

Chapter 182-530 WAC

PRESCRIPTION DRUGS (OUTPATIENT)

WAC

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DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER

182-530-2200	How the medicaid agency develops and maintains the formulary. [Statutory Authority: RCW 41.05.021 and section 1927 of the Social Security Act. WSR 12-18-062, § 182-530-2200, filed 8/31/12, effective 10/1/12.] Repealed by WSR 13-18-035, filed 8/28/13, effective 9/28/13. Statutory Authority: RCW 41.05.021.
182-530-2300	The medicaid agency's nonformulary justification process. [Statutory Authority: RCW 41.05.021 and section 1927 of the Social Security Act. WSR 12-18-062, § 182-

530-2300, filed 8/31/12, effective 10/1/12.] Repealed by WSR 13-18-035, filed 8/28/13, effective 9/28/13. Statutory Authority: RCW 41.05.021.

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 medicaid agency rules and subject to the limitations and requirements in this chapter.

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

(a) Covered. Refer to WAC 182-530-2000 for covered drugs, vitamins, minerals, devices, and drug-related supplies and to WAC 182-530-2100 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 182-530-2000 (1)(b), and over-the-counter (OTC) drugs to promote smoking cessation in WAC 182-530-2000 (1)(g));

(c) Prescribed by:

(i) A provider with an approved core provider agreement;

(ii) A provider who is enrolled as a performing provider on an approved core provider agreement; or

(iii) A provider who is enrolled as a nonbilling provider.

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

(e) Medically necessary as defined in WAC 182-500-0070 and determined according to the process found in WAC 182-501-0165;

(f) Authorized, as required within this chapter;

(g) Billed according to WAC 182-502-0150 and 182-502-0160; and

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

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

[Statutory Authority: 42 C.F.R. 455.410, RCW 41.05.021. WSR 13-19-037, § 182-530-1000, filed 9/11/13, effective 10/12/13. Statutory Authority: RCW 41.05.021 and 42 C.F.R. 455.410. WSR 13-04-095, § 182-530-1000, filed 2/6/13, effective 3/9/13. WSR 11-14-075, recodified as § 182-530-1000, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. WSR 09-05-007, § 388-530-1000, filed 2/5/09, effective 3/8/09. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.700, 2008 c 245. WSR 08-21-107, § 388-530-1000, filed 10/16/08, effective 11/16/08. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. WSR 07-20-049, § 388-530-1000, filed 9/26/07, effective 11/1/07; WSR 06-24-036, § 388-530-1000, filed 11/30/06, effective 1/1/07. Statutory Authority: RCW 74.09.080, 74.04.050 and 42 C.F.R. Subpart K, subsection 162.1102. WSR 02-17-023, § 388-530-1000, filed 8/9/02, effective 9/9/02. Statutory Authority: RCW 74.08.090, 74.04.050. WSR 01-01-028, § 388-530-1000, filed 12/7/00, effective 1/7/01. Stat-

utory Authority: RCW 74.08.090, WSR 96-21-031, § 388-530-1000, filed 10/9/96, effective 11/9/96.]

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.

"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.

"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, WSR 13-18-035, § 182-530-1050, filed 8/28/13, effective 9/28/13. Statutory Authority: RCW 41.05.021 and section 1927 of the Social Security Act, WSR 12-18-062, § 182-530-1050, filed 8/31/12, effective 10/1/12. WSR 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. WSR 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. WSR 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. WSR 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. WSR 02-17-023, § 388-530-1050, filed 8/9/02, effective 9/9/02. Statutory Authority: RCW 74.08.090, 74.04.050. WSR 01-24-066, § 388-530-1050, filed 11/30/01, effective 1/2/02; WSR 01-01-028, § 388-530-1050, filed 12/7/00, effective 1/7/01. Statutory Authority: RCW 74.08.090. WSR 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 medicaid agency requires providers to use tamper-resistant prescription pads or paper for written outpatient prescriptions, including over-the-counter drugs, for Washington apple health 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 agency-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 182-500-0050, 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;

(12/9/15)

(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 under WAC 182-502-0020 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 under WAC 182-502-0160.

(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.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-01-046, § 182-530-1075, filed 12/9/15, effective 1/9/16. WSR 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). WSR 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 depart-

ment-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.

[WSR 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. WSR 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. WSR 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. WSR 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. WSR 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.

(2) A noncovered drug can be requested through the exception to rule process as described in WAC 182-501-0160.

(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. WSR 13-18-035, § 182-530-2100, filed 8/28/13, effective 9/28/13. Statutory Authority: RCW 41.05.021 and section 1927 of the Social Security Act. WSR 12-18-062, § 182-530-2100, filed 8/31/12, effective 10/1/12. WSR 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. WSR 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. WSR 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. WSR 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. WSR 07-20-049, § 388-530-2100, filed 9/26/07, effective 11/1/07.]

AUTHORIZATION

WAC 182-530-3000 When the medicaid agency 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 medicaid agency's pharmacists and medical consultants:

(a) Have determined that authorization for the drug, device, or drug-related supply is required, as described in WAC 182-530-3100; 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 182-530-4100; and

- (i) The prescriber is a nonendorsing practitioner; or
- (ii) The drug is designated as exempt from the therapeutic interchange program per WAC 182-530-4100(6) or 182-530-4150 (2)(a);

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(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 agency identifies clients or groups of clients who would benefit from further clinical review.

(4) The agency designates the prescriber(s) as requiring authorization because the prescriber(s) is under agency 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.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-01-046, § 182-530-3000, filed 12/9/15, effective 1/9/16. WSR 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. WSR 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. WSR 07-20-049, § 388-530-3000, filed 9/26/07, effective 11/1/07.]

WAC 182-530-3100 How the medicaid agency determines when a drug requires authorization. (1) The medicaid agency'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 agency clinical staff, financial experts, and program managers. The agency may also consult with an evidence-based practice center, the drug use review (DUR) board, and 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 agency may determine that the drug, device, or drug-related supply:

(i) Requires authorization;

(ii) Requires authorization to exceed agency-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 182-530-4100.

(3) The agency 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 agency may elect to apply automated authorization criteria according to WAC 182-530-3200.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-01-046, § 182-530-3100, filed 12/9/15, effective 1/9/16. WSR 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. WSR 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.

[WSR 11-14-075, recodified as § 182-530-3200, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.08.090, WSR 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, WSR 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. WSR 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 medicaid agency 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 agency may appoint members of the pharmacy and therapeutics committee established by the agency 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 agency 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 agency has the authority to accept or reject the recommendations of the DUR board in accordance with 42 C.F.R. 456.716(c).

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-01-046, § 182-530-4000, filed 12/9/15, effective 1/9/16. WSR 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. WSR 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 agency'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 or conditions 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 agency 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 agency 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 agency may implement corrective action that includes, but is not limited to:

(a) Educating the provider regarding the problem practice or practices;

(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 or drugs; or

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

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-01-046, § 182-530-4050, filed 12/9/15, effective 1/9/16. WSR 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. WSR 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 medicaid agency and other state agencies cooperate in developing and maintaining the Washington preferred drug list (PDL).

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

(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 centers.

(3) The P&T committee makes recommendations to state agencies as to which drugs 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 an evidence-based practice center 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 182-530-4150.

(6) Drugs in a drug class on the Washington PDL that have not been studied by an evidence-based practice center 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 agency 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 agency-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 an 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 agency 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 Food and Drug Administration's approved drug products with therapeutic equivalence evaluations (orange book).

(12) The dispensing of a brand name or nonpreferred generic 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 182-530-4125 and 182-530-4150(10).

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 15-12-093, § 182-530-4100, filed 6/2/15, effective 7/3/15. WSR 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. WSR 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. WSR 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. WSR 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 medicaid agency uses point-of-sale (POS) claim messaging to tell pharmacies to use a preferred generic drug for the client's first course of treatment in specific drug classes.

(1) The agency may require preferred generic drugs on the Washington preferred drug list (PDL) be used before any brand name or nonpreferred generic 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 182-530-4000 has reviewed the drug class and recommended to the agency 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 agency that 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 182-500-0070.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 15-12-093, § 182-530-4125, filed 6/2/15, effective 7/3/15. WSR 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. WSR 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 medicaid agency'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 or centers;

(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 agency 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 agency may impose nonendorsing status on an endorsing practitioner only under the following circumstances:

(a) The agency 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 agency-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 (a) of this subsection, 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 182-500-0070; or

(iii) Provided the endorsing practitioner two calendar quarters to change their prescribing patterns to align with those of the agency-designated peer groupings.

(8) While the endorsing practitioner is engaged in the activities described in subsection (7)(b)(ii) or (iii) of this section, their 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 the endorsing practitioner's agency-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 182-530-4000 has reviewed the drug class and recommended to the agency that the drug class is appropriate to require generic drugs as a client's first course of treatment.

(11) In accordance with WAC 182-530-4125(3) and 182-501-0165, the agency 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.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-01-046, § 182-530-4150, filed 12/9/15, effective 1/9/16. WSR 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. WSR 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. WSR 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. WSR 07-20-049, § 388-530-4150, filed 9/26/07, effective 11/1/07.]

(12/9/15)

BILLING

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

(a) Use the appropriate agency 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 agency 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 182-502-0020; 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 or items 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 or 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 or packages; 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.

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

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

(3) Pharmacy services for clients on restriction under WAC 182-501-0135 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.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-01-046, § 182-530-5000, filed 12/9/15, effective 1/9/16. WSR 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. WSR 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 medicaid agency's drug file and billed to the agency by national drug code (NDC) are adjudicated by the agency's point-of-sale (POS) system. Claims must be submit-

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ted for payment using the billing unit standard identified in WAC 182-530-5000.

(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 agency 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 agency requirements, the claim will be processed accordingly.

(b) If the resolution to the conflict does not satisfy agency requirements, the agency 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 agency 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 agency requires the documentation be retained for the same period as that described in WAC 182-502-0020.

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

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-01-046, § 182-530-5050, filed 12/9/15, effective 1/9/16. WSR 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. WSR 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 medicaid agency, a pharmacy must:

- (a) Notify the agency in writing of its intent to provide unit dose service;
- (b) Identify the nursing facility or facilities to be served;
- (c) Indicate the approximate date unit dose service to the facility or facilities will commence; and
- (d) Follow agency 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 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 agency 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 agency 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 agency one unit of the tablet or capsule but must credit the agency for the remainder of the ingredient costs for the returned prescription.

(5) Unit dose providers do not have to credit the agency 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 agency 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 agency'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 agency, it must include an updated list of all nursing facilities currently served under unit dose systems.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-01-046, § 182-530-5100, filed 12/9/15, effective 1/9/16. WSR 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. WSR 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 medic-aid agency 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 Washington apple health 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 182-530-4100);
- (ii) Generic drugs; and
- (iii) Drugs that do not have authorization requirements (see WAC 182-530-3000 through 182-530-3200).

(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 182-530-3000).

(c) Other pharmacy restrictions (chapter 182-530 WAC Prescription drugs (outpatient)) continue to apply.

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

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-01-046, § 182-530-6000, filed 12/9/15, effective 1/9/16. WSR 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. WSR 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 non-medicare population.

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

(12/9/15)

(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 non-medicare 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. WSR 12-16-061, § 182-530-7000, filed 7/30/12, effective 11/1/12. WSR 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. WSR 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 182-530-7000 and the exceptions permitted in WAC 182-530-2000, the medicare agency pays a dispensing fee for each covered, prescribed drug.

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

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

- (a) Legislative appropriations for vendor rates;
- (b) Input from provider and 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 agency 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 agency uses total annual prescription volume (both medicaid and nonmedicaid) reported to the agency 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 agency 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 agency determines a pharmacy's annual total prescription volume as follows:

(a) The agency 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 agency 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 agency 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 agency.

(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 agency 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 agency 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 agency may pay true unit dose pharmacies at a different rate for unit dose dispensing.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-01-046, § 182-530-7050, filed 12/9/15, effective 1/9/16. WSR 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. WSR 07-20-049, § 388-530-7050, filed 9/26/07, effective 11/1/07.]

WAC 182-530-7100 Reimbursement—Pharmaceutical supplies. (1) The medicaid agency reimburses for selected pharmaceutical supplies through the pharmacy

point-of-sale (POS) system when it is necessary for client access and safety.

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

(3) The agency 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 agency 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 agency does not pay a dispensing fee for non-drug items, devices, or drug-related supplies. See WAC 182-530-7050.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-01-046, § 182-530-7100, filed 12/9/15, effective 1/9/16. WSR 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. WSR 07-20-049, § 388-530-7100, filed 9/26/07, effective 11/1/07.]

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

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

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

(a) The pharmacist must ensure the need for the adjustment of the drug's therapeutic strength 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 182-530-1050.

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

(6) Compounded prescriptions are reimbursed as follows:

(a) The agency 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 agency applies current prior authorization requirements to drugs used as ingredients in compounded

prescriptions, except as provided under (c) of this subsection. The agency denies payment for a drug requiring authorization when authorization is not obtained.

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

(d) The agency pays a dispensing fee as described under WAC 182-530-7050 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 agency does not pay a separate fee for compounding time.

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

- (a) A necessary component of a compounded drug; and
- (b) Billed by an eleven-digit national drug code (NDC).

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-01-046, § 182-530-7150, filed 12/9/15, effective 1/9/16. WSR 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. WSR 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 medicaid agency 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 agency to be an enrolled provider; and
- (b) Meets the same criteria the agency requires for in-state pharmacy providers.

(2) The agency considers pharmacies located in bordering areas listed in WAC 182-501-0175 the same as in-state pharmacies.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-01-046, § 182-530-7200, filed 12/9/15, effective 1/9/16. WSR 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. WSR 07-20-049, § 388-530-7200, filed 9/26/07, effective 11/1/07.]

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

(1) The agency 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 182-531 WAC Physician-related services;
- (b) Chapter 182-532 WAC Reproductive health/family planning only/TAKE CHARGE; and
- (c) Chapter 182-540 WAC Kidney disease program and kidney center services.

(2) Providers who are purchasers of Public Health Services (PHS) discounted drugs must comply with PHS 340b program requirements. (See WAC 182-530-7900.)

(12/9/15)

(3) The agency 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 or products;
- (d) Drug strength;
- (e) Product description;
- (f) Quantity; and
- (g) Cost, including any free goods associated with the invoice.

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

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-01-046, § 182-530-7250, filed 12/9/15, effective 1/9/16. WSR 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. WSR 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 medicaid agency 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 agency.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-01-046, § 182-530-7300, filed 12/9/15, effective 1/9/16. WSR 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. WSR 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 medicaid agency 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 agency pays pharmacies that provide unit dose delivery services the agency's highest allowable dispensing fee for each unit dose prescription dispensed to clients in nursing facilities. The agency reimburses ingredient costs for drugs under unit dose systems as described in WAC 182-530-7000.

(4) The agency 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 agency considers not deliverable in unit dose form include, but are not limited to, liquids, creams, ointments, ophthalmic and otic solutions. The agency reimburses ingredient costs as described in WAC 182-530-7000.

(5) The agency 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 182-530-7050. The agency reimburses ingredient costs for drugs prepackaged by the manufacturer in unit dose form as described in WAC 182-530-7000.

(6) The agency 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 agency 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 agency pays the pharmacy the dispensing fee applicable to the pharmacy's total annual prescription volume tier.

(8) The agency may pay for unit dose delivery systems for clients of the developmental disabilities administration (DDA) residing in approved community living arrangements.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-01-046, § 182-530-7350, filed 12/9/15, effective 1/9/16. WSR 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. WSR 07-20-049, § 388-530-7350, filed 9/26/07, effective 11/1/07.]

WAC 182-530-7400 Reimbursement—Compliance packaging services. (1) The medicaid agency 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 agency pays a filling fee and reimburses pharmacies for the compliance packaging device and container. The frequency of fills and number of payable compliance packaging devices per client is subject to limits specified by the agency. The agency does not pay filling or preparation fees for blister packs.

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

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-01-046, § 182-530-7400, filed 12/9/15, effective 1/9/16. WSR 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. WSR 07-20-049, § 388-530-7400, filed 9/26/07, effective 11/1/07.]

WAC 182-530-7500 Drug rebate requirement. (1) The medicaid agency 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 the Center for Medicare and Medicaid Services (CMS).

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

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

(4) The agency 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.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-01-046, § 182-530-7500, filed 12/9/15, effective 1/9/16. WSR 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. WSR 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 medicaid agency's managed care contracts, the agency does not reimburse providers for any drugs or pharmaceutical supplies provided to clients who have pharmacy benefits under agency-contracted managed care plans. The managed care plan is responsible for payment.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-01-046, § 182-530-7600, filed 12/9/15, effective 1/9/16. WSR 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. WSR 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 agency pays providers for:
 - (a) An amount up to the agency's maximum allowable fee for drugs medicare does not cover, but the agency covers; or
 - (b) Deductible and/or coinsurance amounts up to medicare's or the agency's maximum allowable fee, whichever is less, for drugs medicare and the agency cover.
- (2) Medicare Part D:
 - (a) Medicare is the payer for drugs covered under the medicare Part D benefit.
 - (b) The agency does not pay for Part D drugs or Part D copayments.
 - (c) For drugs excluded from the basic medicare Part D benefit:
 - (i) The agency offers the same drug benefit as a nondual 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 agency is the payer of last resort.

[Statutory Authority: RCW 41.05.021, 2011 c 5, 2010 2nd sp.s. c 1 § 208 (25), and Section 1902 (n)(3)(B) of the Social Security Act, as modified by Section 4714 of the Balanced Budget Act of 1997. WSR 13-14-052, § 182-530-7700, filed 6/27/13, effective 7/28/13. WSR 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. WSR 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 medicaid agency requires providers to meet the third-party requirements of WAC 182-501-0200.

- (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 agency'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 an agency-contracted plan, or have other insurance that requires the use of "closed pharmacy networks" or "private point-of-sale authorization system." The agency 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 agency consistent with the agency'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

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agency for the amount of the client copayment, coinsurance, and/or deductible. The agency pays the provider the lesser of:

- (i) The billed amount; or
- (ii) The agency's maximum allowable fee for the prescription.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-01-046, § 182-530-7800, filed 12/9/15, effective 1/9/16. WSR 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. WSR 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 Washington apple health clients only by PHS-qualified health facilities and must be billed to the medicaid agency 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 medicaid 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 agency are excluded from the drug rebate claims that are submitted to the manufacturers of the drugs. See WAC 182-530-7500 for information on the drug rebate program.

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

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-01-046, § 182-530-7900, filed 12/9/15, effective 1/9/16. WSR 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. WSR 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 medicaid agency determines estimated acquisition cost (EAC) using:

- (a) Acquisition cost data made available to the agency; 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 agency's programs;
 - (v) Centers for Medicare and Medicaid Services (CMS);
 - (vi) Other third-party payers;
 - (vii) Drug file data bases; and
 - (viii) Actuaries or other consultants.

(2) The agency 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 agency 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 agency considers it necessary. The factors the agency 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 agency's documented clinical concerns; and
- (c) The agency's budget limits.
- (4) The agency bases EAC drug reimbursement on the actual package size dispensed.
- (5) The agency uses EAC as the agency's reimbursement for a drug when EAC is the lowest of the rates calculated under the methods listed in WAC 182-530-7000, or when the conditions of WAC 182-530-7300 are met.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-01-046, § 182-530-8000, filed 12/9/15, effective 1/9/16. WSR 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. WSR 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. WSR 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 medicaid agency adopts the federal upper limit (FUL) set by the Centers for Medicare and Medicaid Services (CMS).

(2) The agency'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 agency.

(3) Except as provided in WAC 182-530-7300, the agency uses the FUL as the agency's reimbursement rate for the drug when the FUL price is the lowest of the rates calculated under the methods listed in WAC 182-530-7000.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-01-046, § 182-530-8050, filed 12/9/15, effective 1/9/16. WSR 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. WSR 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 medicaid agency establishes a maximum allowable cost (MAC) for a multiple-source drug which is available from at least two manufacturers/labelers.

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

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

- (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 182-530-7500(4)).

(b) When specific regional and local drug acquisition cost data is not available, the agency 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 agency as specified under WAC 182-530-3000.

(4) Except as provided in subsection (3) of this section, the agency reimburses providers for a multiple-source drug at the lowest of the rates calculated under the methods listed in WAC 182-530-7000.

(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 or manufacturers of the drug.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-01-046, § 182-530-8100, filed 12/9/15, effective 1/9/16. WSR 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. WSR 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 medicaid agency 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 agency 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 agency sets the percentage discount from AWP for AMAC reimbursement using any of the information sources identified in WAC 182-530-8000.

(4) The agency may set AMAC reimbursement at different percentage discounts from AWP for different multiple source drugs. The agency considers the same factors as those in WAC 182-530-8000.

(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 agency recalculates the AMAC each time the drug file contractor provides a pricing update.

(7) Except as provided in WAC 182-530-7300, the agency reimburses at the lowest of the rates calculated under the methods listed in WAC 182-530-7000.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-01-046, § 182-530-8150, filed 12/9/15, effective 1/9/16. WSR 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. WSR 07-20-049, § 388-530-8150, filed 9/26/07, effective 11/1/07.]