DHS Oregon Department of Human Services

Division of Medical Assistance Programs

Pharmaceutical Services Program

Rulebook

Includes:

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DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE PROGRAMS

DIVISION 121

PHARMACEUTICAL SERVICES

Update Information (most current Rulebook changes)

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Pharmaceutical Services Program Rulebook

Update Information

for

April 1, 2010

DMAP updated the Pharmaceutical Services Program Rulebook with the following administrative rule changes:

AMENDED: 410-121-0146

DMAP temporarily amended 410-121-0146 to clarify the current DMAP policy for 34-day and 100-day supply of drugs dispensed and exceptions to both. Drugs dispensed by the DMAP mail order pharmacy contractor, Indian Health mail order pharmacy providers and 340b pharmacy providers and drugs dispensed as Preferred PDL generics and generics in non-PDL classes that cost less than $10 per month and are maintenance medications can be dispensed up to a 100-day supply, except for those Standard Therapeutic Classes of drugs listed in this rule that can never exceed a 34-day supply no matter what the circumstance.

If you have questions, contact a Provider Services Representative toll-free at 1-800-336-6016 or direct at 503-378-3697.

Other Provider Resources

DMAP has developed the following additional materials not found in this Rulebook to help you bill accurately and receive timely payment for your services.

Supplemental Information

The Pharmaceutical Services Supplemental Information booklet contains important information not found in the rulebook, including:

- ✓ Billing instructions
- ✓ Prior Authorization information
- ✓ Specific billing requirements for certain services
- ✓ Electronic claims information
- ✓ Forms
- ✓ Medicaid Management Information System (MMIS)

Download a copy of the Pharmaceutical Services Supplemental Information booklet at:

http://www.dhs.state.or.us/policy/healthplan/guides/pharmacy/main.html

Note: Check the Web page regularly for changes to the booklet.

Provider Contact Booklet

This booklet lists general information phone numbers, frequent contacts, phone numbers to use to request prior authorization, and mailing addresses.

Download the Provider Contact Booklet at:

http://www.dhs.state.or.us/healthplan/data_pubs/add_ph_conts.pdf

Other Resources

We have posted other helpful information, including provider announcements, at:

http://www.oregon.gov/DHS/healthplan/tools_prov/main.shtml

Medicaid Management Information System (MMIS)

See the Web page called: “Everything you need to know about the new MMIS” found at http://www.oregon.gov/DHS/healthplan/mmis.shtml

This Web page includes information about the new Provider Web Portal at:

https://www.or-medicaid.gov

And, instructions to use the new Provider Web Portal at:

www.oregon.gov/DHS/healthplan/webportal.shtml

410-121-0000 Foreword and Definition of Terms

(1) The Pharmaceutical Services Oregon Administrative Rules (OARs) are designed to assist providers in preparing claims for services provided to Division of Medical Assistance Programs' (DMAP) 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 DMAP, 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) Actual Acquisition Cost: The net amount paid per invoice line item to a supplier. This net amount does not include separately identified discounts for early payment;

(b) Average Net Price: The average of Net Price (definition below) of all drugs in an identified Preferred Drug List (PDL) (definition below) class or group.

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

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

(e) 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;

(f) CMS 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)

(g) Community Based Care Living Facility: For the purposes of the Division of Medical Assistance Programs (DMAP) Pharmacy Program, a home, facility, or supervised living environment licensed or certified by the state of Oregon which 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;

(h) Compounded Prescriptions:

(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);

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

(j) 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;

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

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

(m) 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;

(n) Legend Drug: means 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;

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

(p) 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";

(q) Mental health drug: A type of legend drug defined by the Department 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 of Medical Assistance Programs (DMAP) specifically carved out from capitation from Fully Capitated Health Plans (FCHPs) in accordance with sections (8) through (11) of OAR 410-141-0070

(r) 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;

(s) Net Price: The amount a drug costs DHS and calculated using the following formula. "Estimated Acquisition Cost – CMS Basic Rebate – CMS CPI Rebate – State Supplemental Rebate";

(t)) Non-Preferred Products: Any medication in a class that has been evaluated and that is not listed on the PMPDP PDL in OAR 410-121-0030 and may be subject to co-pays;

(u) Prior Authorization Program: 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 prior authorization (PA);

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

(v) Nursing Facility: An establishment that is licensed and certified by the DHS Seniors and People with Disabilities Division (SPD) as a Nursing Facility;

(w) Physical health drug: All other drugs not included in section (q) of this rule.

(x) Preferred Drug List: A PDL consists of prescription drugs in selected classes that DHS, in consultation with the Health Resources Commission (HRC), has determined represent the most effective drug(s) available at the best possible price. (See details for the DMAP 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 which the Division has identified which shall be exempt from client co-pays and may be subject to Prior Authorization. Drugs prescribed which do not appear on the PDL (non-preferred products) will be subject to both co-pays and Prior Authorization 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. Products which shall be exempt from client co-pay. Any drug prescribed for the treatment of mental health diagnosis shall be exempt from Prior Authorization requirements by the Division.

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

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

(aa) 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 (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;

(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;

(bb) State Supplemental Rebates: DMAP 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;

(cc) 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.

(dd) Urgent Medical Condition: means a medical conditions that arises suddenly, is not life-threatening, and requires prompt treatment to avoid the development of more serious medical problems.

Stat. Auth.: ORS 409.010, 409.025, 409.040, 409.050, 409.110,414.065 & 414.325
Stats. Implemented: ORS 414.065

1-1-10

410-121-0021 Organizations Authorized to Provide Pharmaceutical Prescription Services

(1) Pharmacies, and Medicare certified independent rural health clinics providing urgent medical services for clients as defined in ORS 414.325(7) may provide drug prescription services for fee-for-service Division of Medical Assistance Programs (DMAP) clients and receive reimbursement from DMAP by complying with all the following requirements:

(a) Comply with all applicable Federal and State statutes, regulations and rules;

(b) Meet all current licensing and regulatory requirements;

(c) Be enrolled as a pharmacy provider with DMAP;

(d) Pharmacies must have a current National Association of the Board of Pharmacy (NABP) number to bill DMAP;

(e) Medicare certified independent rural health clinics must have a pharmacist, physician, or nurse practitioner, licensed to dispense and bill drug prescriptions; and

(f) Comply with DMAP pharmacy billing requirements.

(2) Refer to OAR 410-120-1260 for enrollment details.

Statutory Authority: Chapter 409.050

Statutes Implemented: ORS 414.065

7-1-08

410-121-0030 Practitioner-Managed Prescription Drug Plan (PMPDP)

(1) The Practitioner-Managed Prescription Drug Plan (PMPDP) is a plan that ensures that fee for service clients of the Oregon Health Plan will have access to the most effective prescription drugs appropriate for their clinical conditions at the best possible price:

(a) Licensed health care practitioners (informed by the latest peer reviewed research), make decisions concerning the clinical effectiveness of the prescription drugs;

(b) The licensed health care practitioners also consider the health condition of a client or characteristics of a client, including the client's gender, race or ethnicity.

(2) PMPDP Preferred Drug List (PDL):

(a) The PDL is the primary tool that the Department of Human Services (DHS) has developed to inform licensed health care practitioners about the results of the latest peer-reviewed research and cost effectiveness of prescription drugs;

(b) The PDL consists of prescription drugs in selected classes that DHS, in consultation with the Health Resources Commission (HRC), has determined represent the most effective drug(s) available at the best possible price;

(c) For each selected drug class, the PDL will identify the drug(s) in the class that DHS determines to be the most effective drug(s) and determine the Net Price for each drug and Average Net Price of the class;

(d) The PDL will include drugs in the class that are Medicaid reimbursable and which the Food and Drug Administration (FDA) has determined to be safe and effective if the relative cost is less than the Average Net Price. If pharmaceutical manufacturers enter into supplemental rebate agreements with DHS that reduce the cost of their drug below that of the Average Net Price for the class, DHS, in consultation with the HRC recommendations, may include their drug on the PDL;

(e) A copy of the current PDL is available on the web at www.dhs.state.or.us/policy/healthplan/guides/pharmacy/main.html

(3) PMPDP PDL Selection Process:

(a) DHS will utilize the recommendations made by the HRC, which result from an evidence-based evaluation process, as the basis for identifying the most effective drug(s) within a selected drug class;

(b) DHS will determine the drug(s) identified in (3) (a) that is (are) available for the best possible price and will consider any input from the HRC about other FDA-approved drug(s) in the same class that are available for a lesser relative price. DHS will determine relative price using the methodology described in subsection (4);

(c) DHS will evaluate drug classes and selected drug(s) for the drug classes periodically:

(A) Evaluation will occur more frequently at the discretion of DHS if new safety information or the release of new drugs in a class or other information makes an evaluation advisable;

(B) New drugs in classes already evaluated for the PDL will be non-preferred until the new drug has been reviewed by the HRC;

(C) DHS will make all changes or revisions to the PDL, using the rulemaking process and will publish the changes on the DHS Pharmaceutical Services provider rules Web page.

(4) Relative cost and best possible price determination:

(a) DHS will determine the relative cost of all drugs in each selected class that are Medicaid reimbursable and that the FDA has determined to be safe and effective;

(b) DHS may also consider dosing issues, patterns of use and compliance issues. DHS will weigh these factors with any advice provided by the HRC in reaching a final decision;

(c) DHS will determine the Average Net Price for each PDL drug class. ;

(d) DHS will include drugs on the PDL based on all of the above and with a Net Price under the Average Net Price.

(5) Regardless of the PDL, pharmacy providers shall dispense prescriptions in the generic form, unless the practitioner requests otherwise, subject to the regulations outlined in OAR 410-121-0155.

(6) The exception process for obtaining non-preferred physical health drugs that are not on the PDL drugs shall be as follows;

(a) If the prescribing practitioner, in his/her professional judgment, wishes to prescribe a physical health drug not on the PDL, he/she may request an exception, subject to the requirements of OAR 410-121-0040.

(b) The prescribing practitioner must request an exception for physical health drugs not listed in the PDL subject to the requirements of OAR 410-121-0060

(c) Exceptions will be granted in instances:

(i) Where the prescriber in his/her professional judgment determines the non-preferred drug is medically appropriate after consulting with DMAP or the Oregon Pharmacy Help Desk; or

(ii) Where the prescriber requests an exception subject to the requirement of (6) (b) and fails to receive a report of PA status within 24 hours, subject to OAR 410-121-0060.

Table 121-0030-1, PMPDP PDL

Stat. Auth.: ORS 409.010, 409.025, 409.040, 409.050, 409.110, 414.065 & 414.325
Stats. Implemented: ORS 414.065

1-1-10

Table 121-0030-1 Practitioner-Managed Prescription Drug Plan (PMPDP)

All drugs listed below were evaluated by the Health Resources Commission (HRC) using an evidence-based review process. HRC identified drugs of similar or superior benefit when used as the initial treatment for the majority of patients. DHS limited the list of identified drugs to the most cost effective. Therapeutic prior authorization (PA) requirements still apply to drugs listed in the PDL classes (OAR 410-121-0040).

Physical Health PDL

ANALGESICS
Non-Steroidal Anti-inflammatory Drugs:
• diclofenac sodium
• etodolac
• ibuprofen
• indomethacin
• fluriprofen
• ketoprofen
• meloxicam
• naproxen
• naproxen sodium
• nabumetone
• oxaprozin
• piroxicam
• salsalate
• sulindac

Opioids, Long-Acting:

• Kadian®
• levorphanol
• morphine sulfate LA
• methadone

Skeletal Muscle Relaxants:
• baclofen
• cyclobenzaprine
• carisoprodol
• methocarbamol
• orphenadrine
• tizanidine

Triptans:
• Maxalt MLT®
• sumatriptan

Nasal
• sumatriptan
• Zomig®

Subcutaneous:
• sumatriptan

ANTI-INFECTIVES
Hepatitis C Drugs:
• Peg-Intron®
• Pegasys®

ASTHMA/COPD
Short-Acting Beta Agonists:
• albuterol nebulizer
• Maxair Autohaler®
• Proair HFA®
• Proventil HFA®
• Ventolin HFA®
• Xopenex HFA®

Asthma Controlers:
Inhaled Corticosteroids:
Low/Medium potency
• Aerobid®
• Azmacort®
• QVAR®
High potency
• Asmanex®
• Flovent Diskus®
• Flovent HFA®
• Pulmicort Flexhaler®

Long-Acting Beta-Agonists
• Foradil®
• Serevent Diskus®

Leukotriene Modifiers
Accolate®
Singulair®

Combination Inhalers
Advair Diskus®

CARDIOVASCULAR
ACE Inhibitors:
• benzapril
• captopril
• enalapril
• lisinopril
• quinapril

Combinations
• benazepril-HCTZ
• captopril-HCTZ
• enalapril-HCTZ
• lisinopril-HCTZ

Angiotensin Receptor Antagonists:
• Avapro®
• Benicar®
• Cozaar®
• Diovan®
• Micardis®

Combinations
• Avalide®
• Atacand HCT®
• Benicar HCT®
• Diovan HCT®
• Hyzaar ®
• Micardis HCT®

Antiplatlets:
• aspirin
• Aggrenox®
• dipyridamole
• Plavix®

Beta Blockers:
• acebutolol
• atenolol
• bisoprolol
• carvedilol
• labetolol
• metoprolol succinate
• metoprolol tartrate
• nadolol
• pindolol
• propranolol

Calcium Channel Blockers:
Dihydropyridines:
• amlodipine
• nicardipine
• nifedipine ER tablet
• nifedipine XL tablet

NonDihydropyridines:
• diltiazem IR
• diltiazem CR capsule
• diltiazem SA capsule
• diltiazem 24hr capsule
• verapamil IR
• verapamil tab SA
• verapamil 24hr pel

Statins:
Low/Medium Potency
• lovastatin
• pravastatin

High Potency
• simvastatin
• Lipitor®

ENDOCRINE
Diabetes Drugs:
Oral Hypogycemic Drugs:
• glimepriride
• glipizide
• glipizide ER
• glyburide
• glyburide micronized

Thiazolidinediones:
• Avandia
• Actos®

Estrogens:
• Activella
• Cenestin
• estradiol
• estropipate

Transdermal Products
• Alora®
• Combipatch®
• estradiol patch
• Estraderm®
• Vivelle-Dot®

Vaginal Products
• Estring®
• Premarin®
• Vagifem®

GASTROINTESTINAL
Antiemetics:
• granisetron
• ondansetron
• ondansetron ODT

Proton Pump Inhibitors:
• Aciphex®
• omeprazole
• Prilosec OTC®

GENITOURINARY
Overactive Bladder Drugs:
• Detrol LA®
• Enabex®
• oxybutynin
• Oxytrol®
• Sanctura®
• Sanctura XR®
• Vesicare®

IMMUNOMODULATORS
• Amevive®
• Enbrel®
• Humira®
• Kineret®
• Remicade®

NEUROLOGIC
Alzheimers Drugs:
• Aricept®
• Aricept ODT®
• Exelon®
• galantamine
• Namenda®

MS Drugs:
Avonex®
Copaxone®

ADHD Drugs:
• Adderall XR® (brand only)
• amphetamine salt combo IR
• Concerta®
• Daytrana ®
• dexmethylphenidate IR
• dextroamphetamine IR
• Focalin XR®
• methamphetamine IR
• methylphenidate IR
• methylphenidate SR
• Metadate CD®
• Ritalin LA®
• Vyvanse®

Mental Health PDL

Second Generation Antidepressants:
• bupropion IR
• bupropion SR
• citalopram
• fluoxetine
• fluvoxamine
• Lexapro®
• mirtazapine
• paroxetine
• sertraline
• venlafaxine IR

Atypical Antipsychotics:
• clozapine
• Geodon®
• risperidone
• risperidone-ODT
• Seroquel®
• Seroquel XR®

410-121-0032 Supplemental Rebate Agreements

(1) The Division of Medical Assistance Programs (DMAP) has a CMS approved Supplemental Rebate Agreement. This template and instructions are available on the DHS website at; http://www.oregon.gov/DHS/healthplan/supp-rebate/main.shtml

(2) DMAP negotiates Supplemental Rebate Agreements for specific drug products through the Sovereign States Drug Consortium (SSDC) multi-state pool and pharmaceutical manufacturers. Negotiations are confidential, and shall not be disclosed, except in connection with an agreement/contract or as may be required by law. Confidentiality is required of any third party involved in administration of the agreement/contract.

(3) Manufacturers may submit Supplemental Rebate offers for consideration to include their drug(s) on the Practitioner's-Managed Prescription Drug Plan (PMPDP) Preferred Drug List (PDL), OAR 410-121-0030 after gaining access to the SSDC secure web-based offer entry system.

(4) Manufacturers must abide by requirements of the SSDC.

(5) The Practitioner-Managed Prescription Drug List (PMPDP) also called the Preferred Drug List (PDL) consist of drugs after the Food and Drug Administration (FDA) has determined to be safe and effective and reimbursable as determined by the Centers for Medicaid and Medicare Services (CMS), and evaluated using an evidence-based review process by the Oregon Health Resources Commission (HRC). If pharmaceutical manufacturers enter into supplemental rebate agreements with the SSDC that reduced the cost of a drug below the Average Net Price (ANP) for the PDL class, DHS may include that drug on the PDL.

(6) Acceptance of the offer:

(a) DMAP may accept an offer through the SSDC process as long as the offer meets the cost reduction requirements of ANP described above

(b) The SSDC will notify manufacturers of the status of their offer(s).

(c) Supplemental Agreements will be executed after signed by all parties, approved by CMS if required, and added to the PMPDP Preferred Drug List by the Administrative rule process.

(d) DMAP may contract for the functions of tracking utilization, invoicing, and dispute resolution for supplemental rebate products.

Stat. Auth.: ORS 409.010, 409.025, 409.040, 409.050, 409.110 & 414.065

Stats. Implemented: 414.065

1-1-10

410-121-0033 Polypharmacy profiling

(1) The Division of Medical Assistance Programs (DMAP) may impose prescription drug payment limitations on clients with more than 15 unique fee-for-service drug prescriptions in a six-month period.

(2) DMAP will review the client's drug therapy in coordination with the client's prescribing practitioner to evaluate for appropriate drug therapy.

(3) Appropriate drug therapy criteria will include, but is not limited to, the following:

(a) Overuse of selected drug classes;

(b) Under-use of generic drugs;

(c) Therapeutic drug duplication;

(d) Drug to disease interactions;

(e) Drug to drug interactions;

(f) Inappropriate drug dosage;

(g) Drug selection for age;

(h) Duration of treatment;

(i) Clinical abuse or misuse.

(4) The DMAP Medical Director in conjunction with the Drug Utilization Review (DUR) Board will make final determinations on imposed drug prescription payment limitations relating to this policy.

Stat. Authority: ORS Chap. 409.120 & 414.380
Stats. Implemented: 414.065 2-1-10

410-121-0040 Prior Authorization Required for Drugs and Products

(1) Prescribing practitioners are responsible for obtaining Prior Authorization (PA) for the drugs and categories of drugs requiring PA in this rule, using the procedures required in OAR 410-121-0060.

(2) All drugs and categories of drugs, including but not limited to those drugs and categories of drugs that require PA as described in this rule, are subject to the following requirements for coverage:

(a) Each drug must be prescribed for conditions funded by OHP in a manner consistent with the Prioritized List of Health Services (OAR 410-141-0480 through 410-141-0520). If the medication is for a non-covered diagnosis, the medication will not be covered unless there is a co-morbid condition for which coverage would be extended. The use of the medication must meet corresponding treatment guidelines, be included within the client's benefit package of covered services, and not otherwise excluded or limited.

(b) Each drug must also meet other criteria applicable to the drug or category of drug in these Pharmacy Provider rules, including PA requirements imposed in this rule.

(3) The Department of Human Services (DHS) may require PA for individual drugs and categories of drugs to ensure that the drugs prescribed are indicated for conditions funded by OHP and consistent with the Prioritized List of Health Services and its corresponding treatment guidelines (*see* OAR 410-141-0480). The drugs and categories of drugs for which DHS requires PA for this purpose are listed in Table 410-121-0040-1, with their approval criteria.

(4) DHS may require PA for individual drugs and categories of drugs to ensure medically appropriate use or to address potential client safety risk associated with the particular drug or category of drug, as recommended by the Drug Use Review (DUR) Board and adopted by the Department in this rule (*see* OAR 410-121-0100 for a description of the DUR program). The drugs and categories of drugs for which DHS requires PA for this purpose are included in Table 410-121-0040-2, with their approval criteria.

(5) PA is required for brand name drugs that have two or more generically equivalent products available and that are NOT determined Narrow Therapeutic Index drugs by the Oregon Drug Use Review Board.

(a) Immunosuppressant drugs used in connection with an organ transplant must be evaluated for narrow therapeutic index within 180 days after United States patent expiration.

(b) Manufacturers of immunosuppressant drugs used in connection with an organ transplant must notify the department of patent expiration within 30 days of patent expiration for (5)(a) to apply.

(c) Criteria for approval are:

(A) If criteria established in subsection (3) or (4) of this rule applies, follow that criteria.

(B) If (5)(A) does not apply, the prescribing practitioner must document that the use of the generically equivalent drug is medically contraindicated, and provide evidence that either the drug has been used and has failed or that its use is contraindicated based on evidence-based peer reviewed literature that is appropriate to the client's medical condition.

(6) PA is required for non-preferred PDL products in a class evaluated for the PDL except in the following cases:

(a) The drug is a Mental Health drug as defined in OAR 410-121-0000,

(b) The original prescription is written prior 1/1/10,

(c) The prescription is a refill for the treatment of seizures, cancer, HIV or AIDS, or

(d) The prescription is a refill of an immunosuppressant

(7) PA may not be required

(a) When the prescription ingredient cost plus the dispensing fee is less than the PA processing fees as determined by DHS,,

(b) For over-the-counter (OTC) covered drugs when prescribed for conditions covered under OHP or,

(c) If a drug is in a class not evaluated from the Practitioner-Managed Prescription Drug Plan under ORS 414.334

Table 121-0040-1

Table 121-0040-2

Stat. Auth.: ORS Chap. 409.050, 409.110 and 414.065, and 414.334

Stats. Implemented: 414.065
1-1-10

Table 121-0040-1

Drugs Requiring Prior Authorization for Covered Diagnosis

OAR 410-141-0500, and 410-141-0520

Drug Class	Drug Generic (list is subject to market fluctuations)	Drug Brand (list is subject to market fluctuations)	Approval Criteria
Fentanyl Transmucosal	Fentanyl citrate	Actiq Fentora	Any covered diagnosis meeting the recommendations in Table 2 will be approved.
Antifungals, Oral	itraconazole terbinafine	Sporanox Lamisil	Dermatophytosis of the nail and skin and other minor fungal infections are only covered when complicated by an immunocompromised host.
Antifungals, Topical	amphotericin B butenafine ciclopirox clotrimazole clotrimazole/betamethasone econazole ketoconazole naftifine nystatin/triamcinolone oxiconazole sertaconazole sulconazole terbinafine tolnaftate undecylenic acid various others	Fungizole Lotrimin Ultra;Mentax Loprox; Penlac Lotrimin; Mycelex Lotrisone Spectazole Nizoral Naftin Mycolog II Oxistat Ertaczo Exelderm Lamisil Tinactin Desenex Various others	Dermatophytosis of the nail and skin and other minor fungal infections are only covered when complicated by an immunocompromised host.

Drug Class	Drug Generic (list is subject to market fluctuations)	Drug Brand (list is subject to market fluctuations)	Approval Criteria
Antihistamines	Extensive list: all of First Databank Standard Therapeutic Class = 14 except: Diphenhydramine HCL Chlorpheniramine Loratadine Promethazine, HCL Hydroxyzine Pamoate Cetirizine		Allergic rhinitis is not a covered diagnosis unless it is complicated with other covered diagnoses Use must meet recommendations in Table 2.
Antiviral, Topical	acyclovir docosanol peniciclovir	Zovirax Abreva Denavir	HSV infections are covered when complicated by an immunocompromised host.
Benign Prostatic Hypertrothphy Drugs	alfuzosin dutasteride finasteride tamsulosin	Uroxatral Avodart Proscar Flomax	Treatment of enlarged prostate is not covered unless complicated by obstruction. The cosmetic use of these drugs for baldness is not covered.
Brand Drugs, Multi-Source	Various	Various	A covered diagnosis is required for “dispense as written: or “brand medically necessary: reimbursement of a brand product when a generic is available.
Carisoprodol drugs	carisoprodol and all combination products	Soma, Soma Compound, various others	Any above the line diagnosis will be approved within dosing recommendations in Table 2.

Drug Class	Drug Generic (list is subject to market fluctuations)	Drug Brand (list is subject to market fluctuations)	Approval Criteria
Cough and Cold drugs	Extensive list: all of First Databank Standard Therapeutic Class = 16, 17 except Guaifenesin/codeine Guaifenesin DM Guaifenesin P-Ephed/Triprolidine Pseudoephedrine HCL		A covered diagnosis is required.
Dronabinol	dronabinol	Marinol	Any covered diagnosis meeting the recommendations in Table 2 will be approved.
Fibromyalgia Drugs	pregabalin milnacipran	Lyrica Savella	Any covered diagnosis meeting the recommendations in Table 2 will be approved.
Growth Hormones	somatrem somatropin	Accretropin Genotropin Humatrope Norditropin Nutropin Nutropin AQ Nutropin Depot Omnitrope Saizen Serostim Tev-tropin Valtropin Zorbtive	Any covered diagnosis meeting recommendations in Table 2 will be approved.
Ketoralac	ketoralac	Toradol	Any covered diagnosis will be approved within the dosing recommendations in Table 2.
Lupron	leuprolide	Lupron	Covered diagnosis, e.g. endometriosis, prostate cancer, precocious puberty until age 12 in

Drug Class	Drug Generic (list is subject to market fluctuations)	Drug Brand (list is subject to market fluctuations)	Approval Criteria
			girls, age 13 in boys; short-stature when meets medically appropriate criteria
Laxative, selected	Lubiprostone Methylnaltrexone	Amitiza Relistor	Acovered diagnosis will be approved within the guidelines in Table 2.
Leukotriene receptor antagonists	montelukast	Singular	Allergic rhinitis is not a covered diagnosis unless it is complicated with other covered diagnoses Asthma is a covered diagnosis.
Nasal Inhalers	azelastine cromolyn beclomethasone budesonide flunisolide fluticasone mometasone triamcinolone	Astelin Nasalcrom RA Beconase Rhinocort Nasalide Flonase Nasonex Nasacort	Allergic rhinitis is not a covered diagnosis unless it is complicated with other covered diagnoses.
Nutritional Support, Enteral or oral	Nutritional bars, liquids, packets, powders, & wafers, and various others	Ensure, Ensure Plus, Nephro, Pediasure, Promod and various others	Diagnosis being treated must be a covered diagnosis and fall within the recommendations in Table 2.
Opioid Drug, Long-Acting (selected)	Fentanyl Patches Morphine Sulfate Oxymorphone Oxycodone HCL	DURAGESIC(including generic equivalents) Avinza, Kadian (MSContin & Oramorph generic equivalents DO NOT require PA) Opana ER Oxycontin (including generic equivalents)	Any covered diagnosis will be approved.
Opioid Drugs,			Any covered pain

Drug Class	Drug Generic (list is subject to market fluctuations)	Drug Brand (list is subject to market fluctuations)	Approval Criteria
combination products (aka narcotics)	codeine/acetaminophen hydrocodone/acetaminophen dihydrocodone/acetaminophen/ caffeine oxycodone/acetaminophen propoxyphene/acetaminophen pentazocine/acetaminophen codeine/aspirin codeine/aspirin/caffeine oxycodone/aspirin pentazocine/aspirin propoxyphene/aspirin/caffeine various others	Tylenol with Codeine Vicodin, Lortab DHC Plus Percocet Darvocet-N-100 Talacen Empirin with Codeine Fiorinal with Codeine Percodan Talwin Compound Darvon Compound Various others	diagnosis that is appropriate will be approved within dose recommendations in Table 2.
Psoriasis Drugs	alefacept efalizumab methoxsalen trioxsalen isotretinoin acitretin antralin tazarotene calcipotriene coal tar	Amevive Raptiva Psoralen, 8-MOP Trisoralen Accutane, Sotret Soriatane Psoriatec, Drithocreme Tazorac Dovonex Various	Only Stage III, IV psoriasis and psoriatic arthritis are covered. Stages I and II are not. Other, non-experimental, covered diagnoses will be approved.
Sedatives	estazolam eszopiclone flurazepam quazepam ramelteon temazepam triazolam zaleplon zolpidem	Prosom Lunesta Dalmane Doral Rozerem Restoril Halcion Sonata Ambien CR	Chronic insomnia is not a covered diagnoses. Sleep disorders contributing to covered diagnoses (e.g. sleep apnea, bipolar affective disorder, depression, etc.) will be approved.
Stimulants	dextroamphetamine methamphetamine mixed amphetamines dexmethylphenidate	Dexedrine, Dextristat Desoxyn Adderall, Adderall XR Focalin	Obesity is not a covered diagnoses. Use for ADHD, Narcolepsy and

Drug Class	Drug Generic (list is subject to market fluctuations)	Drug Brand (list is subject to market fluctuations)	Approval Criteria
	methylphenidate lisdexamfetamine dimesylate Methylphenidate Transdermal	Methylin, Metadate, Ritalin Vyvanse Daytrana	other covered diagnoses will be approved within the doses recommended in Table 2.
Testosterone, Topical	testosterone	Testoderm Androgel Androgem DHEA	Will be approved for covered diagnoses (e.g. Primary hypogonadism, Hypogonadotropic hypogonadism, AIDS related cachexia)
Topiramate	topiramate	Topamax	Any covered diagnosis meeting the recommendations in Table 2 will be approved.
Weight Loss Drugs	orlistat sibutramine phentermine	Xenical Meridia Fastin	Obesity treatment is not a covered diagnosis. Only diagnoses that are covered will be approved.

Table 121-0040-2

Drugs Requiring Prior Authorization for Medically Appropriate Use

OAR 410-141-0500, and 410-141-0520

Drug Class	Drug Generic (list is subject to market fluctuations)	Drug Brand (list is subject to market fluctuations)	Use Criteria
Fentanyl Transmucosal	Fentanyl	Actiq Fentora	Use restricted to the state adopted DUR Board recommendations on May 12, 2005 for Actiq; on November 29, 2007 for Fentora
Anti-emetics, selected	dolasteron granisetron ondansetron aprepitant	Anzemet Kytril Zofran Emend	Chronic use (>3 days/week) is restricted to indications that are supported by the medical evidence (e.g. nausea associated with chemotherapy)
Antihistamines, Selected	Extensive list: all of First Databank Standard Therapeutic Class = 14 except: Diphenhydramine HCL Chlorpheniramine Loratadine Promethazine, HCL Hydroxyzine Pamoate Cetirizine		Use is restricted to covered diagnoses and therapy is recommended to include an asthma controller drug. Duplication with similar products (i.e. nasal inhalers) is not recommended.
Becaplermin	Becaplermin	Regranex	Use restricted to diabetic neuropathic ulcers.
Buprenorphine sublingual	buprenorphine/ naloxone buprenorphine	Suboxone Subutex	Use restricted to addiction treatment

Drug Class	Drug Generic (list is subject to market fluctuations)	Drug Brand (list is subject to market fluctuations)	Use Criteria
Carisoprodol drugs	carisoprodol and all combination products	Soma, Soma Compound, various others	Carisoprodol is restricted to short-term use (56 tablets / 90days)
Dronabinol	dronabinol	Marinol	Dronabinol use is restricted to indications where the medical evidence supports its use (e.g. nausea associated with chemotherapy or cachexia)
Fibromyalgia Drugs	pregabalin milnacipran	Lyrica Savella	Pregabalin and Milnaciipran use is restricted to indications where the medical evidence supports its use.
Growth Hormones	somatrem somatropin	Accretropin Genotropin Humatrope Norditropin Nutropin Nutropin AQ Nutropin Depot Omnitrope Saizen Serostim Tev-tropin Valtropin Zorbtive	Growth hormone use is restricted to indications of documented hormone deficiency. Serostim may be approved for AIDS wasting within approved parameters.
Hepatitis C Drugs	Pegylated Interferon Ribavirin/Interferon A-2B Ribavirin	Peg-Intron Pegasys Rebetron Rebetol	Restricted to patient selection criteria the state adopted from DUR Board recommendations on May 25, 2004.
Ketoralac	ketoralac	Toradol	Ketoralac is restricted to short-term use (5 days

Drug Class	Drug Generic (list is subject to market fluctuations)	Drug Brand (list is subject to market fluctuations)	Use Criteria
			every 60 days)
Laxitives, selected	Lubiprostone Methylnal Trexone	Amitiza Relistor	Approval requires establishment of chronic constipation secondary to a covered condition and failure of 3 first-line categories of constipation treatments (i.e. diet, fiber, saline, stimulant or osmotic)
Leukotriene receptor antagonists	montelukast	Singular	Duplication with similar products (i.e. nasal inhalers, antihistamines) is not recommended. It is not indicated for COPD and other respiratory disorders without an asthma component.
Lupron	leuprolide	Lupron	Use for precocious puberty restricted to girls age 12 & under, to boys age 13 & under. Initial treatment should begin by age 9 in girls, by age 11 in boys.
Methadone	methadone	Dolophine	Doses above 100mg / Day are enforced based upon the state adopted DUR Board recommendations on September 24, 2009.
Migraine Drugs (aka Triptans)	almotriptan eletriptan frovatriptan naratriptan rizatriptan sumatriptan zolmitriptan	Axert Relpax Frova Amerge Maxalt, Maxalt MLT ImitrexZomig, Zomig ZMT	Monthly quantity limits are enforced based upon the state adopted DUR Board recommendations on May 13, 2003.
Nasal Inhalers	azelastine cromolyn	Astelin Nasalcrom RA	Use is restricted to covered diagnoses and

Drug Class	Drug Generic (list is subject to market fluctuations)	Drug Brand (list is subject to market fluctuations)	Use Criteria
	beclomethasone budesonide flunisolide fluticasone mometasone triamcinolone	Beconase Rhinocort Nasalide Flonase Nasonex Nasacort	therapy is also recommended to include an asthma controller drug. Duplication with similar products (i.e. antihistamines) is not recommended.
Nutritional Support, Enteral or oral	Nutritional bars, liquids, packets, powders, & wafers, and various others	Ensure, Ensure Plus, Nephro, Pediasure, Promod and various others	These products are restricted to patients unable to take food orally in sufficient quantity to maintain adequate weight. Requires annual nutritional assessment to assess continued need.
Opioid Drugs, combination products (aka narcotics)	codeine/acetaminophen hydrocodone/acetaminophen dihydrocodone/acetaminophen/caffeine oxycodone/acetaminophen propoxyphene/acetaminophen pentazocine/acetaminophen codeine/aspirin codeine/aspirin/caffeine oxycodone/aspirin pentazocine/aspirin propoxyphene/aspirin/caffeine various others	Tylenol with Codeine Vicodin, Lortab DHC Plus Percocet Darvocet-N-100 Talacen Empirin with Codeine Fiorinal with Codeine Percocet Talwin Compound Darvon Compound Various others	Monthly quantity limits are enforced for acetaminophen or aspirin levels in these medications that the state adopted from DUR Board recommendations on May 13, 2003.
Polypharmacy	Various	Various	See: 410-121-0033
Proton Pump Inhibitors	esomeprazole lansoprazole lansoprazole w/naproxen	Nexium Prevacid NapraPAC	PPI therapy beyond 8 weeks requires prior

Drug Class	Drug Generic (list is subject to market fluctuations)	Drug Brand (list is subject to market fluctuations)	Use Criteria
	omeprazole pantoprazole rabeprazole	Prilosec Protonix Aciphex	authorization. Chronic use is restricted to those who have failed H2-antagonist therapy or those with severe disease (e.g. Barrett's, ZE, etc.)
Sedatives	estazolam flurazepam quazepam temazepam triazolam	Prosom Dalmane Doral Restoril Halcion	Quantities are restricted to 15 doses/30days unless a covered diagnosis is provided.
Stimulants	dextroamphetamine methamphetamine mixed amphetamines dexmethylphenidate methylphenidate lisdexamfetamine dimesylate Methylphenidate Transdermal	Dexedrine, Dextristat Desoxyn Adderall, Adderall XR Focalin Methylin, Metadate, Ritalin Vyvanse Daytrana	Doses greater than the recommended doses the state adopted from DUR Board recommendations on November 15, 2005, September 20, 2007 & September 18, 2008 require prior authorization.
Topiramate	topiramate	Topamax	Topiramate use is restricted to indications where the medical evidence supports its use (e.g. epilepsy, second-line migraine prophylaxis, second-line bipolar disease).

410-121-0060 How to Get Prior Authorization for Drugs

(1) A prescriber electing to order a drug requiring PA may have any licensed medical personnel in their office request the PA. The PA request may be transmitted to the Oregon Pharmacy Help Desk by any of the following methods:

(a) Call the Oregon Pharmacy Help Desk

(b) FAX the request form shown in the Pharmaceutical Services Supplemental Information on the Department of Human Services website to the Oregon Pharmacy Help Desk

(c) Transmit the request electronically via the secure MMIS web portal.

(2) The status of a PA request received from prescribers or their licensed medical personnel will be reported on the secure MMIS web portal, or by calling the Automated Voice Recognition (AVR) System, within 24 hours of receipt by the Oregon Pharmacy Help Desk

(3) PA approval:

(a) It is the pharmacy personnel's responsibility to check whether the drugs are covered, whether the client is eligible, and to note restrictions such as date ranges and quantities before dispensing any medications that require PA.

(b) The pharmacy personnel must also check whether the client's prescribed medications are covered by a managed care plan because an enrollment may have taken place after PA was received. If the client is enrolled in a managed care plan and the pharmacy receiving the PA is not a participating pharmacy provider in the managed care plan's network, the pharmacy must inform the client that it is not a participating provider in the managed care plan's network and must also recommend that the client contact his or her managed care plan for a list of pharmacies participating in its network..

(c) After a PA request is approved, the patient will be able to fill the prescription at any Medicaid pharmacy provider, if consistent with all other applicable administrative rules.

(3) If the PA request has been denied, notification to client and prescriber will occur in accordance with OHP General Rules 410-120-1860.

(4) Emergency Need: The Pharmacist may request an emergent or urgent dispensing from the Pharmacy Benefits Manager (PBM) when the client is eligible for covered fee-for-service drug prescriptions.

(a) Clients who do not have a PA pending may receive an emergency dispensing for a 96-hour supply.

(b) Clients who do have a PA pending may receive an emergency dispensing up to a seven-day supply.

Stat. Auth.: ORS 409.010, 409.025, 409.040, 409.050, 409.110 & 414.065

Stats. Implemented: ORS 414.065 & 414.325

1-1-10

410-121-0061 Durable Medical Equipment and Medical Supplies

Follow the guidelines in the Durable Medical Equipment and Medical Supplies (OAR 410 Division 122) and Home Enteral/Parenteral Nutrition and IV Services (OAR 410 Division 148) Administrative Rules and Supplemental Information for billing and prior authorization of these medical supplies and services. This information is available on the Department of Human Services website.

Stat. Auth.: ORS 409.010

Stats. Implemented: ORS 414.065

2-1-10

410-121-0100 Drug Use Review

(1) Drug Use Review (DUR) in Division of Medical Assistance Programs (DMAP) is a program designed to measure and assess the proper utilization, quality, therapy, medical appropriateness, appropriate selection and cost of prescribed medication through evaluation of claims data. This is done on both a retrospective and prospective basis. This program shall include, but is not limited to, education in relation to over-utilization, under-utilization, therapeutic duplication, drug-to-disease and drug-to-drug interactions, incorrect drug dosage, duration of treatment and clinical abuse or misuse.

(a) Information collected in a DUR program that identifies an individual is confidential and may not be disclosed by the DMAP DUR Board or contractors to any person other than health care providers appearing on a recipient's medication profile.

(b) Staff of the DUR Board and contractors may have access to identifying information to carry out intervention activities approved by DMAP, after signing an agreement to keep the information confidential. The identifying information may not be released to anyone other than staff members of the DUR Board, or health care providers appearing on a recipient's medication profile. For purposes of DUR activities, identifying information is defined as the names of prescribing providers, pharmacy providers, and clients.

(2) Prospective DUR is the screening for potential drug therapy problems before each prescription is dispensed. It is performed at the point of sale by the dispensing pharmacist.

(a) Dispensing pharmacists must offer to counsel each DMAP client receiving benefits who presents a new prescription, unless the client refuses such counsel. Pharmacists must document these refusals.

(A) Dispensing pharmacists may offer to counsel the client’s caregiver rather than the client presenting the new prescription if the dispensing pharmacist determines that it is appropriate in the particular instance.

(B) Counseling must be done in person whenever practicable.

(C) If it is not practicable to counsel in person, providers whose primary patient population does not have access to a local measured telephone service must provide access to toll-free services (for example, some mail order pharmacy services) and must provide access to toll-free service for long-distance client calls in relation to prescription counseling.

(b) Prospective DUR is not required for drugs dispensed by Fully Capitated Health Plans (FCHPs).

(c) Oregon Board of Pharmacy rules defining specific requirements relating to patient counseling, record keeping and screening must be followed.

(3) Retrospective DUR is the screening for potential drug therapy problems based on paid claims data. DMAP provides a professional drug therapy review for Medicaid clients through this program.

(a)The criteria used in retrospective DUR are compatible with those used in prospective DUR. Retrospective DUR criteria may include Pharmacy Management (Lock-In), Polypharmacy, and Psychotropic Use in Children. Drug therapy review is carried out by pharmacists with the Oregon State University College of Pharmacy, Drug Use Research and Management Program.(b) If therapy problems are identified, an educational letter is sent to the prescribing provider, the dispensing provider, or both. Other forms of education are carried out under this program with DMAP approval.

(4) The DUR Board is a group of individuals who comprise an advisory committee to DMAP.

(a) The DUR Board is comprised of health care professionals with recognized knowledge and expertise in one or more of the following areas:

(A) Clinically appropriate prescribing of outpatient drugs covered by Medicaid;

(B) Clinically appropriate dispensing and monitoring of outpatient drugs covered by Medicaid;

(C) Drug use review, evaluation and intervention; or

(D) Medical quality assurance.

(b) The DUR Board's membership is made up of at least one-third, but not more than 51 percent, licensed and actively practicing physicians and at least one-third licensed and actively practicing pharmacists. The DUR Board is composed of the following:

(A) Four practicing pharmacists;

(B) Five practicing physicians;

(C) Two persons who represent people on Medical Assistance; and

(D) One person actively practicing dentistry.

(c) The Retrospective DUR Reviewer will attend board meetings in an ex officio capacity.

(d) Appointments to the DUR Board are made by the DMAP Director.

(A) Nominations for DUR Board membership may be sought from various professional associations and each member may serve a two-year term.

(B) When a vacancy occurs, a new member is appointed to serve the remainder of the unexpired term.

(C) An individual appointed to the DUR Board may be reappointed upon the completion of the member’s current term of service.

(e) Members of the DUR Board receive no compensation for their services, but subject to any applicable state law, shall be allowed

actual and necessary travel expenses incurred in the performance of their duties.

(f) Members of the DUR Board attend quarterly meetings, two of which must be attended in person.

(5) The DUR Board is designed to develop policy recommendations in the following areas in relation to Drug Use Review :

(a) Appropriateness of criteria and standards for prospective DUR and needs for modification of these areas. DUR criteria are predetermined elements of health care based upon professional expertise, prior experience, and the professional literature with which the quality, medical appropriateness, and appropriateness of health care service may be compared. Criteria and standards will be consistent with the following compendia:

(A) American Hospital Formulary Services Drug Information (AAFS-DI);

(B) US Pharmacopeia-Drug Information for the Health Care Professional (USP-DI);

(C) Drug DEX Information System;

(D) Peer-reviewed medical literature; or

(b) Recommendations for continued maintenance of patient confidentiality will be sought;

(c) The use of different types of education and interventions to be carried out or delegated by the DUR Board and the evaluation of the results of this portion of the program; and

(d) The preparation of an annual report on Oregon Medicaid DUR Program which describes:

(A) DUR Board Activities

(i) A description of how pharmacies comply with prospective DUR;

(ii) Detailed information on new criteria and standards in use; and

(iii) Changes in state policy in relation to DUR requirements for residents in nursing homes.

(B) A summary of the education/intervention strategies developed; and

(C) An estimate of the cost savings in the pharmacy budget and indirect savings due to changes in levels of physician visits and hospitalizations.

Stat. Auth.: ORS 414.355, 414.360, 414.365, 414.370 & 414.380)

Stats. Implemented: ORS 414.065

2-1-10

410-121-0135 Pharmacy Management Program

(1) Pursuant to 42 CFR 431.54, the Pharmacy Management Program limits some fee-for-service clients to receiving their prescription drugs through the following sources:

(a) A single retail pharmacy to pick up prescriptions;

(b) The Division of Medical Assistance Program (DMAP) mail order pharmacy contractor; and

(c) A specialty pharmacy.

(2) DMAP will not include the following clients in the Pharmacy Management Program:

(a) Prepaid Health Plan (PHP) DMAP members;

(b) Clients with Medicare drug coverage in addition to OHP fee-for-service and no other third party pharmacy insurance coverage;

(c) Children in the care and custody of the Department of Human Services;

(d) Inpatients or residents in a hospital, nursing facility, or other medical institution.

(3) DMAP will consider referrals of potential Pharmacy Management Program clients from the following sources:

(a) Providers;

(b) Retro Drug Utilization Review (DUR) staff;

(c) Department of Human Services (DHS) staff; and

(d) DHS contractors.

(4) Reasons for referring a client to DMAP for review and enrollment in the Pharmacy Management Program include, but are not limited to concern for patient safety or risk of drug misuse, where the client:

(a) Used 3 or more pharmacies during the prior 6 months;

(b) Uses multiple prescribers to obtain prescriptions of the same or comparable medications;

(c) Has altered a prescription; or

(d) Exhibits patterns of prescription drug use involving the drug use review factors listed in ORS 414.360 (a) through (h), as those terms are defined in ORS 414.350.

(5) When DMAP identifies a client meeting the criteria in subsection (4) that is appropriate for the Pharmacy Management Program, DMAP will send the client a notice that provides the following information:

(a) DMAP plans to require that the client use a designated pharmacy for an 18-month period and the date when that requirement will begin;

(b) The client's right to request the following, within 45 days of the date of the notice:

(A) A different designated pharmacy;

(B) An administrative hearing to appeal DMAP's decision to enter the client into the Pharmacy Management Program.

(6) Changing the Pharmacy Management Program client's enrolled pharmacy:

(a) Clients may change their enrolled pharmacy if they:

(A) Move out of area;

(B) Are reapplying for OHP benefits; or

(C) Are denied access to pharmacy services by their selected pharmacy for reasons other than the Pharmacy Management Program factors identified by DMAP;

(b) Clients cannot change their choice of pharmacy more than once every 3 months.

(7) Pharmacy Management Program clients may receive drugs from a different pharmacy if the client urgently needs to fill a prescription and the enrolled pharmacy:

(a) Is not available;

(b) Does not have the prescribed drug in stock; or

(c) Is more than 50 miles away from the client's location at the time the prescription needs to be filled.. However, DMAP may deny coverage if the client frequently fills prescriptions out of the area of the enrolled pharmacy.

(8) Call the Oregon Pharmacy Help Desk for authorization to fill a prescription in the situations described in (7)(a-c) above.

(9) The client's appeal rights and the process for appealing a DMAP decision to lock a client into use of a single pharmacy is found in Oregon Administrative Rule (OAR) 410-120-1860.

Stat. Auth.: ORS 409.050 & ORS 414.065

Stat. Implemented: ORS 414.065

1-1-10

410-121-0143 Client Confidentiality

Pharmacists are responsible for maintaining the confidentiality of client information in compliance with HIPAA standards. Facilities shall provide adequate privacy for patient consultations.

Stat. Auth.: ORS 409.010 & ORS 409.110

Stats. Implemented: 414.065

1-1-07

410-121-0144 Notation on Prescriptions

This rule applies to fee-for-service clients only.

(1) Prescribing practitioners must add a notation on pharmacy prescriptions indicating when there is a non-covered diagnosis.

(2) When the client 's diagnosis is excluded or below the current funding line on the Health Services Commission 's Prioritized List of Health Services, use the following notations (or similar language):

(a) "Diagnosis not covered ";

(b) "Excluded diagnosis"; or

(c) "Condition below the funding line".

(3) The Division of Medical Assistance Programs (DMAP) will not provide payment for prescriptions when a diagnosis is:

(a) Below the funding line;

(b) An excluded service; or

(c) On the excluded list.

(4) Payment for prescriptions with an excluded or not covered diagnosis is the responsibility of the client. These prescriptions will not be paid under the Oregon Health Plan. Pharmacies are not to bill DMAP for these prescriptions.

Stat. Auth.: ORS 409.010

Stats. Implemented: ORS 414.065

2-1-10

410-121-0145 Prescription Requirements

(1) Division of Medical Assistance Programs (DMAP) will make payment for covered drugs supplied on drug order or prescription of a licensed practitioner and dispensed by a pharmacist. Dispensings include new prescriptions, refills of existing prescriptions, and over-the-counter (OTC) medications.

(a) Each drug order or prescription filled for a DMAP client must be retained in the pharmacy's file at the pharmacy’s place of business; and,

(b) All drug orders or prescriptions must comply with the Oregon State Board of Pharmacy rules and regulations as listed in OAR 855 Division 041.

(2) Notwithstanding subsection (1) of this rule, the following rules shall apply to over-the-counter Plan B emergency contraceptive drugs:

(a) DMAP may reimburse a pharmacy for distributing over-the-counter Plan B emergency contraceptive drug products to women who are 17 years old and older and who are Medicaid eligible; and,

(b) As a condition of reimbursement for over-the-counter Plan B emergency contraceptive drugs, DMAP may require that the pharmacy show proof that it has complied with Oregon Board of Pharmacy rules pertaining to the distribution of over-the-counter Plan B emergency contraceptive drugs.

Stat. Auth.: ORS 409

Stats. Implemented ORS 414.65

2-1-10

410-121-0146 Dispensing Limitations

(1) The Division of Medical Assistance Programs (DMAP) 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 DMAP dispensing limitations as outlined in this rule.

(2) The pharmacy may only dispense less than the prescribed quantity when the prescribed quantity exceeds the DMAP dispensing limitations.

(3) Most drugs dispensed cannot exceed a 34-day supply except for those circumstances where DMAP allows drug dispensing of up to a 100-day supply, such as:

(a) DMAP mail order pharmacy contractors;

(b) Indian Health mail order pharmacy providers;

(c) 340b pharmacy providers;

(d) Preferred PDL generics; and

(e) Generics in non-PDL classes that cost less than $10 per month and are maintenance medications.

(4) The following Standard Therapeutic Classes of drugs (according to First Databank) cannot exceed a 34-day supply under any circumstances, including those listed in (3) above:

(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

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

(6) For vaccines available in multiple dose packaging, DMAP 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.

(7) 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) DMAP 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).

Stat. Auth.: ORS 409.050 & ORS 414.065

Stats. Implemented: ORS 414.065

4-1-10 (T)

410-121-0147 Exclusions and Limitations

The following items are not covered for payment by the Division of Medical Assistance Programs (DMAP):

(1) Drug Products for diagnoses below the funded line on the Health Services Commission Prioritized List;

(2) Home pregnancy kits;

(3) Fluoride for individuals over 18 years of age;

(4) Expired drug products;

(5) Drug Products from Non-Rebatable Manufacturers;

(6) Drug products that are not assigned a National Drug Code (NDC) number;

(7) Drug products that are not approved by the Food and Drug Administration (FDA);

(8) Drug products dispensed for Citizen/Alien-Waived Emergency Medical client benefit type;

(9) DESI drugs (*see* OAR 410-121-0420);

(10) Medicare Part D covered drugs or classes of drugs for fully dual eligible clients;

(11) Effective on or after April 1, 2008, Section 1903(i) of the Social Security Act requires that written (nonelectronic) prescriptions for covered outpatient drugs for Medicaid clients be executed on a tamper-resistant pad in order to be eligible for federal matching funds. To meet this requirement, DMAP will only reimburse for covered Medicaid outpatient drugs when the written (nonelectronic) prescription is executed on a tamper-resistant pad, or the prescription is electronically submitted to the pharmacy.

Stat. Auth.: ORS 409.010

Stats. Implemented: ORS 414.065

4-1-08

410-121-0148 Dispensing in a Nursing Facility or Community Based Care Living Facility

A pharmacy serving Division of Medical Assistance Programs (DMAP) clients in a nursing facility or a Community Based Care Living Facility must dispense medication in a manner consistent with Board of Pharmacy rules as set out in OAR 855-041.

(a) For the purposes of this rule, “Long term care facility” includes skilled nursing facilities and intermediate care facilities consistent with the definitions in ORS 443.400 to 443.455.

(b) An intermediate care facility is 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 ORS 442.015.

Stat Auth.: ORS 409.050, 404.110 and 414.065

Stats. Implemented ORS 414.065

2-10-10

410-121-0149 Medicaid Temporary Prescription Drug Assistance for Fully Dual Eligible Medicare Part D Clients

(1) This rule is a temporary solution implemented because many pharmacies are not able to verify that the fully dual eligible client is enrolled in one of the federal Medicare Prescription Drug Plans or that the client is eligible for low-income subsidy assistance. DMAP will continue to work with the federal Medicare program to resolve these implementation issues with Part D coverage.

(2) Effective January 14, 2006, for the purposes described in Subsection (1), enrolled pharmacies may send the Division of Medical Assistance Programs (DMAP) claims for Part D drugs and cost-sharing obligations of clients who have both Medicare and Medicaid coverage (fully dual eligible clients) if:

(a) The drug(s) was covered by DMAP for fully dual eligible clients prior to January 1, 2006; and

(b) The pharmacy has attempted to bill Medicare's Part D system but cannot resolve the claim by:

(A) Continuing to bill the Medicare Part D plan as the primary payer identified through an E-1 query;

(B) Trying to resolve the issue with the Medicare Part D plan directly;

(C) Billing Wellpoint/Anthem, Medicare's Point of Sale Solution.

(3) If all the criteria in Subsection (2) are met, then DMAP will consider paying the claim or a portion of the claim, as follows:

(a) The pharmacy must contact the DHS Medicare hotline at 1-877-585-0007 to obtain authorization for claim submission;

(b) The fully dual eligible client is responsible for paying the appropriate Medicare copayment;

(c) DMAP payment authorization will be limited to not greater than a one-month supply; and

(d) DMAP's reimbursement amount will be limited to the amount the Part D drug plan would have paid, had the Part D drug plan adjudicated the claim first, or the amount DMAP would pay for Medicaid clients who are not also Medicare beneficiaries.

(4) This rule supersedes all other rules relating to the limitations and exclusions of drug coverage for clients with Medicare Part D.

Stat. Auth. ORS 409.010, ORS 409.050, & 414.329

Statutes Implemented: ORS 414.065

2-1-10

410-121-0150 Billing Requirements

(1) When billing the Division of Medical Assistance Programs (DMAP) for drug products, the provider must:

(a) Not bill in excess of the usual and customary charge to the general public;

(b) Indicate the National Drug Code (NDC), as it appears on the package from which the prescribed medications are dispensed;

(c) Bill the actual metric decimal quantity dispensed;

(d) When clients have other insurances, bill the other insurances as primary and DMAP as secondary;

(e) When clients have Medicare prescription drug coverage, bill Medicare as primary and DMAP as secondary.

(2) When submitting a paper claim, the provider must accurately furnish all information required on the 5.1 Universal Claims Form.

(3) The prescribing provider's National Provider Identifier (NPI) is mandatory on all fee-for-service client drug prescription claims. Claims will deny for a missing or invalid prescriber NPI. An exception to this includes, but is not limited to a Prescribing provider who does not have an NPI for billing, but who prescribes fee-for-service prescriptions for clients under prepaid health plans (PHP), long-term care, or other capitated contracts. This provider is to be identified with the:

(a) Non-billing NPIassigned for prescription writing only;

(b) Clinic or facility NPI until an individual NPI is obtained; or

(c) Supervising physician's NPI when billing for prescriptions written by the physician assistant, physician students, physician interns, or medical professionals who have prescription writing authority;

(4) Billing for Death With Dignity services:

(a) Claims for Death With Dignity services cannot be billed through the Point-of-Sale system;

(b) Services must be billed directly to DMAP, even if the client is in a PHP;

(c) Prescriptions must be billed on a 5.1 Universal Claims Form paper claim form using an NDC number. Claims should be submitted to the address indicated at the DMAP Supplemental Information for Pharmaceutical Services.

Stat. Auth.: ORS 409.050 & 414.065

Stat. Implemented: ORS 414.065

7-1-09

410-121-0155 Reimbursement

(1) Definitions. For the purposes of this rule:

(a) “Billed amount” is the usual and customary amount billed by the provider; and

(b) “Estimated Acquisition Cost” (EAC) is the lesser of:

(A) The Centers for Medicare and Medicaid Services’ (CMS) federal upper limits (FUL) for payment;

(B) The Oregon Maximum Allowable Cost (OMAC);

(C) Discounted Average Wholesale Price (AWP);

(i) For retail pharmacies: eighty-five percent of AWP of the drug;

(ii) For institutional pharmacies: eighty-nine percent of AWP for long-term care clients in a nursing facility or community based living facility; or

(iii) For contracted mail order pharmacy: seventy-nine percent of AWP for single-source drugs, thirty-two percent of AWP for multiple-source drugs and eighty percent of AWP for injectable drugs.

(c) “Applicable copayments” are defined in Oregon Administrative Rule (OAR) 410-120-1230.

(2) The Division of Medical Assistance Programs (DMAP) will revise its EAC file weekly. Pharmacies must make available to DMAP any information necessary to determine the pharmacy’s actual acquisition cost of drug products dispensed to DMAP clients.

(3) Payment for covered fee-for-service drug products will be the lesser of the billed amount or the EAC of the generic form, minus applicable copayments, plus a professional dispensing fee.

(4) Payment for trade name forms of multiple source products:

(a) Will be the lesser of the billed amount or the Discounted AWP of the trade name form, minus applicable copayments, plus a professional dispensing fee;

(b) DMAP will only pay if the prescribing practitioner has received a prior authorization for the trade name drug.

(6) No professional dispensing fee is allowed for dispensing pill splitters/cutters.

(7) Payment for pill splitters/cutters with a National Drug Code (NDC) number will be the lesser of the billed amount or the EAC.

(a) A practitioner prescription is not required.

(b) DMAP will only pay for one pill splitter/cutter per client in a twelve-month period.

Stat. Auth.: ORS 184.750, 184.770, 409.050 & 414.065

Stat. Implemented ORS 414.065

2-1-10

410-121-0157 Participation in the Medicaid Drug Rebate Program

(1) The Oregon Medicaid Pharmaceutical Services Program is a participant in the Centers for Medicare and Medicaid Services (CMS) Medicaid Drug Rebate Program, created by the Omnibus Budget Reconciliation Act (OBRA) of 1990. The Medicaid Drug Rebate Program requires a drug manufacturer to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services for States to receive federal funding for outpatient drugs dispensed to Medicaid patients. The drug rebate program is administered by CMS's Center for Medicaid and State Operations (CMSO). Pharmaceutical companies participating in this program have signed agreements with CMS to provide rebates to the Division of Medical Assistance Programs (DMAP) on all their drug products. DMAP will reimburse providers only for outpatient drug products manufactured or labeled by companies participating in this program.

(2) Documents in rule by reference: Names and Labeler Code numbers for participants in the Medicaid Drug Rebate Program are the responsibility of and maintained by CMS. DMAP receives this information from CMS in the form of numbered and dated Releases. DMAP includes in rule by reference, the following CMS Releases and subsequent DMAP Master Pharmaceutical Manufacturer's Rebate Lists: Release # 141, dated May 4, 2006; Release # 142, dated July 3, 2006, and Lists updated July 12, 2006; Release # 143, dated August 23, 2006, and Lists updated August 29, 2006; Release #144, dated December 15, 2006; Release #145, dated March 7, 2007; Release #146, dated June 26, 2007; Release #147, dated August 15, 2007;Release #148, dated January 28, 2008; and Release #149, dated May 6, 2008. All CMS Releases are available on the Department of Human Services' website:
www.dhs.state.or.us/policy/healthplan/guides/pharmacy/main.html CMS Releases Drug Product Data and Drug Company Contact information are available at:
www.cms.hhs.gov/MedicaidDrugRebateProgram/02_StateReleases.asp

(3) Retroactive effective dates: The CMS Medicaid Drug Rebate Program experiences frequent changes in participation and often this information is submitted to DMAP after the effective date(s) of some changes. Therefore, certain participant additions and deletions may be effective retroactively. See specific instructions in the CMS Releases for appropriate effective date(s) of changes.

(4) DMAP contracts with a Pharmacy Benefit Manager (PBM) to manage the Medicaid Rebate Dispute Resolution program. Pharmacy providers must verify the accuracy of their Medicaid pharmacy claims with the PBM within 30 days of request in instances where drug manufacturers dispute their claim information. Verification can be photocopies of drug invoices showing that the billed products were in stock during the time of the date of service.

(5) The actual National Drug Code (NDC) dispensed and the actual metric decimal quantity dispensed, must be billed.

Stat. Auth.: ORS 409.050 & 414.065

Stats. Implemented: ORS 414.065

12-1-08

410-121-0160 Dispensing Fees

Unless otherwise provided, the professional dispensing fee allowable for services is as follows:

(a) $3.50 -- Retail Pharmacies.

(b) $3.91 -- Institutional Pharmacies that are enrolled with DMAP as an institutional pharmacy by sending a copy of its institutional pharmacy license with its provider application.

(c) $7.50 – Compound prescriptions with two or more ingredients.

Stat. Auth.: ORS 414.065

Stat. Implemented: ORS 414.065

2-1-10

410-121-0185 Pharmacy Based Immunization Delivery

(1) A pharmacist may administer vaccines to persons who are over the age of eighteen and may administer as provided pursuant to ORS 689.205 and The Board of Pharmacy Administrative rule 855-019-0270.

(2) For Medicaid recipients age 0-18, vaccination serums are free under the federal Vaccinations for Children (VFC) Program and providers must be enrolled in the VFC program. DMAP will not reimburse the providers the cost of a privately purchased vaccination.

(3) Providers use either the CMS-1500 or the Point Of Sale claims processing system to bill for the administration of immunization:

(a) When using the CMS-1500 billing form:

(A) Use the appropriate CPT-code (90471 and 90472) for the administration plus the appropriate immunization code(s) 90476-90749:

(B) An ICD-9 diagnosis must be shown in field 21 of the CMS-1500, and;

(C) The diagnosis code must be shown to the highest degree of specificity.

(b) Providers using the Point-of-Sale system, use the National Drug Code (NDC), as it appears on the package from which the prescribed medications are dispensed. The administration fee for this service will be equivalent to those under 90471–90472.

Stat. Auth.: ORS 409.010, 409.025, 409.040, 409.050, 409.110 & 414.065

Stats. Implemented: ORS 414.065

1-1-09

410-121-0190 Clozapine Therapy

(1) Clozapine is covered only for the treatment of clients who have failed therapy with at least two anti-psychotic medications. Clozapine Supervision is the management and record keeping of clozapine dispensings as required by the manufacturer of clozapine.

(2) Clozapine supervision:

(a) Pharmacists are to bill for Clozapine Supervision by using code 90862, adding TC modifier.

(b) Providers billing for clozapine supervision must document all of the following:

(A) Exact date and results of White Blood Counts (WBCs), upon initiation of therapy and at recommended intervals per the drug labeling;

(B) Notations of current dosage and change in dosage;

(C) Evidence of an evaluation at intervals recommended per the drug labeling requirements approved by the FDA;

(D) Dates provider sent required information to manufacturer.

(E) Only one provider, either pharmacist or physician, may bill per week per client;

(F) Limited to five units per 30 days per client;

(G) An ICD-9 diagnosis must be shown on the CMS-1500 or 837P. The diagnosis code must be shown to the 5th digit on the CMS-1500, DMAP 505, or the 837P.

(3) Drug Products -- The information required on the 5.1 Universal Claim Form must be included in the billing. The actual drug product may be billed electronically or submitted on the 5.1 Universal Claim Form;

(4) Venipuncture -- If the pharmacy performs venipuncture, bill for that procedure on a CMS-1500 or 837P. Use Procedure Code36415.

Stat. Auth.: ORS 409.010 & 414.065

Stat. Implemented: ORS 414.065

2-1-10

410-121-0200 Billing Forms

(1) Prescription Drug Invoice 5.1 Universal Claim Form:

(a) This form is used to bill for all pharmacy services, except durable medical equipment and home enteral/parenteral nutrition and IV services identified with a five-digit HCPCS codes in the Home Enteral/Parenteral Nutrition and IV Services Administrative Rules (OAR 410 Division 148);

(b) The provider may bill on the form when a valid DHS Medical Care Identification has been presented (Refer to OAR 410-120-1140 Verification of Eligibility).

(c) All completed 5.1 Universal Claim Forms should be mailed to the Division of Medical Assistance Programs (DMAP)

(2) All durable medical equipment and certain enteral/parenteral nutrition and IV services must be billed on the CMS-1500, using the billing instructions found in the DMAP Durable Medical Equipment and Medical Supplies Administrative Rules and Supplemental Information, and the DMAP Home Enteral/Parenteral Nutrition and IV Services Administrative Rules and Supplemental Information.

Stat. Auth.: ORS 409.050 & 414.065

Stats. Implemented: ORS 414.065

12-1-08

410-121-0220 Instructions for Completion of the Prescription Drug Invoice

(1) The 5.1 Universal Claim Form is the required billing form for pharmacies billing on a paper claim. Use the standard Instructions for completion of the 5.1 Universal Claim Form.

(2) Enter all applicable information for billing of prescription drug claims for clients on the Oregon Health Plan.

Stat. Auth.: ORS 409
Stats. Implemented: ORS 414.065

1-1-07

410-121-0280 Billing Quantities, Metric Quantities and Package Sizes

(1) Use the actual metric quantity dispensed when billing (up to four decimal places).

(2) Use the following units when billing products:

(a) Solid substances (e.g., powders, creams, ointments, etc.), bill per Gram.

(b) Solid substances that are reconstituted with a liquid (e.g., dry powder ampules and vials) such as antibiotic vials or piggybacks must be billed in metric quantity of one each.

(c) Tablets, capsules, suppositories, lozenges, packets; bill per each unit. Oral contraceptives are to be billed per each tablet.

(d) Injectables that are prepackaged syringe, -- (e.g., tubex, carpujects), bill per ml.

(e) Prepackaged medications and unit doses must be billed per unit (tablet or capsule). Unit dose liquids are to be billed by ml.

(f) Fractional units: Bill exact metric decimal quantities dispensed.

Stat. Auth.: ORS 414.034 & 414.065
Stat. Implemented: ORS 414.065

2-1-10

410-121-0300 CMS Federal Upper Limits for Drug Payments

(1) The Centers for Medicare and Medicaid Services (CMS) Federal Upper Limits for Drug Payments listing of multiple source drugs meets the criteria set forth in 42 CFR 447.332 and 1927(e) of the Act as amended by OBRA 1993 and the DRA 2005.

(2) Payments for multiple source drugs must not exceed, in the aggregate, payment levels determined by applying to each drug entity a reasonable dispensing fee (established by the State and specified in the State Plan), plus an amount based on the limit per unit. CMS has determined the amount based on the limit per unit to be equal to 250 percent of the Average Manufacturer's Price (AMP). CMS will post the AMP to a Website available to the public on a quarterly basis.

(3) The FUL drug listing is published in the State Medicaid Manual, Part 6, Payment for Services, Addendum A. The most current Transmittals and subsequent changes are posted to the CMS website http://www.cms.hhs.gov/Reimbursement/05_FederalUpperLimits.asp#TopOfPage.

Stat. Auth.: ORS 409.010, 409.025, 409.040, 409.050, 409.110 & 414.065
Statutes Implemented: 414.065

1-1-09

410-121-0320 Oregon Maximum Allowable Cost (OMAC)

(1) The Oregon maximum allowable cost, or the maximum amount that the Division of Medical Assistance Programs (DMAP) will reimburse for prescribed drugs, is determined by the DMAP contracted Pharmacy Benefits Manager (PBM). The PBM determines the maximum allowable cost on selected multiple-source drug designation when a bioequivalent drug product is available from at least two wholesalers serving the State of Oregon.

(2) The PBM generates and maintains all official OMAC lists and provides a copy of each list to DMAP. OMAC lists are generated monthly and each list indicates the amount, per product, that DMAP will reimburse to providers for products provided to DMAP clients during that particular month. For example: The OMAC list, January 1, 2008, includes the amounts DMAP will reimburse for products provided during the month of January 2008; the list, February 1, 2008, covers the month of February 2008, etc.

(3) DMAP includes in rule by reference the OMAC lists for January 1, 2006, February 1, 2006, March 1, 2006, April 1, 2006, May 1, 2006, June 1, 2006, July 1, 2006, August 1, 2006, September 1, 2006, October 1, 2006, November 1, 2006, and December 1, 2006.

(4) DMAP includes in rule by reference the OMAC lists for January 1, 2007, February 1, 2007, March 1, 2007, April 1, 2007, May 1, 2007, June 1, 2007, July 1,2007, August 1, 2007, September 1, 2007, October 1, 2007, November 1, 2007 and December 1, 2007.

(5) DMAP includes in rule by reference the OMAC lists for January 1 2008. February 1 2008, March 1 2008, April 1 2008, May 1 2008, June 1 2008, July 1 2008, August 1, September 1 2008, October 1 2008, November 1 2008, December 1 2008.

(6) Current OMAC lists are available for review and/or downloading on the DMAP website: www.dhs.state.or.us/policy/healthplan/guides/pharmacy/. Future lists, referenced in this rule, will be available and posted to the DMAP website upon receipt from the PBM.

(7) The OMAC list does not apply if a prescriber certifies that a single-source (brand) drug is medically necessary.

Stat. Auth.: ORS 184.750, ORS 184.770, ORS 411.300 & ORS 414.065

Stats. Implemented: ORS 414.065

12-1-08

410-121-0420 DESI Less-Than-Effective Drug List

(1) An October 23, 1981 ruling by District of Columbia Federal Court directed the Department of Health and Human Services to stop reimbursement, effective October 30, 1981, under Medicaid and Medicare Part B for all DESI less-than-effective drugs which have reached the Federal Drug Administration Notice-of-Opportunity-for-Hearing stage.

(2) In accordance with Section 1903(i) (5) of the Social Security Act, federal funds participation (FFP) is not available for drugs deemed Less Than Effective (LTE) or Identical, Related of Similar (IRS) drugs for which the Food and Drug Administration (FDA) issued a Notice of Opportunity for a Hearing (NOOH) for all labeled indications.

These drugs are also termed Drug Efficacy Study Implementation (DESI) drugs. DMAP does not reimburse for drugs designated as less than effective or drugs identical, related, or similar to a DESI drug.

(3) A current list of LTE/IRS drugs is available at http://www.cms.hhs.gov/MedicaidDrugRebateProgram/12_LTEIRSDrugs.asp The list is updated on approximately a quarterly basis by CMS after being reviewed for accuracy by the FDA.

(4) The US Food & Drug Administration (FDA) has the responsibility of determining the DESI status of a drug product.

Stat. Auth.: ORS 409.040 & 414.325

Stat. Implemented: ORS 414.065

2-1-10

410-121-0580 Oregon Medicaid and Pharmaceutical Manufacturers' Dispute Resolution Procedures

(1) Within 60 days after the end of each calendar quarter, the Division of Medical Assistance Programs (DMAP) shall report the number of units dispensed for each drug National Drug Code (NDC) for which payment was made to the manufacturer of said product. Utilization reports to manufacturers shall follow this schedule:

(a) The period from January 1 through March 31 will be Quarter 1. Quarter 1 invoices shall be due by May 30 of that same year;

(b) The period from April 1 through June 30 will be Quarter 2. Quarter 2 invoices shall be due by August 29 of that same year;

(c) The period from July 1 through September 30 will be Quarter 3. Quarter 3 invoices shall be due by November 29 of that same year;

(d) The period from October 1 through December 31 will be Quarter 4. Quarter 4 invoices shall be due by February 29 of the following year.

(2) A manufacturer must make payment within 30 days of receipt of utilization reports, i.e., rebate invoice. Using eight days as reasonable time for reports to reach the manufacturer, payment of the invoiced amount is due per the following schedule:

(a) Rebate payment for Quarter 1 shall be due by July 7 of that same year;

(b) Rebate payment for Quarter 2 shall be due by October 7 of that same year;

(c) Rebate payment for Quarter 3 shall be due by January 6 of the following year;

(d) Rebate payment for Quarter 4 shall be due by April 6 of the following year.

(3) DMAP considers any failure to make timely payment in full of the amount due to be a dispute. Timely is defined by DMAP as 38 days after the postmarked date of the invoice.

(4) If a manufacturer does not indicate in writing, by specific NDC number(s), the reason(s) for non-payment in full, a letter asking for clarification will be sent and interest will accrue as set forth in the Rebate Agreement, Section V, Dispute Resolution, beginning 38 days after the postmarked date of each invoice.

(5) Utilization/unit disputes shall be handled by a careful examination of paid claims data to determine the reasonableness of the reported units of products provided to Oregon recipients. If it is determined that the manufacturer is in error a letter notifying the manufacturer of the completed review and findings will be mailed to the manufacturer and interest will accrue as set forth in the Rebate Agreement, Section V, Dispute Resolution.

(6) If a manufacturer determines that incorrect information was sent to the Centers for Medicare and Medicaid Services (CMS), the manufacturer must still make payment in full to Oregon Medicaid for the invoiced rebate amount. Oregon Medicaid will credit the manufacturer's account through CMS's prior period adjustment process.

(7) Interest will accrue as set forth in the Rebate Agreement, Section V, Dispute Resolution, on the 31st day after a manufacturer receives information from DMAP on the number of units paid by NDC number (i.e., rebate invoice).

(8) Manufacturer requests for audit information by product and zip codes will be acknowledged by DMAP in letter form. Each letter will include a DMAP Audit Request Form and instructions to the manufacturer on how to complete the form. The letter will also include a standard explanation of the audit process.

(9) Days referred to in this process shall be considered calendar days.

(10) Efforts should be made through an informal rebate resolution process as outlined in this rule before a hearing will be scheduled. Hearings will follow OAR 410-120-0760 through 410-120-1060 and be held in Marion County, OR.

(11) Oregon Medicaid will notify CMS of all disputing manufacturers in writing.

Stat. Auth.: ORS 409.010 & ORS 409.110

Stats. Implemented: ORS 414.065

1-1-07

410-121-0625 Items Covered in the All-Inclusive Rate for Nursing Facilities

(1) The all-inclusive rate for nursing facilities includes but is not limited to various drug products and OTC items. DMAP requires that nursing facilities be billed for these items.

(2) The all-inclusive list is available for downloading in the Division of Medical Assistance Programs Web page on the Department of Human Services website.

Stat. Auth.: ORS 409.010, 409.025, 409.040, 409.050, 409.110 & 414.065
Stats. Implemented: ORS 414.065

1-1-09