).

(3) The department considers bulk chemical supplies used in compounded prescriptions as nondrug items, which do not require a drug rebate agreement. The department covers such bulk chemical supplies only as specifically approved by the department.

(4) The department reimburses pharmacists for compounding drugs only if the client's drug therapy needs are unable to be met by commercially available dosage strengths and/or forms of the medically necessary drug.

(a) The pharmacist must ensure the need for the adjustment of the drug's therapeutic strength and/or form is well documented in the client's file.

(b) The pharmacist must ensure that the ingredients used in a compounded prescription are for an approved use as defined in "medically accepted indication" in WAC 388-530-1050.

(5) The department requires that each drug ingredient used for a compounded prescription be billed to the department using its eleven-digit national drug code (NDC) number.

(6) Compounded prescriptions are reimbursed as follows:

(a) The department allows only the lowest cost for each covered ingredient, whether that cost is determined by actual acquisition cost (AAC), estimated acquisition cost (EAC), federal upper limit (FUL), maximum allowable cost (MAC), automated maximum allowable cost (AMAC), or amount billed.

(b) The department applies current prior authorization requirements to drugs used as ingredients in compounded prescriptions, except as provided under subsection (6)(c) of this section. The department denies payment for a drug requiring authorization when authorization is not obtained.

(c) The department may designate selected drugs as not requiring authorization when used for compounded prescriptions. For the list of selected drugs, refer to the department's prescription drug program billing instructions.

(d) The department pays a dispensing fee as described under WAC 388-530-7050 for each drug ingredient used in compounding when the conditions of this section are met and each ingredient is billed separately by the eleven digit NDC.

(e) The department does not pay a separate fee for compounding time.

(7) The department requires pharmacists to document the need for each inactive ingredient added to the compounded prescription. The department limits reimbursement to the inactive ingredients that meet the following criteria. To be reimbursed by the department, each inactive ingredient must be:

(a) A necessary component of a compounded drug; and

(b) Billed by an eleven digit national drug code (NDC).

[11-14-075, recodified as § 182-530-7150, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. 07-20-049, § 388-530-7150, filed 9/26/07, effective 11/1/07.]

WAC 182-530-7200 Reimbursement—Out-of-state prescriptions. (1) The department reimburses out-of-state pharmacies for prescription drugs provided to an eligible client within the scope of the client's medical care program if the pharmacy:

(a) Contracts with the department to be an enrolled provider; and

(b) Meets the same criteria the department requires for in-state pharmacy providers.

(2) The department considers pharmacies located in bordering areas listed in WAC 388-501-0175 the same as in-state pharmacies.

[11-14-075, recodified as § 182-530-7200, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. 07-20-049, § 388-530-7200, filed 9/26/07, effective 11/1/07.]

WAC 182-530-7250 Reimbursement—Miscellaneous. The department reimburses for covered drugs, devices, and drug-related supplies provided or administered by nonpharmacy providers under specified conditions, as follows:

(1) The department reimburses for drugs administered or prepared and delivered for individual use by an authorized prescriber during an office visit according to specific program rules found in:

(a) Chapter 388-531 WAC, Physician-related services;

(b) Chapter 388-532 WAC, Reproductive health/family planning only/TAKE CHARGE; and

(c) Chapter 388-540 WAC, Kidney services.

(2) Providers who are purchasers of Public Health Services (PHS) discounted drugs must comply with PHS 340b program requirements. (See WAC 388-530-7900).

(3) The department may request providers to submit a current invoice for the actual cost of the drug, device, or drug-related supply billed. If an invoice is requested, the invoice must show the:

(a) Name of the drug, device, or drug-related supply;

(b) Drug or product manufacturer;

(c) NDC of the product(s);

(d) Drug strength;

(e) Product description;

(f) Quantity; and

(g) Cost, including any free goods associated with the invoice.

(4) The department does not reimburse providers for the cost of vaccines obtained through the state department of health (DOH). The department does pay physicians, advanced registered nurse practitioners (ARNP), and pharmacists a fee for administering the vaccine.

[11-14-075, recodified as § 182-530-7250, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. 07-20-049, § 388-530-7250, filed 9/26/07, effective 11/1/07.]

WAC 182-530-7300 Reimbursement—Requesting a change. Upon request from a pharmacy provider, the department may reimburse at actual acquisition cost (AAC) for a drug that would otherwise be reimbursed at maximum allowable cost (MAC) when:

(1) The availability of lower cost equivalents in the marketplace is severely curtailed and the price disparity between AAC for the drug and the MAC reimbursement affects clients' access; and

(2) An invoice documenting actual acquisition cost relevant to the date the drug was dispensed is provided to the department.

[11-14-075, recodified as § 182-530-7300, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. 07-20-049, § 388-530-7300, filed 9/26/07, effective 11/1/07.]

WAC 182-530-7350 Reimbursement—Unit dose drug delivery systems. (1) The department pays for unit dose drug delivery systems only for clients residing in nursing facilities, except as provided in subsections (7) and (8) of this section.

(2) Unit dose delivery systems may be either true or modified unit dose.

(3) The department pays pharmacies that provide unit dose delivery services the department's highest allowable dispensing fee for each unit dose prescription dispensed to clients in nursing facilities. The department reimburses ingredient costs for drugs under unit dose systems as described in WAC 388-530-7000.

(4) The department pays a pharmacy that dispenses drugs in bulk containers or multidose forms to clients in nursing facilities the regular dispensing fee applicable to the pharmacy's total annual prescription volume tier. Drugs the department considers not deliverable in unit dose form include, but are not limited to, liquids, creams, ointments, ophthalmic and otic solutions. The department reimburses ingredient costs as described in WAC 388-530-7000.

(5) The department pays a pharmacy that dispenses drugs prepackaged by the manufacturer in unit dose form to clients in nursing facilities the regular dispensing fee applicable under WAC 388-530-7050. The department reimburses

ingredient costs for drugs prepackaged by the manufacturer in unit dose form as described in WAC 388-530-7000.

(6) The department limits its coverage and payment for manufacturer-designated unit dose packaging to the following conditions:

(a) The drug is a single source drug and a multidose package for the drug is not available;

(b) The drug is a multiple source drug but there is no other multidose package available among the drug's generic equivalents; or

(c) The manufacturer-designated unit dose package is the most cost-effective package available or it is the least costly alternative form of the drug.

(7) The department reimburses a pharmacy provider for manufacturer-designated unit dose drugs dispensed to clients not residing in nursing facilities only when such drugs:

(a) Are available in the marketplace only in manufacturer-designated unit dose packaging; and

(b) Would otherwise be covered as an outpatient drug. The unit dose dispensing fee does not apply in such cases. The department pays the pharmacy the dispensing fee applicable to the pharmacy's total annual prescription volume tier.

(8) The department may pay for unit dose delivery systems for clients of the division of developmental disabilities (DDD) residing in approved community living arrangements.

[11-14-075, recodified as § 182-530-7350, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. 07-20-049, § 388-530-7350, filed 9/26/07, effective 11/1/07.]

WAC 182-530-7400 Reimbursement—Compliance packaging services. (1) The department reimburses pharmacies for compliance packaging services provided to clients considered at risk for adverse drug therapy outcomes. Clients who are eligible for compliance packaging services must not reside in a nursing home or other inpatient facility, and must meet (a) and either (b) or (c) of this subsection. The client must:

(a) Have one or more of the following representative disease conditions:

(i) Alzheimer's disease;

(ii) Blood clotting disorders;

(iii) Cardiac arrhythmia;

(iv) Congestive heart failure;

(v) Depression;

(vi) Diabetes;

(vii) Epilepsy;

(viii) HIV/AIDS;

(ix) Hypertension;

(x) Schizophrenia; or

(xi) Tuberculosis.

(b) Concurrently consume two or more prescribed medications for chronic medical conditions, that are dosed at three or more intervals per day; or

(c) Have demonstrated a pattern of noncompliance that is potentially harmful to the client's health. The client's pattern of noncompliance with the prescribed drug regimen must be fully documented in the provider's file.

(2) Compliance packaging services include:

(a) Reusable hard plastic containers of any type (e.g., medisets); and

(b) Nonreusable compliance packaging devices (e.g., blister packs).

(3) The department pays a filling fee and reimburses pharmacies for the compliance packaging device and/or container. The frequency of fills and number of payable compliance packaging devices per client is subject to limits specified by the department. The department does not pay filling or preparation fees for blister packs.

(4) Pharmacies must use the CMS-1500 claim form to bill the department for compliance packaging services.

[11-14-075, recodified as § 182-530-7400, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. 07-20-049, § 388-530-7400, filed 9/26/07, effective 11/1/07.]

WAC 182-530-7500 Drug rebate requirement. (1) The department reimburses for outpatient prescription drugs only when they are supplied by manufacturers who have a signed drug rebate agreement with the federal Department of Health and Human Services (DHHS), according to 42 U.S.C.1396r-8. The manufacturer must be listed on the list of participating manufacturers as published by CMS.

(2) The fill date must be within the manufacturer's beginning and ending eligibility dates to be reimbursed by the department.

(3) The department may extend this rebate requirement to any outpatient drug reimbursements as allowed or required by federal law.

(4) The department may exempt drugs from the rebate requirement, on a case-by-case basis, when:

(a) It determines that the availability of a single source drug or innovator multiple source drug is essential to the health of beneficiaries; and

(b) All other rebate exemption requirements of SSA Sec 1927 (42 U.S.C.1396r-8) (3) are also satisfied.

[11-14-075, recodified as § 182-530-7500, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. 07-20-049, § 388-530-7500, filed 9/26/07, effective 11/1/07.]

WAC 182-530-7600 Reimbursement—Clients enrolled in managed care. Except as specified under the department's managed care contracts, the department does not reimburse providers for any drugs or pharmaceutical supplies provided to clients who have pharmacy benefits under department-contracted managed care plans. The managed care plan is responsible for payment.

[11-14-075, recodified as § 182-530-7600, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. 07-20-049, § 388-530-7600, filed 9/26/07, effective 11/1/07.]

WAC 182-530-7700 Reimbursement—Dual eligible clients/medicare. For clients who are dually eligible for medical assistance and medicare benefits, the following applies:

(1) Medicare Part B, the department pays providers for:

(a) An amount up to the department's maximum allowable fee for drugs medicare does not cover, but the department covers; or

(b) Deductible and/or coinsurance amounts up to medicare's or the department's maximum allowable fee, whichever is less, for drugs medicare and the department cover; or

(c) Deductible and/or coinsurance amounts for clients under the qualified medicare beneficiary (QMB) program for drugs medicare covers but the department does not cover.

(2) Medicare Part D:

(a) For payment of medicare Part D drugs:

(i) Medicare is the primary payer for covered Part D drugs;

(ii) The department pays only the copayment up to a maximum amount set by the Centers for Medicare and Medicaid Services (CMS); and

(iii) The client is responsible for copayments above the maximum amount.

(b) For drugs excluded from the basic medicare Part D benefits:

(i) The department offers the same drug benefit as a non-dual eligible client has within those same classes;

(ii) If the client has another third party insurer, that insurer is the primary payer; and

(iii) The department is the payer of last resort.

[11-14-075, recodified as § 182-530-7700, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. 07-20-049, § 388-530-7700, filed 9/26/07, effective 11/1/07.]

WAC 182-530-7800 Reimbursement—Clients with third-party liability. (1) The department requires providers to meet the third party requirements of WAC 388-501-0200.

(2) The following definitions apply to this section:

(a) "Closed pharmacy network" means an arrangement made by an insurer which restricts prescription coverage to an exclusive list of pharmacies. This arrangement prohibits the coverage and/or payment of prescriptions provided by a pharmacy that is not included on the exclusive list.

(b) "Private point-of-sale (POS) authorization system" means an insurer's system, other than the department's POS system, which requires that coverage be verified by or submitted to the insurer for authorization at the time of service and at the time the prescription is filled.

(3) This subsection applies to clients who have a third-party resource that is a managed care entity other than a department-contracted plan, or have other insurance that requires the use of "closed pharmacy networks" or "private point-of-sale authorization system." The department will not pay pharmacies for prescription drug claims until the pharmacy provider submits an explanation of benefits from the private insurance demonstrating that the pharmacy provider has complied with the terms of the third-party's coverage.

(a) If the private insurer pays a fee based on the incident of care, the pharmacy provider must file a claim with the department consistent with the department's billing requirements.

(b) If the private insurer pays the pharmacy provider a monthly capitation fee for all prescription costs related to the client, the pharmacy provider must submit a claim to the department for the amount of the client copayment, coinsurance, and/or deductible. The department pays the provider the lesser of:

(i) The billed amount; or

(ii) The department's maximum allowable fee for the prescription.

[11-14-075, recodified as § 182-530-7800, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. 07-20-049, § 388-530-7800, filed 9/26/07, effective 11/1/07.]

WAC 182-530-7900 Drugs purchased under the Public Health Service (PHS) Act. (1) Drugs purchased under section 340B of the Public Health Service (PHS) Act can be dispensed to medical assistance clients only by PHS-qualified health facilities and must be billed to the department at actual acquisition cost (AAC) as required by laws governing the PHS 340B program.

(2) Providers dispensing drugs under this section are required to submit their valid medical assistance provider number(s) to the PHS health resources and services administration, office of pharmacy affairs. This requirement is to ensure that claims for drugs dispensed under this section and paid by the department are excluded from the drug rebate claims that are submitted to the manufacturers of the drugs. See WAC 388-530-7500 for information on the drug rebate program.

(3) The department reimburses drugs under this section at actual acquisition cost plus a dispensing fee set by the department.

[11-14-075, recodified as § 182-530-7900, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. 07-20-049, § 388-530-7900, filed 9/26/07, effective 11/1/07.]

REIMBURSEMENT METHODOLOGY

WAC 182-530-8000 Reimbursement method—Estimated acquisition cost (EAC). (1) The department determines estimated acquisition cost (EAC) using:

(a) Acquisition cost data made available to the department; or

(b) Information provided by any of the following:

(i) Audit agencies, federal or state;

(ii) Other state health care purchasing agencies;

(iii) Pharmacy benefit managers;

(iv) Individual pharmacy providers participating in the department's programs;

(v) Centers for Medicare and Medicaid Services (CMS);

(vi) Other third party payers;

(vii) Drug file data bases; and/or

(viii) Actuaries or other consultants.

(2) The department implements EAC by applying a percentage adjustment to available reference pricing from national sources such as wholesale acquisition cost, average wholesale price (AWP), average sale price (ASP), and average manufacturer price (AMP).

(3) The department may set EAC for specified drugs or drug categories at a maximum allowable cost other than that determined in subsection (1)(a) of this section when the department considers it necessary. The factors the department considers in setting a rate for a class of drugs under this subsection include, but are not limited to:

(a) Product acquisition cost;

(b) The department's documented clinical concerns; and

(c) The department's budget limits.

(4) The department bases EAC drug reimbursement on the actual package size dispensed.

(5) The department uses EAC as the department's reimbursement for a drug when EAC is the lowest of the rates calculated under the methods listed in WAC 388-530-7000, or when the conditions of WAC 388-530-7300 are met.

[11-14-075, recodified as § 182-530-8000, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.04.050 and 74.08.090. 10-24-021, § 388-530-8000, filed 11/19/10, effective 12/20/10. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. 07-20-049, § 388-530-8000, filed 9/26/07, effective 11/1/07.]

WAC 182-530-8050 Reimbursement—Federal upper limit (FUL). (1) The department adopts the federal upper limit (FUL) set by the Centers for Medicare and Medicaid Services (CMS).

(2) The department's maximum payment for multiple-source drugs for which CMS has set FULs will not exceed, in the aggregate, the prescribed upper limits plus the dispensing fees set by the department.

(3) Except as provided in WAC 388-530-7300, the department uses the FUL as the department's reimbursement rate for the drug when the FUL price is the lowest of the rates calculated under the methods listed in WAC 388-530-7000.

[11-14-075, recodified as § 182-530-8050, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. 07-20-049, § 388-530-8050, filed 9/26/07, effective 11/1/07.]

WAC 182-530-8100 Reimbursement—Maximum allowable cost (MAC). (1) The department establishes a maximum allowable cost (MAC) for a multiple-source drug which is available from at least two manufacturers/labelers.

(2) The department determines the MAC for a multiple-source drug:

(a) When specific regional and local drug acquisition cost data is available, the department:

(i) Identifies what products are available from wholesalers for each drug being considered for MAC pricing;

(ii) Determines pharmacy providers' approximate acquisition costs for these products; and

(iii) Establishes the MAC at a level which gives pharmacists access to at least one product from a manufacturer with a qualified rebate agreement (see WAC 388-530-7500(4)).

(b) When specific regional and local drug acquisition cost data is not available, the department may estimate acquisition cost based on national pricing sources.

(3) The MAC established for a multiple-source drug does not apply if the written prescription identifies that a specific brand is medically necessary for a particular client. In such cases, the estimated acquisition cost (EAC) for the particular brand applies, provided authorization is obtained from the department as specified under WAC 388-530-3000.

(4) Except as provided in subsection (3) of this section, the department reimburses providers for a multiple-source drug at the lowest of the rates calculated under the methods listed in WAC 388-530-7000.

(5) The MAC established for a multiple-source drug may vary by package size, including those identified as unit dose national drug codes (NDCs) by the manufacturer(s) of the drug.

[11-14-075, recodified as § 182-530-8100, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. 07-20-049, § 388-530-8100, filed 9/26/07, effective 11/1/07.]

WAC 182-530-8150 Reimbursement—Automated maximum allowable cost (AMAC). (1) The department uses the automated maximum allowable cost (AMAC) pricing methodology for multiple-source drugs that are:

(a) Not on the published maximum allowable cost (MAC); and

(b) Produced by two or more manufacturers/labelers, at least one of which must have a current, signed federal drug rebate agreement.

(2) The department establishes AMAC as a specified percentage of the published average wholesale price (AWP) or other nationally accepted pricing source in order to estimate acquisition cost.

(3) The department sets the percentage discount from AWP for AMAC reimbursement using any of the information sources identified in WAC 388-530-8000.

(4) The department may set AMAC reimbursement at different percentage discounts from AWP for different multiple source drugs. The department considers the same factors as those in WAC 388-530-8000.

(5) AMAC reimbursement for all products with the same ingredient, form and strength is at the AMAC determined for the second lowest priced product, or the AMAC of the lowest priced drug from a manufacturer with a current, signed federal rebate agreement.

(6) The department recalculates AMAC each time the drug file contractor provides a pricing update.

(7) Except as provided in WAC 388-530-7300, the department reimburses at the lowest of the rates calculated under the methods listed in WAC 388-530-7000.

[11-14-075, recodified as § 182-530-8150, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. 07-20-049, § 388-530-8150, filed 9/26/07, effective 11/1/07.]