Chapter 182-530 WAC
PRESCRIPTION DRUGS (OUTPATIENT)

Last Update: 6/18/21

WAC

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 Repealed by WSR 13-18-035, filed 8/28/13, effective 9/28/13.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 Repealed by WSR 13-18-035, filed 8/28/13, effective 9/28/13.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. Statutory 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)" - Refers to one of the following:

(1) Provider AAC - The true cost a provider paid for a specific drug or product in the package size purchased, including discounts, rebates, charge backs that affect the provider's invoice price, and other adjustments to the price of the drug, device or drug-related supply, excluding dispensing fees;

(2) 340B AAC - The true cost paid by a public health service (PHS)-qualifying entity for a specific drug, excluding dispensing fees; or

(3) POS AAC - The agency-determined rate paid to pharmacies through the point-of-sale (POS) system, and intended to reflect pharmacy providers' actual acquisition cost.

"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" - Means the following people acting jointly: The director of the Washington state health care authority and the director of the Washington state department of labor and industries.

"Authorized generic drug" – Any drug sold, licensed, or marketed under a new drug application (NDA) approved by the Food and Drug Administration (FDA) under section 505(c) of the Federal Food, Drug and Cosmetic Act (FFDCA) that is marketed, sold or distributed under a different labeler code, product code, trade name, trademark, or packaging (other than repackaging the listed drug for use in institutions) than the brand name drug.

"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)" - A reference price of a drug product that is published at a point in time and reported to the medicaid agency or its designee by the agency's drug file contractor.

"Brand name drug" – A single-source or innovator multiple-source drug.

"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" - Means professional dispensing fee. See professional dispensing fee.

"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-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 (Washington 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 drug reviews" - The application of a set of principles and methods for comprehensive independent and objective evaluation of clinical evidence provided in well-designed and well-conducted 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. Classifying evidence by its epistemologic strength and requiring that only the strongest types (coming from meta-analyses, systematic reviews, and randomized controlled trials) can yield strong recommendations; weaker types (such as from case-control studies) can yield weak recommendations.

"Evidence-based practice center" or **"EPC"** - A research organization that has been designated by the Agency for Healthcare Research and Quality (AHRQ) to develop evidence reports and technology assessments on topics relevant to clinical and other health care organization and delivery issues, specifically those that are common, expensive, or significant for the medicare and medicaid populations.

"Federal drug rebates" - Dollars returned to medicaid from pharmaceutical manufacturers under the terms of the manufacturers' nation-

al rebate agreement with the federal Department of Health and Human Services (DHHS).

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

"Generic drug" - A drug that is approved by the Food and Drug Administration (FDA) under an abbreviated new drug application.

"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" - A multiple-source drug that was originally marketed under a new drug application (NDA) approved by the Food and Drug Administration (FDA), including an authorized generic drug. This includes:

(1) A drug product marketed by any cross-licensed producers, labelers, or distributors operating under the NDA; or

(2) A covered outpatient drug approved under a biologics license application (BLA), product license application (PLA), establishment license application (ELA), or antibiotic drug application (ADA).

"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 federal 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.

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

"Medicaid preferred drug list (medicaid PDL)" - The list of all drugs in drug classes approved for inclusion by the Washington medicaid drug use review (DUR) board and each drug's preferred or nonpreferred status as approved by the agency director or designee. The list includes at minimum all drugs and drug classes on the Washington PDL and may include additional drugs and drug classes recommended by the DUR board and approved by the agency director or designee.

"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 for which there is at least one other drug product sold in the United States that is pharmaceutically equivalent and bioequivalent, as determined by the Food and Drug Administration (FDA).

"National drug code (NDC)" - The eleven-digit numerical code that includes the labeler code, product code, and package code.

"National rebate agreement" - The agreement developed by the Centers for Medicare and Medicaid Services (CMS) to implement section 1927 of the Social Security Act, and entered into by a manufacturer and the federal Department of Health and Human Services (DHHS).

"Noninnovator multiple-source drug" - A drug that is:

(1) A multiple-source drug that is not an innovator multiple-source drug or a single-source drug;

(2) A multiple-source drug marketed under an abbreviated new drug application (ANDA) or an abbreviated antibiotic drug application;

(3) A covered outpatient drug that entered the market before 1962 and was originally marketed under a new drug application (NDA); or

(4) Any drug that has not gone through a Food and Drug Administration (FDA) approval process but otherwise meets the definition of a covered outpatient drug.

If any of the drug products listed in this definition of a noninnovator multiple-source drug subsequently receive an NDA or ANDA approval from the FDA, the product's drug category changes to correlate with the new product application type.

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

"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" - A drug within a therapeutic class of drugs on the medicaid preferred drug list (medicaid PDL) that has been selected as a preferred drug.

"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.

"Professional dispensing fee":

(1) The fee the medicaid agency or its designee pays pharmacists and dispensing providers for covered prescriptions. The fee pays for costs in excess of the ingredient cost of a covered outpatient drug when a covered outpatient drug is dispensed; and

(2) Includes only costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a medicaid beneficiary. Pharmacy and dispensing provider costs include, but are not limited to, reasonable costs associated with a prescriber's time in checking the computer for information about an individual's coverage, performing drug utilization review and preferred drug list review activities, measurement or mixing of the covered outpatient drug, filling the container, beneficiary counseling, physically providing the completed prescription to the medicaid beneficiary, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the dispensing entity.

"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.

"Single-source drug" - A drug produced or distributed under an original new drug application (NDA) approved by the Food and Drug Administration (FDA) with an approved new drug application (NDA) number issued by the FDA. This includes:

(1) A drug product marketed by any cross-licensed producers, labelers, or distributors operating under the NDA; or

(2) A drug approved under a biologics license application (BLA), product license application (PLA), establishment license application (ELA), or antibiotic drug application (ADA).

For the purposes of this definition, an ANDA is not an NDA.

"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" - Refers to either the actual wholesale cost paid by a wholesaler for drugs purchased from a manufacturer or a list price published as wholesale acquisition cost.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 17-07-001, § 182-530-1050, filed 3/1/17, effective 4/1/17. 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;

(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.]

WAC 182-530-1080 Requirements for prescribing and dispensing controlled substances—Prescription monitoring program (PMP). This section identifies the steps prescribers must take before prescribing

a controlled substance and the steps pharmacists must take when dispensing a controlled substance from an outpatient pharmacy to check an apple health client's prescription drug history in the prescription monitoring program (PMP) described in chapter 246-470 WAC.

(1) **PMP review required.** Except as identified in subsection (4) of this section, a prescriber, before prescribing, and a pharmacist, when dispensing, must check all of a client's current prescriptions in the PMP, including any prescriptions not paid for by apple health.

(2) **Retrieval by delegates allowed.** A prescriber or pharmacist may delegate the retrieval of the client's PMP information to anyone in their practice setting with authorization to access the PMP, so long as the prescriber or pharmacist reviews all of the client's current prescriptions in the PMP before prescribing or when dispensing a controlled substance.

(3) **Documentation.** The prescriber and pharmacist must document in the client's record the date and time of the:

(a) Retrieval of information from the PMP; and

(b) Review of information from the PMP.

(4) **Good faith effort exception.**

(a) If a prescriber, pharmacist, or their delegate is unable to access the client's record in the PMP after a good faith effort, that attempt must be documented in the client's record.

(b) A prescriber or pharmacist must document the reason or reasons they were unable to conduct the check.

[Statutory Authority: RCW 41.05.021, 41.05.160 and Public Law 115-271. WSR 21-13-099, § 182-530-1080, filed 6/18/21, effective 10/1/21.]

COVERAGE

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

(a) Outpatient drugs, including over-the-counter (OTC) drugs, as defined in WAC 182-530-1050, 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 182-530-1050;

(iii) The drug is not excluded from coverage under WAC 182-530-2100;

(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 182-530-7500; and

(v) The drug is prescribed by a provider with prescriptive authority. Exceptions to the prescription requirement exist for family planning and emergency contraception in (b) of this subsection.

(b) Family planning drugs, devices, and drug-related supplies per chapter 182-532 WAC and as follows:

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

(ii) Family planning drugs that do not meet the federal drug rebate requirement in WAC 182-530-7500 on a case-by-case basis; and

(iii) Contraceptive patches, contraceptive rings, and oral contraceptives, excluding emergency contraception, when dispensed in a one-year supply only, unless:

(A) A smaller supply is directed by the prescriber;

(B) A smaller supply is requested by the client;

(C) The pharmacy does not have adequate stock.

(c) Vitamins, minerals, and enzymes when prescribed for:

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

(ii) A medical condition caused by a clinically documented deficiency;

(iii) A United States Preventive Services Task Force recommendation with an A or B rating;

(iv) Fluoride for clients under age twenty-one; or

(v) A clinically documented medical condition that causes vitamin, mineral, or enzyme deficiencies, and the deficiency cannot be treated through other dietary interventions.

(d) OTC drugs, vitamins, and minerals when determined by the agency to be the least costly therapeutic alternative for a medically accepted indication. All covered OTC products determined to be the least costly therapeutic alternatives for medically accepted indications will be included on the agency's published apple health preferred drug list. This subsection does not apply to products prescribed for the treatment of cough or cold symptoms. See this subsection (1)(h) of this section and WAC 182-530-2100 (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 182-530-2100; and

(iv) Determined by the agency that a product covered under chapter 182-543 WAC related to medical equipment and supplies should be available at retail pharmacies.

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

(g) OTC and prescription drugs to promote tobacco/nicotine cessation.

(h) For the treatment of cough and cold, only those products included with a preferred status on the apple health preferred drug list (PDL), as described in WAC 182-530-4100, on the date a client's prescription is dispensed.

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

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 21-02-004, § 182-530-2000, filed 12/23/20, effective 1/23/21. Statutory Authority: RCW 41.05.021, 41.05.160 and section 1927, (42 U.S.C. 1396r-8)(d)(2)(D) and (G), (d)(7)(A), (k)(4). WSR 19-22-016, § 182-530-2000, filed 10/25/19, effective 11/25/19. Statutory Authority: RCW 41.05.021, 41.05.160. WSR 16-17-071, § 182-530-2000, filed 8/16/16, effective 9/16/16. 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)(h).

(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)(h).

(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.

(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 and 41.05.160. WSR 21-02-004, § 182-530-2100, filed 12/23/20, effective 1/23/21. Statutory Authority: RCW 41.05.021, 41.05.160 and section 1927, (42 U.S.C. 1396r-8) (d)(2)(D) and (G), (d)(7)(A), (k)(4). WSR 19-22-016, § 182-530-2100,

filed 10/25/19, effective 11/25/19. Statutory Authority: RCW 41.05.021, 41.05.160. WSR 16-17-071, § 182-530-2100, filed 8/16/16, effective 9/16/16. 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. Covered drugs, devices, or drug-related supplies require authorization for reimbursement when:

(1) The medicaid agency's pharmacists or 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 drug, device, or drug-related supply as described in WAC 182-530-3100.

(2) The drug, device, or drug-related supply is in a 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);

(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) The agency is promoting safety, efficacy, and effectiveness of drug therapy, or 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 for 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 17-07-001, § 182-530-3000, filed 3/1/17, effective 4/1/17; 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 or medical consultants periodically evaluate covered drugs, covered indications, or new dosages approved by the Food and Drug Administration (FDA) to determine the drug authorization requirement.

(a) The clinical team evaluates and grades available information for each drug or drug class based on quality evidence contained in compendia of drug information and peer-reviewed medical literature. The information evaluated includes, but is not limited to:

(i) Evidence for efficacy and safety;

(ii) Cost comparisons of drugs with similar existing drugs;

(iii) Potential for clinical misuse;

(iv) Potential for client misuse or abuse;

(v) Drugs with a narrow therapeutic index;

(vi) Other safety concerns; or

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

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

(c) Based on the clinical team's evaluation, 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) 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.

(3) 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 17-07-001, § 182-530-3100, filed 3/1/17, effective 4/1/17; 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 medicaid agency's authorization process. (1) The agency may establish automated ways for pharmacies to meet authorization requirements for specified drugs, devices, and drug-related supplies, or circumstances as listed in WAC 182-530-3000 including, but not limited to:

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

(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 agency'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 agency 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 182-530-3000; 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 182-502-0020(5).

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

(a) The agency 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 agency 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 agency's request.

(B) The agency 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 agency will deny the requested service. The agency sends a copy of the request to the client at the time of denial.

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

(a) Requirements under this chapter and WAC 182-501-0165;

(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 agency 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 182-501-0169.

(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 agency must receive justification from the provider within seven days of the fill date to be reimbursed for the emergency fill.

(7) The agency may remove authorization requirements under WAC 182-530-3000 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 agency at the pharmacies' lower acquisition cost.

(8) Authorization requirements in WAC 182-530-3000 are not a denial of service.

(9) Rejection of a claim due to the authorization requirements listed in WAC 182-530-3000 is not a denial of service.

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

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

(12) The agency's authorization:

(a) Is a decision of medical appropriateness; and

(b) Does not guarantee payment.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 17-07-001, § 182-530-3200, filed 3/1/17, effective 4/1/17; WSR 16-17-071, § 182-530-3200, filed 8/16/16, effective 9/16/16. 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;

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

(iv) Obtain authorization as described in WAC 182-530-3200 prior to dispensing when required by the agency or an agency designee.

(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, excessive utilization, inappropriate or medically unnecessary care, or prescribing billing practices that indicate abuse or excessive utilization among physicians, pharmacists, and individuals receiving benefits.

(2) The agency reviews a periodic sampling of claims to determine if drugs are appropriately ordered, prescribed, administered, dispensed, and billed. If a review of the sample finds that a provider is inappropriately ordering, prescribing, administering, 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 ordering, prescribing, administering, dispensing, or billing practices;

(c) Applying additional provider-specific requirements for obtaining authorization prior to ordering, prescribing, administering, dispensing, or billing for drugs;

(d) Recouping the payment for the drug or drugs; or

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

[Statutory Authority: RCW 41.05.021, 41.05.160, H.R. 6, § 1004, 42 U.S.C. 1396a(a) and 1396r-8(g). WSR 20-06-077, § 182-530-4050, filed 3/4/20, effective 4/4/20. 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 Medicaid preferred drug list (medicaid PDL). (1) The medicaid agency contracts with a vendor to perform systematic evidence-based drug reviews.

(2) The pharmacy and therapeutics (P&T) committee or the drug use review (DUR) board reviews and evaluates the safety, efficacy, and outcomes of prescribed drugs, using evidence-based drug reviews.

(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. The DUR board makes recommendations to the medicaid agency about which additional drug classes to include in the medicaid PDL.

(4) The agency director or designee makes the final selection of drugs or drug classes included on the medicaid PDL.

(5) Drugs in a drug class on the medicaid PDL which are not on the Washington PDL are not subject to therapeutic interchange program (TIP) and dispense as written (DAW) rules under WAC 182-530-4150.

(6) Drugs in a drug class on the medicaid PDL that have not been reviewed by the P&T committee or the DUR board may be treated as nonpreferred drugs and are not subject to DAW or TIP.

(7) A nonpreferred drug 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 medicaid PDL may be designated as preferred drugs for special populations or specific indications.

(9) Drugs in a drug class on the medicaid PDL may require authorization regardless of preferred or nonpreferred status.

(10) When a preferred innovator drug or biological product on the medicaid PDL loses its patent, the agency may:

(a) Designate an available, equally effective, generic equivalent, or biosimilar biological product as a preferred drug; and

(b) Make the innovator drug or biological product nonpreferred.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 17-07-001, § 182-530-4100, filed 3/1/17, effective 4/1/17; 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 Au-

thority: 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. (1) The medicaid agency may require preferred generic drugs on the Washington preferred drug list (Washington 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, according to RCW 69.41.190.

(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 drug use review (DUR) board will be subject to authorization to establish medical necessity as defined in WAC 182-500-0070.

(4) The 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.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 17-07-001, § 182-530-4125, filed 3/1/17, effective 4/1/17; 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.

(1) TIP applies only to drugs:

(a) Within therapeutic classes on the Washington preferred drug list (Washington PDL);

(b) Included in a motion passed by the pharmacy and therapeutics (P&T) committee; and

(c) Prescribed by an endorsing practitioner.

(2) TIP does not apply to a drug when:

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

(b) Prescribed by a nonendorsing practitioner;

(c) The endorsing practitioner signs the prescription "dispense as written (DAW)"; or

(d) Otherwise prohibited under RCW 69.41.190.

(3) The agency may impose nonendorsing status on an endorsing practitioner only under the circumstances outlined in RCW 69.41.190.

(4) Except as otherwise provided in subsection (5) of this section, the agency may restrict a client's first course of treatment

within a therapeutic class, according to the provisions in RCW 69.41.190.

(5) 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 17-07-001, § 182-530-4150, filed 3/1/17, effective 4/1/17; 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.]

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 the signature of either the client or the provider, the 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 21-05-043, § 182-530-5000, filed 2/11/21, effective 3/14/21; 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 submitted 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 and specialty pharmacy services. Clients may elect to receive pharmacy services through any mail-order or specialty pharmacy enrolled with the agency.

(1) Mail-order pharmacies or specialty pharmacies licensed to do business in Washington state under RCW 18.64.360 may enroll with the agency in the same manner as other pharmacies according to chapter 182-502 WAC, including out-of-state mail-order or specialty pharmacies.

(2) The agency considers mail-order and specialty classes of trade the same as retail class of trade for the purpose of enrollment with the agency. When enrolling with the agency, a mail-order or specialty pharmacy must enroll as a retail pharmacy unless participating with the agency under a mail-order or specialty pharmacy contract. Mail-order and specialty pharmacies cannot enroll under a mail-order designation by taxonomy or other indicator except when providing services under a mail-order contract with the agency separate from and in addition to the pharmacy's core provider agreement.

(3) Out-of-state pharmacies must comply with all applicable Revised Code of Washington and Washington Administrative Code when serving agency clients.

(4) The provisions of this chapter apply equally to all pharmacies and services provided by pharmacies regardless of the pharmacy's class of trade, except when those services are provided under a contract with the agency separate from and in addition to the pharmacy's core provider agreement.

(5) The agency may contract with one or more mail-order or specialty pharmacies separate from and in addition to the pharmacy's core provider agreement.

(a) Provisions of the contract may differ from requirements detailed in this chapter including, but not limited to, reimbursement rates, dispensing limitations, and authorization requirements.

(b) Mail-order or specialty pharmacy contract provisions supersede individual sections or subsections of this chapter when specifically cited in contract, leaving in effect all other provisions of this chapter.

(c) Mail-order contract provisions for a dispensing pharmacy must not allow for a higher reimbursement than is allowed under this chapter for a retail pharmacy.

(d) When opening enrollment under a mail-order or specialty contract, the agency will make publicly available the contract provisions and minimum requirements to participate under the contract including, but not limited to, the reimbursement rate and methodology the provider must accept. Any pharmacy enrolled with Washington medicaid as a billing provider may choose to accept and participate with the agency under the terms of the mail-order or specialty pharmacy contract.

(e) The agency may use the same contract for both mail-order and specialty pharmacies, or may have separate standard contracts for each class of trade.

(f) The agency may base contract provisions on information supplied through a request for information to interested parties before making the finalized contract publicly available.

(6) The agency may implement programs or contract provisions that provide favorable conditions to contracted mail-order pharmacies, specialty pharmacies, or clients to encourage participation by pharmacies or the use of mail-order and specialty services by clients.

(7) The agency may designate specific products or classes of products to be made available to clients through mail-order or specialty pharmacies only.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 17-07-001, § 182-530-6000, filed 3/1/17, effective 4/1/17; 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 reimbursement for a prescription drug dispensed through point-of-sale (POS) must not exceed the lesser of actual acquisition cost (AAC) plus a professional dispensing fee or the provider's usual and customary charge.

(2) The agency selects the sources for pricing information used to set POS AAC.

(3) The POS AAC is calculated as the lowest of:

(a) National average drug acquisition cost (NADAC);

(b) Maximum allowable cost (MAC);

(c) Federal upper limit (FUL);

(d) 340B Actual acquisition cost (340B AAC) for drugs purchased under section 340B of the Public Health Service (PHS) Act (see WAC 182-530-7900 for exceptions); or

(e) Automated maximum allowable cost (AMAC).

(4) Where NADAC does not exist, other available reference prices from national sources such as wholesale acquisition cost, or average manufacturer price will be used as the basis of the reimbursement.

(5) Where NADAC does not accurately reflect the actual acquisition costs in Washington state, a percentage adjustment to NADAC will be made to the reimbursement.

(6) The agency may set POS AAC for specified drugs or drug categories at a maximum allowable cost other than that determined in subsection (2) of this section based on specific product acquisition costs. The agency considers product acquisition costs in setting a rate for a drug or a class of drugs.

(7) The agency bases POS AAC drug reimbursement on the actual package size dispensed.

(8) 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.

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

(10) 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.

(11) 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 and 41.05.160. WSR 17-07-001, § 182-530-7000, filed 3/1/17, effective 4/1/17. 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 medicaid agency pays a dispensing fee for each covered, prescribed drug.

(2) The agency does not pay a dispensing fee for:

(a) Nondrug items, devices, or drug-related supplies; or

(b) Drugs administered by a health care professional.

(3) The agency periodically examines the sufficiency of pharmacy dispensing fees and may adjust 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 17-07-001, § 182-530-7050, filed 3/1/17, effective 4/1/17; 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 nondrug 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), 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 professional 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 17-07-001, § 182-530-7150, filed 3/1/17, effective 4/1/17; 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. (1) The medicaid agency reimburses for covered drugs, devices, and drug-related sup-

plies provided or administered by nonpharmacy providers under specified conditions, as follows:

(a) 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:

(i) Chapter 182-531 WAC, Physician-related services;

(ii) Chapter 182-532 WAC, Reproductive health/family planning only/TAKE CHARGE; and

(iii) Chapter 182-540 WAC, Kidney disease program and kidney center services.

(b) Providers who are purchasers of Public Health Services (PHS) discounted drugs must comply with PHS 340B program requirements and Washington medicaid requirements for 340B providers participating with medicaid. (See WAC 182-530-7900.)

(2) 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 discounts or free goods associated with the invoice.

(3) 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 17-07-001, § 182-530-7250, filed 3/1/17, effective 4/1/17; 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 the provider's actual acquisition cost (provider 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 17-07-001, § 182-530-7300, filed 3/1/17, effective 4/1/17; 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 serv-

ices 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) The agency pays medicare coinsurance, copayments, and deductibles for Part A, Part B, and medicare advantage Part C, subject to the limitations in WAC 182-502-0110.

(2) Medicare Part D:

(a) Medicare is the payer for drugs included in 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 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 and 41.05.160. WSR 17-07-001, § 182-530-7700, filed 3/1/17, effective 4/1/17. 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 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) Providers dispensing or administering 340B drugs to Washington apple health clients are required to submit their valid medicaid provider number(s) or national provider identification (NPI) number to the PHS health resources and services administration, office of pharmacy affairs. See WAC 182-530-7500 for information on the drug rebate program.

(2) Drugs purchased under section 340B of the Public Health Service (PHS) Act can be billed to Washington apple health only by PHS-qualified entities. The Washington medicaid rebate process excludes 340B claims from invoicing only when the drug is billed by a medicaid provider number or national provider identification (NPI) number listed on the PHS office of pharmacy affairs national medicaid exclusion file. See WAC 182-530-7500 for information on the drug rebate program.

(3) As part of participation in the 340B program, providers must submit a completed annual attestation form (HCA 13-0047) to the agency

acknowledging that all claims for Washington apple health clients in both fee-for-service and managed care are subject to their respective 340B rules. Providers who fail to submit a completed attestation form to the agency may receive a compliance audit and be at risk of duplicate discounts.

(4) With the exception of claim types identified in subsection (5) of this section, all 340B purchased drugs under the medicaid fee-for-service program must be billed to the medicaid agency at the 340B actual acquisition cost (340B AAC).

(5) Exceptions to the 340B AAC billing requirement are only made for:

(a) Outpatient hospital claims paid under the enhanced ambulatory payment group (EAPG) methodology (see WAC 182-550-7000); and

(b) Ambulatory surgery claims paid under payment groups methodology.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 21-08-021, § 182-530-7900, filed 3/29/21, effective 5/1/21; WSR 17-07-001, § 182-530-7900, filed 3/1/17, effective 4/1/17; 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—Actual acquisition cost (AAC). The medicaid agency uses the following sources to determine point-of-sale actual acquisition cost (POS AAC) including, but not limited to:

(1) National average drug acquisition cost (NADAC) published by the Centers for Medicare and Medicaid Services (CMS);

(2) Acquisition cost data made available to the agency by:

(a) Audit results from federal or state agencies;

(b) Other state health care purchasing organizations;

(c) Pharmacy benefit managers;

(d) Individual pharmacy providers participating in the agency's programs;

(e) Other third-party payers;

(f) Drug file databases; and

(g) Actuaries or other consultants.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 17-07-001, § 182-530-8000, filed 3/1/17, effective 4/1/17; 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 actual acquisition cost (AAC) 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 17-07-001, § 182-530-8100, filed 3/1/17, effective 4/1/17; 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 national average drug acquisition cost (NADAC) or other nationally accepted pricing source in order to estimate acquisition cost.

(3) The agency sets the percentage discount from NADAC 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 NADAC 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, 41.05.160. WSR 17-07-001, § 182-530-8150, filed 3/1/17, effective 4/1/17; 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.]