RULE-MAKING ORDER

CR-103P (May 2009)
(Implements RCW 34.05.360)

Agency: Health Care Authority, Washington Apple Health

Permanent Rule Only

Effective date of rule:

Permanent Rules

☒ 31 days after filing.

☐ Other (specify) _____ **(If less than 31 days after filing, a specific finding under RCW 34.05.380(3) is required and should be stated below)**

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

☐ Yes ☒ No If Yes, explain:

Purpose: The agency is revising this chapter to align with the Centers for Medicare and Medicaid Services (CMS) new covered outpatient drug rule, CMS-2345-FC. The agency is also amending these rules to increase the number of drug classes eligible for supplemental rebates. Changes include but are not limited to definition updates; new language about drugs, devices, and drug-related supplies; authorization updates; new language about point-of-sale and actual acquisition costs; updates to therapeutic interchange program; clarified processes for mail order and specialty pharmacy services; added information on 340B providers; added information on Medicare Part A, B, and C; and revised section on drugs purchased under the Public Health Services act.

Citation of existing rules affected by this order:

Repealed: None

Amended: 182-530-1050, 182-530-3000, 182-530-3100, 182-530-3200, 182-530-4100, 182-530-4125, 182-530-4150, 182-530-6000, 182-530-7000, 182-530-7050, 182-530-7150, 182-530-7250, 182-530-7300, 182-530-7700, 182-530-7900, 182-530-8000, 182-530-8100, 182-530-8150

Suspended: None

Statutory authority for adoption: RCW 41.05.021, 41.05.160

Other authority:

PERMANENT RULE (Including Expedited Rule Making)

Adopted under notice filed as WSR 17-02-083 on January 4, 2017.

Describe any changes other than editing from proposed to adopted version: See Appendix

If a preliminary cost-benefit analysis was prepared under RCW 34.05.328, a final cost-benefit analysis is available by contacting:

Name: phone ( ) _____

Address: fax ( ) _____

e-mail _____

Date adopted: March 1, 2017

NAME (TYPE OR PRINT)
Wendy Barcus

SIGNATURE

TITLE
HCA Rules Coordinator

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: March 01, 2017
TIME: 12:29 PM

WSR 17-07-001

(COMPLETE REVERSE SIDE)

Note: If any category is left blank, it will be calculated as zero. No descriptive text.

Count by whole WAC sections only, from the WAC number through the history note. A section may be counted in more than one category.

The number of sections adopted in order to comply with:

Federal statute:	New	_____	Amended	_____	Repealed	_____
Federal rules or standards:	New	_____	Amended	_____	Repealed	_____
Recently enacted state statutes:	New	_____	Amended	_____	Repealed	_____

The number of sections adopted at the request of a nongovernmental entity:

New _____ Amended _____ Repealed _____

The number of sections adopted in the agency's own initiative:

New _____ Amended _____ Repealed _____

The number of sections adopted in order to clarify, streamline, or reform agency procedures:

New _____ Amended 18 Repealed _____

The number of sections adopted using:

Negotiated rule making:	New	_____	Amended	_____	Repealed	_____
Pilot rule making:	New	_____	Amended	_____	Repealed	_____
Other alternative rule making:	New	_____	Amended	18	Repealed	_____

Appendix

Note: Strikeouts and underlines indicate language deleted or added since the proposal.

WAC 182-530-1050

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

WAC 182-530-1050

"Evidence-based drug reviews" ~~and evidenced-based medicine (EBM)~~ The application of a set of principles and ~~a~~ methods for comprehensive independent and objective evaluation of clinical evidence provided in ~~for the review of~~ 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.

WAC 182-530-1050

"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.

WAC 182-530-1050

"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 ~~determined~~ 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 ~~at the discretion of~~ recommended by the DUR board and approved by the agency director or designee.

WAC 182-530-3100 (1)(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.

WAC 182-530-4100(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 ~~information provided by the vendor~~.

WAC 182-530-4100 (5)

Drugs in a drug class on the medicaid PDL ~~only but~~ 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.

WAC 182-530-7900(4):

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.~~; and~~

~~(c) Family planning clinics billing contraceptives designated by the agency to be paid at 340B ceiling price plus a professional dispensing fee.~~

AMENDATORY SECTION (Amending WSR 13-18-035, filed 8/28/13, effective 9/28/13)

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

"Active ingredient" - The chemical component of a drug responsible for a drug's prescribed/intended therapeutic effect. The medicaid agency or its designee limits coverage of active ingredients to those with an eleven-digit national drug code (NDC) and those specifically authorized by the agency or its designee.

"Actual acquisition cost (AAC)" - ((~~The net cost a provider paid for a drug, device, or drug-related supply marketed in the package size purchased. The AAC includes discounts, rebates, charge backs and other adjustments to the price of the drug, device or drug-related supply, but excludes dispensing fees.~~)) 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" - ((~~For the evidence-based prescription drug program of the participating agencies in the state-operated health care programs, the following persons acting jointly: The director of the health care authority (HCA), the secretary of the department of social and health services (DSHS), and the director of the department of labor and industries (L&I).~~)) 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)" - ((~~The average~~)) A reference price of a drug product that is ((~~calculated from wholesale list prices nationwide~~)) published at a point in time and reported to the medicaid agency or its designee by the agency's drug file contractor.

((~~**"Combination drug"** - A commercially available drug including two or more active ingredients.~~)) **"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" - ((~~The fee the medicaid agency or its designee sets to pay pharmacy providers for dispensing agency-covered prescriptions. The fee is the agency's maximum reimbursement for expenses involved in the practice of pharmacy and is in addition to the agency's reimbursement for the costs of covered ingredients.~~

~~**"Drug evaluation matrix"** - The criteria-based scoring sheet used to objectively and consistently evaluate the food and drug administration (FDA) approved drugs to determine drug coverage status.~~)) 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 rebates"** - Reimbursements provided by pharmaceutical manufacturers to state medicaid programs under the terms of the manufacturers' agreements with the Department of Health and Human Services (DHHS).~~))

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

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

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

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

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

"Endorsing practitioner" - A practitioner who has reviewed the Washington preferred drug list (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((~~" and "evidenced-based medicine (EBM)~~)) drug reviews" - The application of a set of principles and ((~~a method for the review of~~)) 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) ((~~of the U.S. government to conduct systematic reviews of all the evidence to produce evidence tables and technology assessments to guide health care decisions~~)) 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' national 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.

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

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

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

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

"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 ((~~marketed or sold by:~~
~~(1) Two or more manufacturers or labelers; or~~
~~(2) The same manufacturer or labeler:~~
~~(a) Under two or more different proprietary names; or~~
~~(b) Under a proprietary name and a generic name~~)) 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 ((~~number the FDA and manufacturer or labeler assigns to a pharmaceutical product and attaches to the product container at the time of packaging. The NDC is composed of digits in 5-4-2 groupings. The first five digits comprise the labeler code assigned to the manufacturer by the Food and Drug Administration (FDA). The second grouping of four digits is assigned by the manufacturer to describe the ingredients, dose form, and strength. The last grouping of two digits describes the package size.~~

~~**"Noncontract drugs"** - Are drugs manufactured or distributed by manufacturers/labelers who have not signed a drug rebate agreement with the federal Department of Health and Human Services~~)) 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 ((~~that has not been selected as a preferred drug~~)) within ((~~the~~)) a therapeutic ((~~class(es)~~)) 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" - ((~~Drug(s) of choice within a selected therapeutic class that are selected based on clinical evidence of safety, efficacy, and effectiveness.~~

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

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

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

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

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

~~(2) A therapeutically equivalent drug other than the identical base or salt~~)) 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" - ((~~The price~~)) 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.

AMENDATORY SECTION (Amending WSR 16-01-046, filed 12/9/15, effective 1/9/16)

WAC 182-530-3000 When the medicaid agency requires authorization. ((~~Pharmacies must obtain authorization for covered drugs, devices, or drug-related supplies in order to receive reimbursement as described in this section.~~)) Covered drugs, devices, or drug-related supplies require authorization for reimbursement when:

(1) The medicaid agency's pharmacists ((~~and~~)) 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 ((~~manufacturer's dossier of drug information submitted in the Academy of Managed Care Pharmacy (AMCP) format~~)) drug, device, or drug-related supply as described in WAC 182-530-3100.

(2) The drug, device, or drug-related supply is in ((~~the~~)) 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) ((~~For the purpose of~~)) 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 ((~~of~~)) 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.

AMENDATORY SECTION (Amending WSR 16-01-046, filed 12/9/15, effective 1/9/16)

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

(a) The clinical team ((~~uses a drug evaluation matrix to evaluate and score the benefit/risk assessment and cost comparisons of drugs to similar existing drugs~~)) 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) ((~~Information reviewed in the drug evaluation matrix includes, but is not limited to, the following:~~

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

~~(ii) Potential for clinical misuse;~~

~~(iii) Potential for client misuse/abuse;~~

~~(iv) Narrow therapeutic indication;~~

~~(v) Safety concerns;~~

~~(vi) Availability of less costly therapeutic alternatives; and~~

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

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

(i) Requires authorization;

(ii) Requires authorization to exceed agency-established limitations; or

(iii) Does not require authorization.

(2) ((~~Drugs in therapeutic classes on the Washington preferred drug list are not subject to determination of authorization requirements through the drug evaluation matrix. Authorization requirements are determined by their preferred status according to WAC 182-530-4100.~~

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

((~~(4)~~)) (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.

AMENDATORY SECTION (Amending WSR 16-17-071, filed 8/16/16, effective 9/16/16)

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 ((~~(3) and (4)~~)) including, but not limited to:

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

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

(c) Use of diagnosis codes; and

(d) Evidence of previous therapy within the 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 ((~~(3) and (4)~~)); and

(b) Keep documentation on file of the prescriber's medical justification that is communicated to the pharmacy by the prescriber at the time the prescription is filled. The records must be retained for the period specified in WAC 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 <u>determination</u> 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.

AMENDATORY SECTION (Amending WSR 15-12-093, filed 6/2/15, effective 7/3/15)

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

~~(1) Washington state~~)) (1) The medicaid agency contracts with ((~~evidence-based practice centers for~~)) 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 ((~~information provided by the evidence-based practice centers~~)) 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 ((~~appointing authority~~)) agency director or designee makes the final selection of drugs or drug classes included on the ((~~Washington~~)) medicaid PDL.

(5) Drugs in a drug class on the ((~~Washington PDL that have been studied by an evidence-based practice center and reviewed by the P&T committee and which have not been selected as preferred are considered nonpreferred drugs and are subject to the~~)) 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 ((~~Washington~~)) medicaid PDL that ((~~have not been studied by an evidence-based practice center and~~)) have not been reviewed by the P&T committee ((~~will~~)) or the DUR board may be treated as nonpreferred drugs and are not subject to ((~~the dispense as written (DAW) or the therapeutic interchange program (TIP)~~)) DAW or TIP.

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

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

(b) Met agency-established criteria for the nonpreferred drug.

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

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

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

~~(11)~~)) When a ((~~brand-name~~)) preferred innovator drug ((~~has been reviewed by the P&T committee~~)) or biological product on the medicaid PDL loses its patent, the agency may ((~~immediately~~)):

(a) Designate an available, ((~~less expensive,~~)) equally effective, generic equivalent, or biosimilar biological product as a preferred drug((~~. For the purpose of this chapter, generic equivalent drugs are those identified in the Food and Drug Administration's approved drug products with therapeutic equivalence evaluations (orange book).~~

~~(12) The dispensing of a brand name or nonpreferred generic drug in a drug class on the Washington PDL as a client's first course of treatment within that therapeutic class may be subject to restrictions under WAC 182-530-4125 and 182-530-4150(10)~~)); and

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

AMENDATORY SECTION (Amending WSR 15-12-093, filed 6/2/15, effective 7/3/15)

WAC 182-530-4125 Generics first for a client's first course of treatment. ((~~The medicaid agency uses point-of-sale (POS) claim messaging to tell pharmacies to use a preferred generic drug for the client's first course of treatment in specific drug classes.~~)) (1) The 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, ((~~when:~~

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

~~(b) The drug use review (DUR) board established under WAC 182-530-4000 has reviewed the drug class and recommended to the agency that the drug class is appropriate to require generic drugs as a client's first course of treatment~~)) 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.

AMENDATORY SECTION (Amending WSR 16-01-046, filed 12/9/15, effective 1/9/16)

WAC 182-530-4150 Therapeutic interchange program (TIP). This section contains the medicaid agency's rules for the endorsing practitioner therapeutic interchange program (TIP). TIP is established under RCW 69.41.190 and 70.14.050((~~. The statutes require state-operated prescription drug programs to allow physicians and other prescribers to endorse a Washington preferred drug list (PDL) and, in most cases, requires pharmacists to automatically substitute a preferred, equivalent drug from the list~~)).

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

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

(b) ((~~Studied by the evidence-based practice center or centers;~~

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

((~~(d)~~)) (c) Prescribed by an endorsing practitioner.

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

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

(b) ((~~To a drug~~)) Prescribed by a nonendorsing practitioner((~~.~~

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

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

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

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

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

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

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

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

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

~~(a) Antipsychotic;~~

~~(b) Antidepressant;~~

~~(c) Antiepileptic;~~

~~(d) Chemotherapy;~~

~~(e) Antiretroviral;~~

~~(f) Immunosuppressive; or~~

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

~~(7)~~));

(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 ((~~following~~)) circumstances((~~:~~

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

~~(b) The medical director has:~~

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

~~(ii) Provided the endorsing practitioner an opportunity to explain the variation in prescribing patterns as medically necessary as defined under WAC 182-500-0070; or~~

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

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

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

~~(10)~~)) outlined in RCW 69.41.190.

(4) Except as otherwise provided in subsection ((~~(11)~~)) (5) of this section, ((~~for~~)) the agency may restrict a client's first course of treatment within a therapeutic class ((~~of drugs, the endorsing practitioner's option to write DAW does not apply when:~~

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

~~(b) The drug use review (DUR) board established under WAC 182-530-4000 has reviewed the drug class and recommended to the agency that the drug class is appropriate to require generic drugs as a client's first course of treatment.~~

~~(11)~~)), 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.

AMENDATORY SECTION (Amending WSR 16-01-046, filed 12/9/15, effective 1/9/16)

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

~~(1) The contracted mail-order pharmacy service is available as an option to all Washington apple health clients, subject to the:~~

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

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

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

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

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

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

~~(i) Preferred drugs (see WAC 182-530-4100);~~

~~(ii) Generic drugs; and~~

~~(iii) Drugs that do not have authorization requirements (see WAC 182-530-3000 through 182-530-3200).~~

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

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

~~(ii) Drugs having authorization requirements (see WAC 182-530-3000).~~

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

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

tract 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.

AMENDATORY SECTION (Amending WSR 12-16-061, filed 7/30/12, effective 11/1/12)

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

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

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

(d) 340B Actual acquisition cost (340B AAC) ((~~plus a dispensing fee~~)) 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) ((~~plus a dispensing fee; or~~

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

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

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

(4) 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.

((~~(5)~~)) (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.

((~~(6)~~)) (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.

((~~(7)~~)) (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.

AMENDATORY SECTION (Amending WSR 16-01-046, filed 12/9/15, effective 1/9/16)

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((s)) 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.

AMENDATORY SECTION (Amending WSR 16-01-046, filed 12/9/15, effective 1/9/16)

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

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

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

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

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

(b) The pharmacist must ensure that the ingredients used in a compounded prescription are for an approved use as defined in "medically accepted indication" in WAC 182-530-1050.

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

(6) Compounded prescriptions are reimbursed as follows:

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

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

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

(d) The agency pays a 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 follow-

ing 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).

AMENDATORY SECTION (Amending WSR 16-01-046, filed 12/9/15, effective 1/9/16)

WAC 182-530-7250 Reimbursement—Miscellaneous. (1) The medicaid agency reimburses for covered drugs, devices, and drug-related supplies provided or administered by nonpharmacy providers under specified conditions, as follows:

((~~(1)~~)) (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:

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

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

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

((~~(2)~~)) (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.)

((~~(3)~~)) (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.

((~~(4)~~)) (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.

AMENDATORY SECTION (Amending WSR 16-01-046, filed 12/9/15, effective 1/9/16)

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.

AMENDATORY SECTION (Amending WSR 13-14-052, filed 6/27/13, effective 7/28/13)

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

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

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

~~(b) Deductible and/or coinsurance amounts up to medicare's or the agency's maximum allowable fee, whichever is less, for drugs medicare and the agency cover.~~)) 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 ((~~covered under~~)) 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 ((~~basic~~)) medicare Part D benefit:

(i) The agency offers the same drug benefit as a nondual eligible client has within those same classes;

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

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

AMENDATORY SECTION (Amending WSR 16-01-046, filed 12/9/15, effective 1/9/16)

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

~~(2)~~)) Providers dispensing ((~~drugs under this section~~)) 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. ((~~This requirement is to ensure that claims for drugs dispensed under this section and paid by the agency are excluded from the drug rebate claims that are submitted to the manufacturers of the drugs.~~)) See WAC 182-530-7500 for information on the drug rebate program.

((~~(3) The agency reimburses drugs under this section at actual acquisition cost plus a dispensing fee set by the agency.~~)) (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) With the exception of claim types identified in subsection (4) of this section, all 340B purchased drugs must be billed to the medicaid agency at the 340B actual acquisition cost (340B AAC).

(4) 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.

AMENDATORY SECTION (Amending WSR 16-01-046, filed 12/9/15, effective 1/9/16)

WAC 182-530-8000 Reimbursement method—((~~Estimated~~)) Actual acquisition cost ((~~(EAC)~~)) (AAC). ((~~(1)~~)) The medicaid agency ((~~determines estimated~~)) uses the following sources to determine point-of-sale actual acquisition cost ((~~(EAC) using:~~

~~(a)~~)) (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((~~; or~~

~~(b) Information provided by any of the following~~)) by:

((~~(i)~~)) (a) Audit ((~~agencies,~~)) results from federal or state agencies;

((~~(ii)~~)) (b) Other state health care purchasing ((~~agencies~~)) organizations;

((~~(iii)~~)) (c) Pharmacy benefit managers;

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

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

~~(vi)~~)) (e) Other third-party payers;

((~~(vii)~~)) (f) Drug file data bases; and

((~~(viii)~~)) (g) Actuaries or other consultants.

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

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

~~(a) Product acquisition cost;~~

~~(b) The agency's documented clinical concerns; and~~

~~(c) The agency's budget limits.~~

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

~~(5) The agency uses EAC as the agency's reimbursement for a drug when EAC is the lowest of the rates calculated under the methods listed in WAC 182-530-7000, or when the conditions of WAC 182-530-7300 are met.~~))

AMENDATORY SECTION (Amending WSR 16-01-046, filed 12/9/15, effective 1/9/16)

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

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

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

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

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

(iii) Establishes the MAC at a level which gives pharmacists access to at least one product from a manufacturer with a qualified rebate agreement (see WAC 182-530-7500(4)).

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

(3) The MAC established for a multiple-source drug does not apply if the written prescription identifies that a specific brand is medically necessary for a particular client. In such cases, the ((~~estimated~~)) actual acquisition cost ((~~(EAC)~~)) (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.

AMENDATORY SECTION (Amending WSR 16-01-046, filed 12/9/15, effective 1/9/16)

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

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

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

(2) The agency establishes AMAC as a specified percentage of the published ((~~average wholesale price (AWP)~~)) 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 ((~~AWP~~)) 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 ((~~AWP~~)) 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.