

Secretary of State
NOTICE OF PROPOSED RULEMAKING HEARING
A Statement of Need and Fiscal Impact accompanies this form.

Oregon Health Authority (OHA), Division of Medical Assistance Programs (Division)	410
Agency and Division	Administrative Rules Chapter Number

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Rules Coordinator	Address	Telephone

RULE CAPTION

Implement Prescription Synchronization Policy for Medical Assistance Recipients Not Enrolled in a Coordinated Care Organization

December 15, 2015	10:30 a.m.	500 Summer St. NE, Salem, OR 97301 Room 137C	Sandy Cafourek
Hearing Date	Time	Location	Hearings Officer

Auxiliary aids for persons with disabilities are available upon advance request.

RULEMAKING ACTION

Secure approval of new rule numbers (Adopted or Renumbered rules) with the Administrative Rules Unit prior to filing.

ADOPT:

AMEND: OAR 410-121-0000, 410-121-0146

REPEAL:

RENUMBER:

AMEND & RENUMBER:

Stat. Auth.: ORS 413.042, 414.065 & 414.325

Other Auth.:

Stats. Implemented: ORS 414.065

RULE SUMMARY

The Authority is amending OAR 410-121-0000 and OAR 410-121-0146 to implement a prescription synchronization policy for fee-for-service medical assistance recipients. Synchronization aligns a patient's refills to maximize the number that may be refilled at the same time. The amendment aligns policy with legislative intent, as contained in Oregon Laws 2015, chapter 800, section 2 (SB 841).

The agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing the negative economic impact of the rule on business.

December 17, 2015 by 5 p.m. Send written comments to: dmap.rules@state.or.us
Last Day for Public Comment (Last day to submit written comments to the Rules Coordinator)


Signature

Rhonda Busek
Printed name

11/5/15
Date

Note: Hearing Notices must be submitted by the 15th day of the month to be published in the next month's *Oregon Bulletin*.

Secretary of State
STATEMENT OF NEED AND FISCAL IMPACT

A Notice of Proposed Rulemaking Hearing or a Notice of Proposed Rulemaking accompanies this form.

Oregon Health Authority (Authority), Division of Medical Assistance Programs (Division) 410
Agency and Division Administrative Rules Chapter Number

Implement Prescription Synchronization Policy for Medical Assistance Recipients Not Enrolled in a Coordinated Care Organization

Rule Caption (Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.)

In the Matter of: The amendment of OAR 410-121-0000, 410-121-0146

Statutory Authority: ORS 413.042, 414.065 & 414.325

Other Authority:

Stats. Implemented: ORS 414.065

Need for the Rule(s): The rules need to be amended to align with a new Oregon statute, Oregon Laws 2015, chapter 800, section 2 (SB 841).

Documents Relied Upon, and where they are available: None

Fiscal and Economic Impact: None

Statement of Cost of Compliance:

1. Impact on state agencies, units of local government and the public (ORS 183.335(2)(b)(E)): Amending these rules will have no fiscal impact on the Authority, other state agencies, units of local government, the public, or businesses, including small businesses.

2. Cost of compliance effect on small business (ORS 183.336):

a. Estimate the number of small businesses and types of business and industries with small businesses subject to the rule: Small businesses will not be affected by this rule.

b. Projected reporting, recordkeeping and other administrative activities required for compliance, including costs of professional services: There is no anticipated increase.

c. Equipment, supplies, labor and increased administration required for compliance: There is no anticipated increase.

How were small businesses involved in the development of this rule? Small businesses were not involved in the development of this rule as it will not affect them.

Administrative Rule Advisory Committee consulted?: No. If not, why?: A RAC was held on October 21, 2015 but cancelled when no one attended. The RAC invitation was sent to 128 individuals who previously expressed interest in OHP policy changes.


Signature

Rhonda Busek
Printed Name

11/5/15
Date

Administrative Rules Unit, Archives Division, Secretary of State, 800 Summer Street NE, Salem, Oregon 97310.

410-121-0000

Foreword and Definition of Terms

(1) The Division of Medical Assistance Program's (Division) Oregon Administrative Rules (OAR) are designed to assist providers in preparing claims for services provided to the Division's fee-for-service clients. Providers must use Pharmaceutical OARs in conjunction with the General Rules OARs (chapter 410, division 120) for Oregon Medical Assistance Programs.

(2) Pharmaceutical services delivered through managed care plans contracted with the Division, under the Oregon Health Plan (OHP), are subject to the policies and procedures established in the OHP administrative rules (chapter 410, division 141) and by the specific managed health care plans.

(3) Definition of Terms:

(a) **Actively Practicing:** The active practice of medicine as described in ORS chapter 689, or the active practice of pharmacy as described in ORS chapter 677.

(b) **Actual Acquisition Cost (AAC):** The cost or basis for reimbursement of supplies. The AAC will be established by the Division or its contractor by rolling surveys of enrolled pharmacies to verify the actual invoice amount paid by the pharmacy or corporate entity to wholesalers, manufacturers, or distribution centers for the product and as such will serve as the basis for reimbursement;

(c) **Authority:** The Oregon Health Authority, see Oregon Health Authority definition in General Rules (chapter 410, division 120);

(d) **Average Actual Acquisition Cost (AAAC):** The AAAC will be the average of AAC invoice amounts for individual drug products based on the Generic Sequence Number (GSN);

(e) **Average Manufacturer's Price (AMP):** The average price that manufacturers sell medication to wholesalers and retail pharmacies, as further clarified in 42 CFR 447;

(f) **Bulk Dispensing:** Multiple doses of medication packaged in one container labeled as required by pertinent Federal and State laws and rules;

(g) **Centers for Medicare and Medicaid Services (CMS) Basic Rebate:** The quarterly payment by the manufacturer of a drug pursuant to the Manufacturer's CMS Medicaid Drug Rebate Agreement made in accordance with Section 1927(c)(3) of the Social Security act 42 U.S.C. 1396r-8(c)(1) and 42 U.S.C. 1396r-8 (c)(3). See 410-121-0157;

(h) **CMS Consumer Price Index (CPI) Rebate:** The quarterly payment by the manufacturer pursuant to the Manufacturer's CMS Medicaid Drug Rebate Agreement

made in accordance with Section 1927(c)(2) of the Social Security act (42 U.S.C. 1396r-8(c)(2));

(i) Compendia: Those resources widely accepted by the medical profession in the efficacious use of drugs, including the following sources:

(A) The American Hospital Formulary Service drug information;

(B) The United States Pharmacopeia drug information;

(C) The American Medical Association drug evaluations;

(D) Peer-reviewed medical literature;

(E) Drug therapy information provided by manufacturers of drug products consistent with the federal Food and Drug Administration requirements;

(j) Community Based Care Living Facility: For the purposes of the Division's Pharmacy Program, a home, facility, or supervised living environment licensed or certified by the state of Oregon that provides 24 hour care, supervision, and assistance with medication administration. These include, but are not limited to:

(A) Supportive Living Facilities;

(B) 24-Hour Residential Services;

(C) Adult Foster Care;

(D) Semi-Independent Living Programs;

(E) Assisted Living and Residential Care Facilities;

(F) Group Homes and other residential services for people with developmental disabilities or needing mental health treatment; and

(G) Inpatient hospice;

(k) Compounded Prescription:

(A) A prescription that is prepared at the time of dispensing and involves the weighting of at least one solid ingredient that must be a reimbursable item or a legend drug in a therapeutic amount;

(B) Compounded prescription is further defined to include the Oregon Board of Pharmacy definition of compounding (see OAR 855-006-0005);

(L) Dispensing: Issuance of a prescribed quantity of an individual drug entity by a licensed pharmacist;

(m) Director: The Director of the Authority;

(n) Drug Order/Prescription:

(A) A medical practitioner's written or verbal instructions for a patient's medications; or

(B) A medical practitioner's written order on a medical chart for a client in a nursing facility;

(o) Durable Medical Equipment and supplies (DME): Equipment and supplies as defined in OAR 410-122-0010, Durable Medical Equipment, Prosthetics, Orthotics, and Supplies;

(p) Estimated Acquisition Cost (EAC): The estimated cost that the pharmacy can obtain the product listed in OAR 410-121-0155;

(q) Intermediate Care Facility: A facility providing regular health-related care and services to individuals at a level above room and board, but less than hospital or skilled nursing levels as defined in ORS 442.015;

(r) Legend Drug: A drug limited by § 503(b)(1) of the Federal Food, Drug, and Cosmetic Act to being dispensed by or upon a medical practitioner's prescription because the drug is:

(A) Habit-forming;

(B) Toxic or having potential for harm; or

(C) Limited in its use to use under a practitioner's supervision by the new drug application for the drug;

(i) The product label of a legend drug is required to contain the statement: "CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT A PRESCRIPTION.";

(ii) A legend drug includes prescription drugs subject to the requirement of § 503(b)(1) of the federal Food, Drug, and Cosmetic Act which shall be exempt from § 502(F)(1) if certain specified conditions are met;

(s) Long Term Care Facility: Includes skilled nursing facilities and intermediate care facilities with the exclusions found in ORS 443.400 to 443.455;

(t) Maintenance Medication: Drugs that have a common indication for treatment of a chronic disease and the therapeutic duration is expected to exceed one year. This is determined by a First DataBank drug code maintenance indicator of “Y” or “1”;

(u) Mental Health Drug: A type of legend drug defined by the Oregon Health Authority (Authority) by rule that includes, but is not limited to those drugs classified by First DataBank in the following Standard Therapeutic Classes:

(A) Therapeutic Class 7 ataractics-tranquilizers; and Therapeutic Class 11 psychostimulants-antidepressants;

(B) Depakote, Lamictal and their generic equivalents and other drugs that the Division specifically carved out from capitation from Fully Capitated Health Plans (FCHPs) in accordance with OAR 410-141-0070;

(v) Narrow Therapeutic Index (NTI) Drug: A drug that has a narrow range in blood concentrations between efficacy and toxicity and requires therapeutic drug concentration or pharmacodynamic monitoring;

(w) Net Price: The amount a drug costs the Division and is calculated using the following formula: “Estimated Acquisition Cost minus CMS Basic Rebate minus CMS CPI Rebate minus State Supplemental Rebate”;

(x) Non-Preferred Products: Any medication in a class that has been evaluated and that is not listed on the Practitioner-Managed Prescription Drug Plan Preferred Drug List in OAR 410-121-0030 and may be subject to co-pays;

(y) Nursing Facility: An establishment that is licensed and certified by the Department’s Aging and People with Disabilities Division (APD) as a Nursing Facility;

(z) Pharmacist: An individual who is licensed as a pharmacist under ORS chapter 689;

(aa) Physical Health Drug: All other drugs not included in section (u) of this rule;

(bb) Point-of-Sale (POS): A computerized, claims submission process for retail pharmacies that provides on-line, real-time claims adjudication;

(cc) Preferred Drug List (PDL): A PDL consists of prescription drugs in selected classes that the Authority, in consultation with the Pharmacy & Therapeutics Committee (P & T), has determined represent the most effective drug(s) available at the best possible price. (See details for the Division’s PMPDP PDL in OAR 410-121-0030):

(A) Enforceable Physical Health Preferred Drug List: The list of drug products used to treat physical health diagnosis that the Division has identified which shall be exempt from client co-pays and may be subject to prior authorization (PA). Drugs prescribed

that do not appear on the PDL (non-preferred products) shall be subject to both co-pays and PA as determined to be appropriate by the Division;

(B) Voluntary Mental Health Preferred Drug List: The list of drug products used to treat mental health diagnosis. These drugs are exempt from client co-pay. Any drug prescribed for the treatment of mental health diagnosis shall be exempt from PA requirements by the Division;

(dd) Preferred Products: Products in classes that have been evaluated and placed on the Practitioner Managed Prescription Drug Plan (PMPDP) PDL in OAR 410-121-0030 and are not subject to co-pays;

(ee) Prescriber: Any person authorized by law to prescribe drugs;

(ff) Prescription Splitting: Any one or a combination of the following actions:

(A) Reducing the quantity of a drug prescribed by a licensed practitioner for prescriptions not greater than 34 days, except as needed for Prescription Synchronization (see OAR 410-121-0146);

(B) Billing the agency for more than one dispensing fee when the prescription calls for one dispensing fee for the quantity billed, except as needed for Prescription Synchronization (see OAR 410-121-0146);

(C) Separating the ingredients of a prescribed drug and billing the agency for separate individual ingredients, with the exception of compounded medications (see OAR 410-121-0146); or

(D) Using multiple 30-day cards to dispense a prescription when a lesser number of cards will suffice;

(gg) Prescription Synchronization: The process of, at the client's direction, aligning the refill dates of a client's prescription drugs so that are refilled at the same frequency may be refilled concurrently;

(gghh) Prior Authorization Program (PA): The Prior Authorization Program is a system of determining, through a series of therapeutic and clinical protocols, which drugs require authorizations prior to dispensing:

(A) OAR 410-121-0040 lists the drugs or categories of drugs requiring PA;

(B) The practitioner, or practitioner's licensed medical personnel listed in OAR 410-121-0060, may request a PA;

(hhij) State Supplemental Rebates: The Division and CMS approved discounts paid by manufacturers per unit of drug. These rebates are authorized by the Social Security Act

section 42 USC 1396r-8(a)(1) and are in addition to federal rebates mandated by the Omnibus Budget Rehabilitation Act (OBRA 90) and the federal rebate program;

(iii) Unit Dose: A sealed, single unit container of medication, so designed that the contents are administered to the patient as a single dose, direct from the container, and dispensed following the rules for unit dose dispensing system established by the Oregon Board of Pharmacy;

(jjk) Urgent Medical Condition: A medical condition that arises suddenly, is not life-threatening, and requires prompt treatment to avoid the development of more serious medical problems;

(kkll) Usual and Customary Price: A pharmacy's charge to the general public that reflects all advertised savings, discounts, special promotions, or other programs including membership based discounts, initiated to reduce prices for product costs available to the general public, a special population, or an inclusive category of customers;

(Hmnn) Wholesale Acquisition Cost (WAC): The price paid by a wholesaler for drugs purchased from the wholesaler's supplier, typically the manufacturer of the drug. WAC is the price of a covered product by the National Drug Code (NDC) as published by First DataBank, MediSpan or Red Book;

(mmnn) 340B Pharmacy: A federally designated community health center or other federally qualified covered entity that is listed on the Health Resources and Services Administration (HRSA) website.

[ED NOTE: Publications referenced are available from the agency.]

Stat. Auth.: ORS 413.042, 414.065 & 414.325
Stats. Implemented: ORS 414.065

410-121-0146

Dispensing Limitations

(1) The Division of Medical Assistance Programs (Division) will reimburse the pharmacy for dispensed medication the lesser of:

(a) The quantity indicated by the prescriber on the prescription; or

(b) The quantity indicated by the Division dispensing limitations as outlined in this rule;
or:

(c) The quantity needed for Prescription Synchronization.

(2) The pharmacy may only dispense less than the prescribed quantity when the prescribed quantity exceeds the Division's dispensing limitations, or when a lesser quantity is needed for Prescription Synchronization.

(3) The pharmacy may, at the client's direction, dispense less than the prescribed quantity of a maintenance medication in order to align the refill dates if the client has received the same dose for two months or more.

(34) Unless otherwise specified in this rule, the Division will not reimburse claims for medications exceeding a 34-day supply.

(45) Exceptions to the 34-day supply do not apply to claims for the following Standard Therapeutic Classes of medications. Claims exceeding a 34-day supply for these medications will not be reimbursed under any circumstances:

(a) Ataractics, Tranquilizers — 07;

(b) Muscle Relaxants — 08;

(c) CNS Stimulants — 10;

(d) Psychostimulants, Antidepressants — 11;

(e) Amphetamine Preps — 12;

(f) Narcotic Analgesics — 40;

(g) Sedative Barbiturate — 46;

(h) Sedative Non-Barbiturate — 47.

(56) The Division will allow reimbursement for more than a 34-day supply if the medication's original package size cannot be divided.

(67) Except for medications listed in (45), claims for up to a 100-day supply of the following types of medications may be reimbursed to the Division's mail order pharmacy contractor, Indian Health mail order pharmacy providers, and 340B providers:

(a) A preferred PDL generic; and

(b) A generic drug not on the PDL, costing \$10 per month or less.

(78) Any pharmacy provider will be reimbursed for up to a 100-day supply of family planning drugs.

~~(89)~~ Maintenance Medications — Any pharmacy provider will be reimbursed for up to a 100-day supply of select classes of medications if the client has received the same dose for two months or more. See ~~Table 121-0146-1 Maintenance Medications~~. Maintenance medications shall be determined by the Division based on the following criteria:

- (a) Have low probability for dosage or therapy changes due to side effects; and
- (b) Are used most commonly to treat a chronic disease state and not considered curative or promoting recovery; and
- (c) Are administered continuously rather than intermittently.

~~(910)~~ Selected medications identified by the Division will be limited to a 15-day supply for initial fills. These medications have been identified as having high side effect profiles, high discontinuation rates, or needing frequent dose adjustments.

~~(1011)~~ After stabilization of a diabetic, the pharmacy should provide a minimum of a one-month supply of insulin per dispensing.

~~(1112)~~ For vaccines available in multiple dose packaging, the Division will allow a dispensing fee for each multiple dose. When vaccines are administered at the pharmacy, refer to Oregon Administrative Rule (OAR) 410-121-0185.

~~(1213)~~ Splitting prescriptions:

(a) For compounded prescriptions, bill components of the prescription separately. Third party payments for compounded prescriptions must be split and applied equally to each component;

(b) The Division will consider any other form of prescription splitting as a billing offense and take appropriate action as described in the General Rules (OAR 410 division 120).

~~(13) Table 121-0146-1 Maintenance Medications.~~

~~[ED. NOTE: Tables referenced are not included in rule text. [Click here for PDF copy of table\(s\).](#)]~~

Stat. Auth.: ORS 413.042 & 414.065

Stats. Implemented: ORS 414.065