WSR 25-04-118
EXPEDITED RULES
HEALTH CARE AUTHORITY
[Filed February 5, 2025, 11:21 a.m.]

Title of Rule and Other Identifying Information: WAC 182-530-1050 Definitions, 182-540-170 Items and services not included in the composite rate, and 182-540-200 Epoetin alpha (EPO) therapy.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: The health care authority (HCA) is correcting WAC cross citations. The proposed rule corrects typographical errors without changing the rule's effect.

Reasons Supporting Proposal: HCA is amending these rules to update the department of health (DOH) WAC cross references to the correct WAC citation. WAC 182-530-1050 cross references WAC 246-863-100, which was repealed by DOH. The new citation is WAC 246-945-350. Both WAC 182-540-170 and 182-540-200 cross reference WAC 246-905-020, which was also repealed by DOH and is now found under WAC 246-945-090.

Statutory Authority for Adoption: RCW 41.05.021 and 41.05.160.

Statute Being Implemented: RCW 41.05.021 and 41.05.160.

Rule is not necessitated by federal law, federal or state court decision.

Name of Proponent: HCA, governmental.

Name of Agency Personnel Responsible for Drafting: Valerie Freudenstein, P.O. Box 42716, Olympia, WA 98504-2716, 360-725-1344; Implementation and Enforcement: Donna Sullivan and Fawn Ross, P.O. Box 42716, Olympia, WA 98504-2716, 360-725-1564 and 360-725-1611.

This notice meets the following criteria to use the expedited adoption process for these rules:

Corrects typographical errors, makes address or name changes, or clarifies language of a rule without changing its effect.

Explanation of the Reason the Agency Believes the Expedited Rule-Making Process is Appropriate: The expedited rule-making process is appropriate because the proposed rule corrects typographical errors without changing the rule's effect.

NOTICE

THIS RULE IS BEING PROPOSED UNDER AN EXPEDITED RULE-MAKING PROCESS THAT WILL ELIMINATE THE NEED FOR THE AGENCY TO HOLD PUBLIC HEARINGS, PREPARE A SMALL BUSINESS ECONOMIC IMPACT STATEMENT, OR PROVIDE RESPONSES TO THE CRITERIA FOR A SIGNIFICANT LEGISLATIVE RULE. IF YOU OBJECT TO THIS USE OF THE EXPEDITED RULE-MAKING PROCESS, YOU MUST EXPRESS YOUR OBJECTIONS IN WRITING AND THEY MUST BE SENT TO Rules Coordinator, HCA, P.O. Box 42716, Olympia, WA 98504-2716, phone 360-725-1306, fax 360-586-9727, email arc@hca.wa.gov, BEGINNING February 6, 2025, 8:00 a.m., AND RECEIVED BY April 8, 2025, 11:59 p.m.

February 5, 2025
Wendy Barcus
Rules Coordinator

RDS-6164.1

AMENDATORY SECTION (Amending WSR 24-08-061, filed 3/29/24, effective 5/1/24)

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.

"340B program" - The federal program that requires drug manufacturers participating in the medicaid drug rebate program (MDRP) to provide covered outpatient drugs to enrolled "covered entities" at or below the ceiling price, as described in 42 U.S.C. § 256b. This requirement is described in section 340B of the Public Health Service Act and codified in 42 U.S.C. § 256b.

"340B provider" or **"PHS-qualified covered entity"** - Any provider including, but not limited to, a clinic, facility, hospital, pharmacy, or program listed in 42 U.S.C. § 256b as eligible to purchase, dispense, or administer outpatient drugs through the 340B program, has submitted its valid medicaid provider number(s) or national provider identification (NPI) number to the public health service (PHS), health resources and services administration (HRSA), office of pharmacy affairs (OPA), and has registered with and been approved by OPA.

"340B maximum allowable cost (340B MAC)" - The maximum amount the medicaid agency reimburses a participating 340B public health services (PHS)-qualified covered entity to purchase, dispense, or administer a covered outpatient drug, device, or drug-related supply.

"Active ingredient" - The chemical component of a drug responsible for a drug's prescribed/intended therapeutic effect. The medicaid agency or the agency's designee limits coverage of active ingredients to those with an 11-digit national drug code (NDC) and those specifically authorized by the agency or the agency's designee.

"Actual acquisition cost (AAC)" - The true cost 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.

"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" - 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.

"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 wholesaler's 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' 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.

"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 11-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 publi-

cation 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~~)) 246-945-350 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 11-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.

RDS-6165.1

AMENDATORY SECTION (Amending WSR 15-14-040, filed 6/24/15, effective 7/25/15)

WAC 182-540-170 Items and services not included in the composite rate. The following items and services are not included in the composite rate and must be billed separately, subject to the restrictions or limitations in this section and other applicable published WAC:

(1) Drugs related to treatment((~~,~~)) including, but not limited to, epoetin alpha (EPO) and diazepam. The drug must:

(a) Be prescribed by a physician;

(b) Meet the rebate requirements described in WAC 182-530-7500; and

(c) Meet the requirements of WAC ((~~246-905-020~~)) 246-945-090 when provided for home use.

(2) Supplies used to administer drugs and blood;

(3) Blood processing fees charged by the blood bank (refer to WAC 182-540-190); and

(4) Home dialysis helpers.

AMENDATORY SECTION (Amending WSR 15-14-040, filed 6/24/15, effective 7/25/15)

WAC 182-540-200 Epoetin alpha (EPO) therapy. The medicaid agency reimburses the kidney center for EPO therapy when:

(1) Administered in the kidney center to a client:

(a) With a hematocrit less than ((~~thirty-three~~)) 33 percent or a hemoglobin less than ((~~eleven~~)) 11 when therapy is initiated;

(b) Continuing EPO therapy with a hematocrit between ((~~thirty and thirty-six~~)) 30 and 36 percent; or

(c) Medical justification documented in the client's record is required for hematocrits more than ((~~thirty-six~~)) 36 or hemoglobins more than ((~~twelve~~)) 12. Medical justification includes:

(i) Documentation that the dose is being titrated downward to bring a patient's hematocrit back within target range; or

(ii) Documentation that it is medically necessary for the client to have a target hematocrit more than ((~~thirty-six~~)) 36 percent.

(2) Provided to a home dialysis client:

(a) Under the same hematocrit and hemoglobin guidelines as stated in (1)(a) and (b) of this section; and

(b) When permitted by Washington board of pharmacy rules. (Refer to WAC ((~~246-905-020~~)) 246-945-090 Home dialysis program—Legend drugs.)