



# PROPOSED RULE MAKING

## CR-102 (June 2012)

(Implements RCW 34.05.320)

Do NOT use for expedited rule making

Agency: Health Care Authority, Washington Apple Health

- |  |   |
|--|---|
| <input type="checkbox"/> Preproposal Statement of Inquiry was filed as WSR _____; or           | <input checked="" type="checkbox"/> Original Notice       |
| <input type="checkbox"/> Expedited Rule Making--Proposed notice was filed as WSR _____; or     | <input type="checkbox"/> Supplemental Notice to WSR _____ |
| <input checked="" type="checkbox"/> Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1). | <input type="checkbox"/> Continuance of WSR _____         |

### Title of rule and other identifying information:

The following sections within Chapter 182-530 Prescription Drugs (Outpatient):  
 182-530-1075; 182-530-3000; 182-530-3100; 182-530-4000; 182-530-4050; 182-530-4150; 182-530-5000;  
 182-530-5050; 182-530-5100; 182-530-6000; 182-530-7050; 182-530-7100; 182-530-7150; 182-530-7200;  
 182-530-7250; 182-530-7300; 182-530-7350; 182-530-7400; 182-530-7500; 182-530-7600; 182-530-7800;  
 182-530-7900; 182-530-8000; 182-530-8050; 182-530-8100; 182-530-8150.

**Hearing location(s):**  
 Health Care Authority  
 Cherry Street Plaza Building; Sue Crystal Conf Rm 106A  
 626 - 8<sup>th</sup> Avenue, Olympia WA 98504

Metered public parking is available street side around building. A map is available at:  
[http://www.hca.wa.gov/documents/directions\\_to\\_csp.pdf](http://www.hca.wa.gov/documents/directions_to_csp.pdf)  
 or directions can be obtained by calling: 360-725-1000

Date: **December 8, 2015** Time: **10:00 a.m.**

**Date of intended adoption:** Not sooner than **December 9, 2015**  
 (Note: This is NOT the effective date)

**Submit written comments to:**  
 Name: HCA Rules Coordinator  
 Address: PO Box 45504, Olympia WA, 98504-5504  
 Delivery: 626 – 8<sup>th</sup> Avenue, Olympia WA 98504  
 e-mail [arc@hca.wa.gov](mailto:arc@hca.wa.gov)  
 fax (360) 586-9727

by **December 8, 2015**

**Assistance for persons with disabilities:**  
 Contact Amber Lougheed  
 TTY (800) 848-5429 or (360) 725-1349 or e-mail:  
[amber.lougheed@hca.wa.gov](mailto:amber.lougheed@hca.wa.gov)

### Purpose of the proposal and its anticipated effects, including any changes in existing rules:

The agency is making housekeeping changes to update agency names and rule citations.

**Reasons supporting proposal:** The proposed rules improve clarity for the reader without changing the effect of the rules.

**Statutory authority for adoption:** RCW 41.05.021, 41.05.160

**Statute being implemented:** : RCW 41.05.021, 41.05.160

**Is rule necessary because of a:**

Federal Law?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Federal Court Decision?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
State Court Decision?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No

If yes, CITATION:

**DATE**  
 October 29, 2015

**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: October 29, 2015**

**TIME: 9:08 AM**

**WSR 15-22-045**

**Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:**

N/A

**Name of proponent:** Health Care Authority

- Private
- Public
- Governmental

**Name of agency personnel responsible for:**

Name	Office Location	Phone
Drafting..... Melinda Froud	P.O. Box 42716	(360) 725-1408
Implementation.... Charles Agte	P.O. Box 45506	(360) 725-1301
Enforcement..... Charles Agte	P.O. Box 45506	(360) 725-1301

**Has a small business economic impact statement been prepared under chapter 19.85 RCW or has a school district fiscal impact statement been prepared under section 1, chapter 210, Laws of 2012?**

Yes. Attach copy of small business economic impact statement or school district fiscal impact statement.

A copy of the statement may be obtained by contacting:

Name:

Address:

phone ( ) \_\_\_\_\_

fax ( ) \_\_\_\_\_

e-mail \_\_\_\_\_

No. Explain why no statement was prepared.

The proposed filing does not create a disproportionate impact on small businesses.

**Is a cost-benefit analysis required under RCW 34.05.328?**

Yes A preliminary cost-benefit analysis may be obtained by contacting:

Name:

Address:

phone ( ) \_\_\_\_\_

fax ( ) \_\_\_\_\_

e-mail \_\_\_\_\_

No: Please explain:

RCW 34.05.328 does not apply to Health Care Authority rules unless requested by the Joint Administrative Rules Review Committee or applied voluntarily.

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

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

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

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

(3) This requirement does not apply to:

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

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

(c) Telephone, fax, or electronic prescriptions.

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

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

(f) An institutional setting, as defined in WAC (~~(388-500-0005)~~) 182-500-0050, where the prescriber writes the order into the medical records and the orders go directly to the pharmacy.

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

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

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

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

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

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

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

(8) Record retention requirements (~~((WAC 388-502-0020))~~) under WAC 182-502-0020 remain in effect. Additional documentation is required as follows:

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

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

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

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

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

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

(d) The pharmacy must reimburse the client (~~(in accordance with WAC 388-502-0160)~~) under WAC 182-502-0160.

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

AMENDATORY SECTION (Amending WSR 11-14-075, filed 6/30/11, effective 7/1/11)

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

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

(a) Have determined that authorization for the drug, device, or drug-related supply is required, as described in WAC ~~((388-530-3100))~~ 182-530-3100; or

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

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

(a) Nonpreferred as described in WAC ~~((388-530-4100))~~ 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 ~~((388-530-4100(6) or 388-530-4150(2)(c)))~~ 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 promoting safety, efficacy, and effectiveness of drug therapy, the ((department)) agency identifies clients or groups of clients who would benefit from further clinical review.

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

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

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

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

(c) Therapeutic duplication;

(d) Therapeutic contraindication;

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

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

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

AMENDATORY SECTION (Amending WSR 11-14-075, filed 6/30/11, effective 7/1/11)

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

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

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

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

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

(ii) Potential for clinical misuse;

(iii) Potential for client misuse/abuse;

(iv) Narrow therapeutic indication;

(v) Safety concerns;

(vi) Availability of less costly therapeutic alternatives; and

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

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

- (i) Requires authorization;
- (ii) Requires authorization to exceed ((department)) 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 ((388-530-4100)) 182-530-4100.

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

(4) For any drug, device, or drug-related supply with limitations or requiring authorization, the ((department)) agency may elect to apply automated authorization criteria according to WAC ((388-530-3200)) 182-530-3200.

AMENDATORY SECTION (Amending WSR 11-14-075, filed 6/30/11, effective 7/1/11)

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

- (1) The DUR board:
  - (a) Includes health professionals who are actively practicing and licensed in the state of Washington and who have recognized knowledge and expertise in one or more of the following:
    - (i) The clinically appropriate prescribing of outpatient drugs;
    - (ii) The clinically appropriate dispensing and monitoring of outpatient drugs;
    - (iii) Drug use review, evaluation, and intervention; and
    - (iv) Medical quality assurance.
  - (b) Is made up of at least one-third but not more than fifty-one percent physicians, and at least one-third pharmacists.

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

- (3) The DUR board meets periodically to:
  - (a) Advise the ((department)) agency on drug use review activities;
  - (b) Review provider and patient profiles;
  - (c) Review scientific literature to establish evidence-based guidelines for the appropriate use of drugs, including the appropriate indications and dosing;
  - (d) Recommend adoption of standards and treatment guidelines for drug therapy;
  - (e) Recommend interventions targeted toward correcting drug therapy problems; and
  - (f) Produce an annual report.

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

AMENDATORY SECTION (Amending WSR 11-14-075, filed 6/30/11, effective 7/1/11)

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

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

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

(ii) Screen for potential drug therapy problems; and

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

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

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

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

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

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

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

AMENDATORY SECTION (Amending WSR 11-14-075, filed 6/30/11, effective 7/1/11)

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

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

(a) Within therapeutic classes on the Washington PDL;

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

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

(d) Prescribed by an endorsing practitioner.

(2) TIP does not apply:

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

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

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

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

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

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

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

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

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

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

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

(a) Antipsychotic;

(b) Antidepressant;

(c) Antiepileptic;

(d) Chemotherapy;

(e) Antiretroviral;

(f) Immunosuppressive; or

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

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

(a) The ~~((department))~~ 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 ~~((department))~~ 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 ~~((subsection—(7)))~~ (a) of this ~~((section))~~ 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 (~~(388-500-0005)~~) 182-500-0070; or

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

(8) While the endorsing practitioner is engaged in the activities described in subsection (7)(b)(ii) or (~~(7)(b)~~) (iii) of this section, (~~(his or her)~~) 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 (~~(his or her department)~~) the endorsing practitioner's agency-designated peer-grouping over a period of four calendar quarters, with a ninety-five percent confidence interval.

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

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

(b) The drug use review (DUR) board established under WAC (~~(388-530-4000)~~) 182-530-4000 has reviewed the drug class and recommended to the (~~(department)~~) agency that the drug class is appropriate to require generic drugs as a client's first course of treatment.

(11) In accordance with WAC (~~(388-530-4125(3) and WAC 388-501-0165, the department)~~) 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 non-preferred generic drugs for the client's first course of treatment.

AMENDATORY SECTION (Amending WSR 11-14-075, filed 6/30/11, effective 7/1/11)

**WAC 182-530-5000 Billing requirements—Pharmacy claim payment.**

(1) When billing the (~~(department)~~) medicaid agency for pharmacy services, providers must:

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

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

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

(d) Meet the general provider documentation and record retention requirements in WAC (~~(388-502-0020)~~) 182-502-0020; and

(e) Maintain proof of delivery receipts.

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

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

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

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

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

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

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

(3) Pharmacy services for clients on restriction under WAC (~~(388-501-0135)~~) 182-501-0135 must be prescribed by the client's primary care provider and are paid only to the client's primary pharmacy, except in cases of:

(a) Emergency;

(b) Family planning services; or

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

AMENDATORY SECTION (Amending WSR 11-14-075, filed 6/30/11, effective 7/1/11)

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

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

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

(a) Therapeutic duplication;

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

(c) Drug-to-drug interaction;

(d) Drug disease precaution;

(e) High dose;

(f) Ingredient duplication;

(g) Drug-to-client age conflict;

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

(i) Refill too soon.

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

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

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

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

(6) The ~~((department))~~ agency requires providers to retain documentation of the justification for the use of payment system override codes as described in subsections (4) and (5) of this section. The ~~((department))~~ agency requires the documentation be retained for the same period as that described in WAC ~~((388-502-0020))~~ 182-502-0020.

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

AMENDATORY SECTION (Amending WSR 11-14-075, filed 6/30/11, effective 7/1/11)

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

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

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

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

(d) Follow ~~((department))~~ agency requirements for unit dose payment.

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

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

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

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

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

- (a) To conform with a nursing facility's drug delivery system; or
- (b) For the nursing facility's convenience.

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

- (a) Facility name and address;
- (b) Client's name and patient identification code (PIC);
- (c) Drug name/strength;
- (d) National drug code (NDC);
- (e) Quantity and date dispensed;
- (f) Quantity and date returned;
- (g) Value of returned drugs or amount credited;
- (h) Explanation for no credit given or nonreusable returns; and
- (i) Prescription number.

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

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

AMENDATORY SECTION (Amending WSR 11-14-075, filed 6/30/11, effective 7/1/11)

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

(1) The contracted mail-order pharmacy service is available as an option to all ((medical-assistance)) 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 ((~~388-530-4100~~)) 182-530-4100);

(ii) Generic drugs; and

(iii) Drugs that do not have authorization requirements (see WAC ((~~388-530-3000~~ through ~~388-530-3200~~)) 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 ((~~388-530-3000~~)) 182-530-3000).

(c) Other pharmacy restrictions (chapter ((~~388-530~~ WAC, Pharmacy services)) 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.

AMENDATORY SECTION (Amending WSR 11-14-075, filed 6/30/11, effective 7/1/11)

**WAC 182-530-7050 Reimbursement—Dispensing fee determination.**

(1) Subject to the provisions of WAC ((~~388-530-7000~~)) 182-530-7000 and the exceptions permitted in WAC ((~~388-530-2000~~)) 182-530-2000, the ((~~department~~)) medicaid agency pays a dispensing fee for each covered, prescribed drug.

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

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

(a) Legislative appropriations for vendor rates;

(b) Input from provider and ((~~for~~)) advocacy groups;

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

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

(4) The ((~~department~~)) 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 ((~~department~~)) agency uses total annual prescription volume (both medicaid and nonmedicaid) reported to the ((~~department~~)) 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 ((~~department~~)) 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 ((department)) agency determines a pharmacy's annual total prescription volume as follows:

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

AMENDATORY SECTION (Amending WSR 11-14-075, filed 6/30/11, effective 7/1/11)

**WAC 182-530-7100 Reimbursement—Pharmaceutical supplies.** (1)

The ((department)) medicaid agency reimburses for selected pharmaceutical supplies through the pharmacy point-of-sale (POS) system when it is necessary for client access and safety.

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

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

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

(b) Medicare's reimbursement rate for the item; or  
(c) A specified discount off the item's list price or manufacturer's suggested retail price (MSRP).

(4) The ~~((department))~~ agency does not pay a dispensing fee for nondrug items, devices, or drug-related supplies. See WAC ~~((388-530-7050))~~ 182-530-7050.

AMENDATORY SECTION (Amending WSR 11-14-075, filed 6/30/11, effective 7/1/11)

**WAC 182-530-7150 Reimbursement—Compounded prescriptions.** (1)

The ~~((department))~~ medicaid agency does not consider reconstitution to be compounding.

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

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

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

(b) The pharmacist must ensure that the ingredients used in a compounded prescription are for an approved use as defined in "medically accepted indication" in WAC ~~((388-530-1050))~~ 182-530-1050.

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

(6) Compounded prescriptions are reimbursed as follows:

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

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

(d) The ~~((department))~~ agency pays a dispensing fee as described under WAC ~~((388-530-7050))~~ 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 ((department)) agency does not pay a separate fee for compounding time.

(7) The ((department)) agency requires pharmacists to document the need for each inactive ingredient added to the compounded prescription. The ((department)) agency limits reimbursement to the inactive ingredients that meet the following criteria. To be reimbursed by the ((department)) 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 11-14-075, filed 6/30/11, effective 7/1/11)

**WAC 182-530-7200 Reimbursement—Out-of-state prescriptions.** (1)

The ((department)) medicaid agency reimburses out-of-state pharmacies for prescription drugs provided to an eligible client within the scope of the client's medical care program if the pharmacy:

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

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

(2) The ((department)) agency considers pharmacies located in bordering areas listed in WAC ((388-501-0175)) 182-501-0175 the same as in-state pharmacies.

AMENDATORY SECTION (Amending WSR 11-14-075, filed 6/30/11, effective 7/1/11)

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

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

(a) Chapter ((388-531)) 182-531 WAC((τ)) Physician-related services;

(b) Chapter ((388-532)) 182-532 WAC((τ)) Reproductive health/family planning only/~~TAKE CHARGE~~; and

(c) Chapter ((388-540)) 182-540 WAC((τ)) Kidney disease program and kidney center services.

(2) Providers who are purchasers of Public Health Services (PHS) discounted drugs must comply with PHS 340b program requirements. (See WAC ((388-530-7900)) 182-530-7900).

(3) The ((department)) agency may request providers to submit a current invoice for the actual cost of the drug, device, or drug-rela-

ted supply billed. If an invoice is requested, the invoice must show the:

- (a) Name of the drug, device, or drug-related supply;
- (b) Drug or product manufacturer;
- (c) NDC of the product ~~((s))~~ or products;
- (d) Drug strength;
- (e) Product description;
- (f) Quantity; and
- (g) Cost, including any free goods associated with the invoice.

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

AMENDATORY SECTION (Amending WSR 11-14-075, filed 6/30/11, effective 7/1/11)

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

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

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

AMENDATORY SECTION (Amending WSR 11-14-075, filed 6/30/11, effective 7/1/11)

**WAC 182-530-7350 Reimbursement—Unit dose drug delivery systems.**

(1) The ~~((department))~~ medicaid agency pays for unit dose drug delivery systems only for clients residing in nursing facilities, except as provided in subsections (7) and (8) of this section.

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

(3) The ~~((department))~~ agency pays pharmacies that provide unit dose delivery services the ~~((department's))~~ agency's highest allowable dispensing fee for each unit dose prescription dispensed to clients in nursing facilities. The ~~((department))~~ agency reimburses ingredient costs for drugs under unit dose systems as described in WAC ~~((388-530-7000))~~ 182-530-7000.

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

((department)) agency reimburses ingredient costs as described in WAC ((388-530-7000)) 182-530-7000.

(5) The ((department)) agency pays a pharmacy that dispenses drugs prepackaged by the manufacturer in unit dose form to clients in nursing facilities the regular dispensing fee applicable under WAC ((388-530-7050)) 182-530-7050. The ((department)) agency reimburses ingredient costs for drugs prepackaged by the manufacturer in unit dose form as described in WAC ((388-530-7000)) 182-530-7000.

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

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

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

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

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

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

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

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

AMENDATORY SECTION (Amending WSR 11-14-075, filed 6/30/11, effective 7/1/11)

**WAC 182-530-7400 Reimbursement—Compliance packaging services.**

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

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

- (i) Alzheimer's disease;
- (ii) Blood clotting disorders;
- (iii) Cardiac arrhythmia;
- (iv) Congestive heart failure;
- (v) Depression;
- (vi) Diabetes;
- (vii) Epilepsy;
- (viii) HIV/AIDS;
- (ix) Hypertension;

(x) Schizophrenia; or

(xi) Tuberculosis.

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

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

(2) Compliance packaging services include:

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

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

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

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

AMENDATORY SECTION (Amending WSR 11-14-075, filed 6/30/11, effective 7/1/11)

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

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

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

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

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

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

AMENDATORY SECTION (Amending WSR 11-14-075, filed 6/30/11, effective 7/1/11)

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

AMENDATORY SECTION (Amending WSR 11-14-075, filed 6/30/11, effective 7/1/11)

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

(2) The following definitions apply to this section:

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

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

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

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

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

(i) The billed amount; or

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

AMENDATORY SECTION (Amending WSR 11-14-075, filed 6/30/11, effective 7/1/11)

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

(2) Providers dispensing drugs under this section are required to submit their valid ~~((medical assistance))~~ medicaid provider number(s) to the PHS health resources and services administration, office of pharmacy affairs. This requirement is to ensure that claims for drugs dispensed under this section and paid by the ~~((department))~~ agency are excluded from the drug rebate claims that are submitted to the manufacturers of the drugs. See WAC ~~((388-530-7500))~~ 182-530-7500 for information on the drug rebate program.

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

AMENDATORY SECTION (Amending WSR 11-14-075, filed 6/30/11, effective 7/1/11)

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

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

(b) Information provided by any of the following:

(i) Audit agencies, federal or state;

(ii) Other state health care purchasing agencies;

(iii) Pharmacy benefit managers;

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

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

(vi) Other third-party payers;

(vii) Drug file data bases; and ~~((/or))~~

(viii) Actuaries or other consultants.

(2) The ~~((department))~~ 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 ~~((department))~~ 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 ~~((department))~~ agency considers it necessary. The factors the ~~((department))~~ 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 ~~((department's))~~ agency's documented clinical concerns; and

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

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

(5) The ~~((department))~~ agency uses EAC as the ~~((department's))~~ agency's reimbursement for a drug when EAC is the lowest of the rates calculated under the methods listed in WAC ~~((388-530-7000))~~ 182-530-7000, or when the conditions of WAC ~~((388-530-7300))~~ 182-530-7300 are met.

AMENDATORY SECTION (Amending WSR 11-14-075, filed 6/30/11, effective 7/1/11)

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

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

(3) Except as provided in WAC ~~((388-530-7300))~~ 182-530-7300, the ~~((department))~~ agency uses the FUL as the ~~((department's))~~ agency's reimbursement rate for the drug when the FUL price is the lowest of the rates calculated under the methods listed in WAC ~~((388-530-7000))~~ 182-530-7000.

AMENDATORY SECTION (Amending WSR 11-14-075, filed 6/30/11, effective 7/1/11)

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

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

(a) When specific regional and local drug acquisition cost data is available, the ~~((department))~~ 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 ~~((388-530-7500))~~ 182-530-7500(4)).

(b) When specific regional and local drug acquisition cost data is not available, the ~~((department))~~ 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 medi-

cally necessary for a particular client. In such cases, the estimated acquisition cost (EAC) for the particular brand applies, provided authorization is obtained from the ((department)) agency as specified under WAC ((~~388-530-3000~~)) 182-530-3000.

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

AMENDATORY SECTION (Amending WSR 11-14-075, filed 6/30/11, effective 7/1/11)

**WAC 182-530-8150 Reimbursement—Automated maximum allowable cost (AMAC).** (1) The ((department)) 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 ((department)) agency establishes AMAC as a specified percentage of the published average wholesale price (AWP) or other nationally accepted pricing source in order to estimate acquisition cost.

(3) The ((department)) agency sets the percentage discount from AWP for AMAC reimbursement using any of the information sources identified in WAC ((~~388-530-8000~~)) 182-530-8000.

(4) The ((department)) agency may set AMAC reimbursement at different percentage discounts from AWP for different multiple source drugs. The ((department)) agency considers the same factors as those in WAC ((~~388-530-8000~~)) 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 ((department)) agency recalculates the AMAC each time the drug file contractor provides a pricing update.

(7) Except as provided in WAC ((~~388-530-7300~~)) 182-530-7300, the ((department)) agency reimburses at the lowest of the rates calculated under the methods listed in WAC ((~~388-530-7000~~)) 182-530-7000.