DHS Oregon Department of Human Services

Division of Medical Assistance Programs

Pharmaceutical Services Program

Rulebook

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MEDICAL ASSISTANCE PROGRAMS

DIVISION 121

PHARMACEUTICAL SERVICES

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Pharmaceutical Services Program Rulebook

Update Information

for

March 1, 2011

(March 4 and 7 corrections)

The Division of Medical Assistance Programs (Division) updated OAR 410-121-0030, Table 121-0030-1 effective March 1, 2011. We made corrections to this table as follows:

March 4, 2011:

The Division removed a drug (*Abilify*) from the *Oregon Fee-for-Service Voluntary Mental Health Preferred Drug List* that was previously listed in error.

March 7, 2011:

The Division added a drug (*Avonex)* to Table 410-121-0030-1, Neurologic MS Drugs that was missed due to an oversight. We made other non-substantive, "housekeeping" corrections for clarification and formatting purposes.

To view all changes to Table 121-0030-1 effective March 1, 2011, see the Temporary rule (with revisions in red) posted to our Web page at: http://www.dhs.state.or.us/policy/healthplan/rules/temps/temp.html

Pharmaceutical Services Program Rulebook

Update Information

for

March 1, 2011

The Division of Medical Assistance Programs (Division) updated this Rulebook by amending OAR 410-121-0030 as follows:

The Division amended 410-121-0030 to remove ineligible products from the PDL (Table 121-0030-1). The failure of certain manufacturers to execute Supplemental Rebate Agreements with the State resulted in the Net Price of their drug products being above the ANP for their drug class. Consequently, the Division must immediately amend OAR 410-121-0030 to remove those drugs from the PDL that are no longer eligible for placement on the PDL under the Division's rules.

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

RB 225 0311

Other Provider Resources

DMAP has developed the following additional materials 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 billing information
- ✓ Forms
- ✓ Other helpful information not found in the rulebook

Be sure to download a copy of the Pharmaceutical Services Supplemental Information booklet at:

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

Note: DMAP revises the supplement booklet throughout the year, without notice. Check the Web page regularly for changes to this document.

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.oregon.gov/DHS/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

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http://www.oregon.gov/DHS/govdelivery.shtml

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) 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;

(b) 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);

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

(d) 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;

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

(f) 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;

(g) 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);

(h) 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;

(i) 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);

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

(k) 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;

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

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

(n) 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;

(o) 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;

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

(q) 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”;

(r) 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 specifically carved out from capitation from Fully Capitated Health Plans (FCHPs) in accordance with sections (8) through (11) of OAR 410-141-0070;

(s) 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;

(t) 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”;

(u) 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;

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

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

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

(y) Preferred Drug List (PDL): A PDL consists of prescription drugs in selected classes that the Department, 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 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;

(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) 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;

(cc) 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;

(dd) 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;

(ee) 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;

(ff) Usual and Customary Price: The amount an individual without prescription drug coverage would pay at a retail pharmacy. The usual and customary price may also be referred to as the retail price;

(gg) 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;

(hh) 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.

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

1-1-11

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 (Division) clients and receive reimbursement from the Division 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 the Division;

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

(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 the Division pharmacy billing requirements.

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

Stat. Auth.: ORS 409.050
Stats. Implemented: ORS 414.065

7-1-08

7-1-10 (Hk only)

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 shall 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 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 the Department, 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 shall identify the drug(s) in the class that the Department 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 shall include drugs in the class that are Medicaid reimbursable and 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 the Department that reduce the cost of their drug below that of the Average Net Price for the class, the Department, 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: http://www.dhs.state.or.us/policy/healthplan/guides/pharmacy/clinical.html.

(3) PMPDP PDL Selection Process:

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

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

(c) The Department shall evaluate drug classes and selected drugs for the drug classes periodically:

(A) Evaluation shall occur more frequently at the discretion of the Department 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 shall be non-preferred until the new drug has been reviewed by the HRC;

(C) The Department shall make all changes or revisions to the PDL, using the rulemaking process and shall publish the changes on the Department's Pharmaceutical Services provider rules Web page.

(4) Relative cost and best possible price determination:

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

(c) The Department shall determine the Average Net Price for each PDL drug class;

(d) The Department shall 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 their professional judgment, wishes to prescribe a physical health drug not on the PDL, they 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 shall be granted in instances:

(A) Where the prescriber in their professional judgment determines the non-preferred drug is medically appropriate after consulting with the Division or the Oregon Pharmacy Help Desk; or

(B) 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.

(7) Table 121-0030-1, PMPDP PDL (Revised, effective 3/1/11)

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

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

3-1-11(T)

Table 121-0030-1 Oregon Fee-for-Service Enforceable Physical Health Preferred Drug List
Effective March 1, 2011

System	Class	Preferred	
Allergy/Cold	Antihistamines 2nd Generation	Cetirizine HCL	Tablet
		Cetirizine HCL	Solution
		Loratadine	Tablet
		Loratadine	Solution
		Loratadine	Tab RAPDIS
Analgesics	Gout	Allopurinol	Tablet
		Probenecid-Colchicine	Tablet
Analgesics	Long-Acting Opioids	Avinza	CPMP 24HR
		Duragesic (brand only)	Patch TD72
		Methadone**	Oral Conc.
		Methadone HCL**	Tablet
		Methadone HCL**	Solution
		Methadone Intensol**	Oral Conc.
		Morphine Sulfate	Tablet SA
		Oxycontin (brand only)	Tab SR 12HR
Analgesics	NSAIDs	Diclofenac Sodium	Tablet DR
		Etodolac	Tablet
		Etodolac	Capsule
		Flurbiprofen	Tablet
		Ibuprofen	Capsule
		Ibuprofen	Tablet
		Ibuprofen	Oral Susp.
		Ibuprofen IB	Tab chew
		Indomethacin	Capsule
		Infant's Ibuprofen	Drops Susp.
		Meloxicam	Tablet
		Nabumetone	Tablet
		Naproxen	Tablet
		Naproxen	Tablet DR
		Naproxen Sodium	Tablet
		Oxaprozin	Tablet
		Piroxicam	Capsule
		Salsalate	Tablet
		Sulindac	Tablet
Analgesics	Short-Acting Opioids	Codeine Sulfate	Tablet
		Hydrocodone-Acetaminophen	Tablet
		Hydromorphone HCL	Tablet
		Morphine sulfate	Tablet
		Morphine sulfate	Solution
		Oxycodone HCL	Tablet
		Oxycodone HCL	Oral Conc.
		Oxycodone HCL	Capsule
		Oxycodone HCL	Solution
		Oxycodone-Acetaminophen	Capsule
		Oxycodone-Acetaminophen	Tablet
		Tramadol HCL	Tablet
Analgesics	Skeletal Muscle Relaxants	Carisoprodol**	
		Baclofen	
		Carisoprodol Compound**	
		Cyclobenzaprine HCL	
		Methocarbamol	
		Orphenadrine Citrate	
		Orphenadrine Compound Forte	

*Drug coverage subject to meeting clinical prior authorization criteria.
**Drug coverage subject to quantity limits.

Table 121-0030-1 Oregon Fee-for-Service Enforceable Physical Health Preferred Drug List
Effective March 1, 2011

System	Class	Preferred	
Analgesics	Skeletal Muscle Relaxants (Cont.)	Tizanidine HCL	
Analgesics	Topical	Capsaicin	Cream
Analgesics	Triptans	Axert**	Tablet
		Imitrex (brand only)**	Spray
		Imitrex (brand only)**	Pen IJ KIT
		Imitrex (brand only)**	Vial
		Maxalt**	Tablet
		Maxalt MLT**	Tab RAPDIS
		Naratriptan**	Tablet
		Sumatriptan**	Tablet
		Zomig**	Spray
Antibiotic	Amoxicillin-Clavulanate	Amox TR-Potassium Clavulanate	Tablet
		Amox TR-Potassium Clavulanate	Susp. Recon.
Antibiotic	Cephalosporin, 1st Gen	Cephalexin	Capsule
		Cephalexin	Susp. Recon.
Antibiotic	Cephalosporin, 2nd Gen	Cefaclor	Capsule
		Cefprozil	Susp. Recon.
		Cefprozil	Tablet
		Cefuroxime	Tablet
Antibiotic	Cephalosporin, 3rd Gen	Cefdinir	Capsule
		Cefdinir	Susp. Recon.
		Cefpodoxime Proxetil	Tablet
		Suprax	Tablet
		Suprax	Susp. Recon.
Antibiotic	Fluoroquinolones, Oral	Avelox	Tablet
		Avelox ABC Pack	Tablet
		Cipro	Susp. MC Recon.
		Ciprofloxacin HCL	Tablet
Antibiotic	Macrolide/Ketolide	Azithromycin	Susp. Recon.
		Azithromycin	Tablet
		Clarithromycin	Tablet
		E.E.S. 200	Susp. Recon.
		E.E.S. 400	Tablet
		Eryped 200	Susp. Recon.
		Eryped 400	Susp Recon.
		Ery-tab	Tablet DR
		Erythrocin Stearate	Tablet
		Erythromycin	Tablet
		Erythromycin	Capsule DR
		Erythromycin Ethylsuccinate	Tablet
Antibiotic	Tetracyclines, Oral	Doxycycline Hyclate	Tablet
		Doxycycline Hyclate	Capsule
		Doxycycline Monohydrate	Capsule
		Doxycycline Monohydrate	Tablet
		Minocycline HCL	Capsule
		Tetracycline HCL	Capsule
		Vibramycin	Susp. Recon.
Antifungal	Antifungal, Oral	Clotrimazole	Troche
		Fluconazole	Tablet
		Fluconazole	Susp. Recon.
		Ketoconazole	Tablet
		Nystatin	Oral Susp.

*Drug coverage subject to meeting clinical prior authorization criteria.
**Drug coverage subject to quantity limits.

Table 121-0030-1 Oregon Fee-for-Service Enforceable Physical Health Preferred Drug List
Effective March 1, 2011

System	Class	Preferred	
Antifungal	Antifungal, Oral (Cont.)	Nystatin	Tablet
Antiviral	Hepatitis B	EPIVIR HBV Viread Baraclude	
Antiviral	Hepatitis C	Pegasys*	
Antiviral	HSV, Oral	Acyclovir Acyclovir Acyclovir	Capsule Tablet Oral Susp.
Antiviral	Influenza	Amantadine Amantadine Amantadine Rimantadine HCL Tamiflu** Tamiflu**	Syrup Capsule Tablet Tablet Susp. Recon. Capsule
Cardiovascular	Anticoagulants, SQ	Fragmin Enoxaparin	
Cardiovascular	Anti-Platelet Drugs	Aggrenox Aspirin Dipyridamole Plavix	CPMP 12HR Tablet Tablet Tablet
Cardiovascular	Beta-Blockers	Acebutolol HCL Atenolol Carvedilol Labetalol HCL Metoprolol Tartrate Nadolol Propranolol HCL	Capsule Tablet Tablet Tablet Tablet Tablet Tablet
Cardiovascular	Calcium Channel Blockers - DH	Amlodipine Besylate Nicardipine HCL Nifedipine ER Nifedipine ER	Tablet Capsule Tab ER 24 Tablet SA
Cardiovascular	Calcium Channel Blockers - NDH	Diltiazem 24HR ER Diltiazem ER Diltiazem ER Diltiazem HCL Verapamil HCL Verapamil HCL Verapamil HCL	Cap.SR 24HR Capsule CR Capsule SA Tablet Cap24H PEL Tablet Tablet SA
Cardiovascular	DRIs, ACE-Is and ARBs	Benazepril Benicar Captopril Enalapril Fosinopril Lisinopril Losartan Micardis Moexipril Quinapril Ramipril Trandolapril	

*Drug coverage subject to meeting clinical prior authorization criteria.
**Drug coverage subject to quantity limits.

Table 121-0030-1 Oregon Fee-for-Service Enforceable Physical Health Preferred Drug List
Effective March 1, 2011

System	Class	Preferred	
Cardiovascular	DRIs, ACE-Is and ARBs + HCT	Benazepril-Hydrochlorothiazide	
		Benicar HCT	
		Captopril/hydrochlorothiazide	
		Enalapril-Hydrochlorothiazide	
		Fosinopril-Hydrochlorothiazide	
		Lisinopril-Hydrochlorothiazide	
		Losartan-Hydrochlorothiazide	
		Micardis HCT	
		Moexipril-Hydrochlorothiazide	
		Quinapril-Hydrochlorothiazide	
Cardiovascular	HP Statins & Combos	Lipitor	
		Simvastatin	
Cardiovascular	LMP Statins & Combos	Lovastatin	
		Pravastatin	
Dermatologic	Antifungal, Topical	Miconazole Nitrate	Cream
		Nystatin	Cream
		Nystatin	Oint.
Dermatologic	Anti-Parasite	Permethrin	Cream
		Permethrin	Liquid
		Pip butox/pyrethrins/permeth	Kit
		Piperonyl butoxide/pyrethrins	Gel
		Piperonyl butoxide/pyrethrins	Kit
		Piperonyl butoxide/pyrethrins	Liquid
		Piperonyl butoxide/pyrethrins	Shampoo
Dermatologic	Impetigo Agents	Bacitracin	Oint.
		Bacitracin Zinc	Oint.
		Bacitracin-Polymyxin	Oint.
		Gentamicin Sulfate	Cream
		Mupirocin	Oint.
		Neomy sulf/bacitrac zn/poly	Oint.
Dermatologic	Psoriasis, Topical	Anthralin*	Cream
		Calcipotriene*	Solution
		Dovone*	Cream
		Taclonex*	Oint.
Dermatologic	Steroids, Topical	Alclometasone Dipropionate	Cream
		Alclometasone Dipropionate	Oint.
		Betamethasone Dipropionate	Cream
		Betamethasone Dipropionate	Lotion
		Betamethasone Dipropionate	Oint.
		Betamethasone Valerate	Cream
		Betamethasone Valerate	Oint
		Clobetasol Propionate	Cream
		Clobetasol Propionate	Oint.
		Desonide	Cream
		Desonide	Oint.
		Fluocinolone Acetonide	Cream
		Fluocinolone Acetonide	Solution
		Fluocinonide	Cream
		Fluocinonide	Solution
		Fluocinonide/emollient	Cream
		Hydrocortisone	Cream

*Drug coverage subject to meeting clinical prior authorization criteria.
**Drug coverage subject to quantity limits.

Table 121-0030-1 Oregon Fee-for-Service Enforceable Physical Health Preferred Drug List
Effective March 1, 2011

System	Class	Preferred	
Dermatologic	Steroids, Topical (Cont.)	Hydrocortisone	Oint.
		Hydrocortisone Acetate	Cream
		Hydrocortisone Butyrate	Solution
		Triamcinolone Acetonide	Cream.
		Triamcinolone Acetonide	Oint.
Endocrine	Androgens	Androderm*	Patch TD24
		Androgel*	Gel Packet
		Testosterone Cypionate	Vial
		Testosterone Enanthate	Vial
Endocrine	Bone Metabolism Drugs	Actonel	Tablet
		Alendronate Sodium	Tablet
		Boniva	Tablet
		Fosamax	Solution
		Fosamax Plus D	Tablet
Endocrine	DM-Insulin	Lantus*	Cartridge
		Lantus	Vial
		Lantus Solostar*	Insulin Pen
		Novolin 70-30	Vial
		Novolin 70-30 Innolet*	Insulin Pen
		Novolin L	Vial
		Novolin N	Vial
		Novolin N Innolet*	Insulin Pen
		Novolin R	Vial
		Humulin R	Vial
		Humulin N	Vial
		Humulin 50-50	Vial
		Humulin 70-30	Vial
		Humulin N*	Insulin Pen
		Humulin 70-30*	Insulin Pen
Endocrine	DM-Insulin	Humalog	Vial
		Humalog 50-50	Vial
		Humalog 70-25	Vial
		Humalog*	Insulin Pen
		Humalog*	Cartridge
		Humalog 50-50*	Insulin Pen
		Humalog 70-25*	Insulin Pen
		Novolog*	Cartridge
		Novolog*	Insulin Pen
		Novolog	Vial
		Novolog Mix 70-30*	Insulin Pen
		Novolog Mix 70-30	Vial
Endocrine	DM-Oral Hypoglycemics	Glimepiride	Tablet
		Glipizide	Tablet
		Glyburide	Tablet
		Metformin HCL	Tablet
		Metformin HCL ER	Tab SR 24HR
Endocrine	DM-Thiazolidinediones	Actos	
Endocrine	Growth Hormone	Saizen*	Cartridge
		Nutropin*	Vial
		Nutropin AQ*	Cartridge
		Omnitrope*	

*Drug coverage subject to meeting clinical prior authorization criteria.
**Drug coverage subject to quantity limits.

Table 121-0030-1 Oregon Fee-for-Service Enforceable Physical Health Preferred Drug List
Effective March 1, 2011

System	Class	Preferred	
Endocrine	HRT - Estrogen, Oral	Cenestin Estradiol Estropipate Femhrt	
Endocrine	HRT - Estrogen, Topical	Alora Climara Estradiol	Patch TDSW Patch TDWK Patch TDWK
Endocrine	HRT - Estrogen, Vaginal	Estring Premarin Vagifem	
Gastrointestinal	Antiemetics, Newer	Ondansetron HCL** Ondansetron ODT** Ondansetron HCL**	Solution Tab. RAPDIS Tablet
Gastrointestinal	Digestive Enzymes	Creon Zenpep	
Gastrointestinal	H2-Antagonists	Cimetidine Cimetidine Famotidine Ranitidine HCL Ranitidine HCL Ranitidine HCL	Tablet Solution Tablet Tablet Syrup Capsule
Gastrointestinal	Inflammatory Bowel	Apriso Asacol Dipentum Mesalamine sfRowasa Sulfasalazine Sulfasalazine Dr Sulfazine Sulfazine EC	Cap SR 24HR Tablet DR Capsule Kit Enema Tablet Tablet DR Tablet Tablet DR
Gastrointestinal	PPIs	Aciphex Omeprazole Omeprazole Prilosec OTC	Tablet DR Capsule DR Tablet DR Tablet DR
Genitourinary	BPH	Doxazosin Mesylate Finasteride Tamsulosin HCL Terazosin HCL	Tablet Tablet Cap.SR 24HR Capsule
Genitourinary	Overactive Bladder Drugs	Detrol Hyomax-SR Hyoscyamine Sulfate Hyoscyamine Sulfate Hyosyne Oxybutynin Chloride Oxybutynin Chloride Oxybutynin Chloride ER Oxytrol Toviaz	Tablet Tab.SR12HR Drops Elixir Elixir Tablet Syrup Tab ER 24 Patch TDSW Tab.SR 24HR
Hematology	Colony Stimulating Factors	Neupogen Neulasta Leukine	

*Drug coverage subject to meeting clinical prior authorization criteria.
**Drug coverage subject to quantity limits.

Table 121-0030-1 Oregon Fee-for-Service Enforceable Physical Health Preferred Drug List
Effective March 1, 2011

System	Class	Preferred	
Hematology	Hematopoietic Agents	Aranesp*	Vial
		Procrit*	Vial
Immunologics	Immunosuppressants	Azathioprine	Tablet
		Cellcept	Susp. Recon.
		Cyclosporine	Capsule
		Gengraf	Solution
		Gengraf	Capsule
		Mycophenolate Mofetil	Capsule
		Mycophenolate Mofetil	Tablet
		Neoral	Capsule
		Prograf	Capsule
		Rapamune	Solution
		Rapamune	Tablet
		Sandimmune	Capsule
		Zortress	Tablet
Immunologics	Targeted Immune Modulators	Enbrel	
		Humira	
		Remicade	
Neurologic	Alzheimer's Dx	Aricept	Tablet
		Galantamine	Tablet
		Namenda	Tablet
Neurologic	Anticonvulsants	Banzel	Tablet
		Carbamazepine	Tablet
		Carbamazepine	Tab Chew
		Carbamazepine	Oral Susp.
		Carbamazepine XR	Tab.SR 12HR
		Carbatrol	CPMP 12HR
		Celontin	Capsule
		Clonazepam	Tablet
		Clonazepam	Tab RAPDIS
		Depakote Sprinkle	Cap. Sprink
		Diastat (brand only)	Kit
		Diastat Acudial (brand only)	Kit
		Dilantin	Tab chew
		Dilantin	Capsule
		Divalproex Sodium	Tablet DR
		Divalproex Sodium ER	Tab.SR 24HR
		Epitol	Tablet
		Ethosuximide	Syrup
		Ethosuximide	Capsule
		Gabapentin	Capsule
		Gabitril	Tablet
		Keppra	Solution
		Lamotrigine	Tablet
		Levetiracetam	Tablet
		Mebaral	Tablet
		Mephobarbital	Tablet
		Oxcarbazepine	Tablet
		Peganone	Tablet
		Phenobarbital	Tablet
		Phenobarbital	Elixir
		Phenytek	Capsule

*Drug coverage subject to meeting clinical prior authorization criteria.
**Drug coverage subject to quantity limits.

Table 121-0030-1 Oregon Fee-for-Service Enforceable Physical Health Preferred Drug List
Effective March 1, 2011

System	Class	Preferred	
Neurologic	Anticonvulsants (Cont.)	Phenytoin	Oral Susp.
		Phenytoin Sodium Extended	Capsule
		Primidone	Tablet
		Tegretol XR	Tab.SR 12HR
		Topiramate*	Tablet
		Trileptal	Oral Susp.
		Valproic Acid	Syrup
		Valproic Acid	Capsule
		Vimpat	Tablet
		Zonisamide	Capsule
Neurologic	MS Drugs	Avonex	
		Betaseron	
		Copaxone	
Neurologic	Parkinson's Drugs	Benztropine Mesylate	Tablet
		Carbidopa-levodopa	Tablet
		Comtan	Tablet
		Requip*	Tablet
		Ropinirole HCL*	Tablet
		Selegiline HCL	Capsule
		Stalevo	Tablet
		Trihexyphenidyl HCL	Tablet
		Trihexyphenidyl HCL	Elixir
Opthalmic	Antibiotic/Steroid	Blephamide	Drops Susp.
		Blephamide S.O.P.	Oint.
		Neomycin-Bacitracin-Poly-HC	Oint.
		Neomycin-Polymyxin-Dexameth	Drops Susp.
		Tobradex	Oint.
		Tobramycin-Dexamethasone	Drops Susp.
Opthalmic	Antibiotics	Bacitracin-Polymyxin	Oint.
		Ciprofloxacin HCL	Drops
		Erythromycin	Oint.
		Gentak	Oint.
		Gentamicin Sulfate	Drops
		Natacyn	Drops Susp.
		Neomycin-Polymyxin-Gramicidin	Drops
		Ofloxacin	Drops
		Polymyxin B Sul-Trimethoprim	Drops
		Quixin	Drops
		Sulfacetamide Sodium	Drops
		Sulfamide	Drops
		Tobramycin Sulfate	Drops
		Tobrex	Oint.
		Vigamox	Drops
		Zymar	Drops
Opthalmic	Anti-Inflammatory Drugs	Dexamethasone Sodium Phosphate	Drops
		Diclofenac Sdium	Drops
		Fluorometholone	Drops Susp.
		Flurbiprofen Sdium	Drops
		FML S.O.P.	Oint.(GM)
		Ketorolac Tomethamine	Drops
		Lotemax	Drops Susp.
		Maxidex	Drops Susp.

*Drug coverage subject to meeting clinical prior authorization criteria.
**Drug coverage subject to quantity limits.

Table 121-0030-1 Oregon Fee-for-Service Enforceable Physical Health Preferred Drug List
Effective March 1, 2011

System	Class	Preferred	
Opthalmic	Anti-Inflammatory Drugs (Cont.)	Prednisolone Acetate	Drops Susp.
Opthalmic	Glaucoma	Azopt	Drops Susp.
		Brimonidine tartrate (0.15, 0.2%)	Drops
		Combigan	Drops
		Isopto carpine	Drops
		Levobunolol HCL	Drops
		Pilocar	Drops
		Timolol Maleate	Drops
		Timolol Maleate	Sol-Gel
		Travatan	Drops
		Travatan Z	Drops
Otic	Antibiotic	Ciprodex	Drops Susp.
		Cortisporin-TC	Drops Susp.
		Neomycin-Polymyxin-HC	Drops Susp.
		Ofloxacin	Drops
Psychiatric	ADHD	Amphetamine Salt Combo**	Tablet
		Concerta**	Tab. ER 24
		Daytran**	PATCH TD24
		Dexmethylphenidate HCL**	Tablet
		Dextroamphetamine Sulfate**	Tablet
		Methylphenidate HCL**	Tablet
		Methylphenidate SR**	Tablet SA
		Ritalin LA**	CPMP 50-50
		Vyvanse**	Capsule
Psychiatric	Sedatives	Zolpidem	Tablet
Pulmonary	Anticholinergic Inhalers	Atrovent HFA	HFA AER AD
		Combivent	AER W/ADAP
		Ipratropium Bromide	Solution
		Ipratropium-Albuterol	AMPUL-NEB
		Spiriva	Cap w/dev
Pulmonary	Asthma Controllers	Accolate	Tablet
		Aerobid	AER W/ADAP
		Asmanex	AER POW BA
		Flovent Diskus	Disk w/dev
		Flovent HFA	AER W/ADAP
		Foradil	CAP W/DEV
		Pulmicort Flexhaler	AER POW BA
		Qvar	AER W/ADAP
		Serevent Diskus	Disk w/dev
		Singulair*	Tablet
		Singulair*	Tab chew
		Singulair*	Gran pack
Pulmonary	Asthma Rescue	Albuterol Sulfate	Solution
		Albuterol Sulfate	VIAL-NEB
		Maxair Autohaler	AER BR.ACT
		Proair HFA	HFA AER AD
		Proventil HFS	HFA AER AD
		Ventolin HFA	HFA AER AD
		Xopenex HFS	HFA AER AD
Pulmonary	PAH	Adcirca	Tablet
		Revatio	Tablet
		Tracleer	Tablet
Renal	Phosphate Binders	Calcium Acetate	Capsule

*Drug coverage subject to meeting clinical prior authorization criteria.
**Drug coverage subject to quantity limits.

Table 121-0030-1 Oregon Fee-for-Service Voluntary Mental Health Preferred Drug List
Effective March 1, 2011

System	Class	Preferred	
Psychiatric	Antidepressants 2nd Generation	Bupropion HCL	Tablet
		Bupropion HCL SR	Tablet SA
		Citalopram	Solution
		Citalopram HBR	Tablet
		Fluoxetine HCL	Capsule
		Fluoxetine HCL	Solution
		Fluoxetine HCL	Tablet
		Fluvoxamine Maleate	Tablet
		Lexapro	Solution
		Lexapro	Tablet
		Mirtazapine	Tablet
		Mirtazapine	Tab RAPDIS
		Paroxetine HCL	Tablet
		Sertraline HCL	Tablet
		Sertraline HCL	Oral Conc.
		Venlafaxine HCL	Tablet
Psychiatric	Antipsychotics 2nd Generation	Clozapine	Tablet
		Geodon	Capsule
		Risperidone	Tablet
		Risperidone	Solution
		Risperidone	Tab RAPDIS
		Seroquel	Tablet

410-121-0032 Supplemental Rebate Agreements

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

(2) The Division 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, the Department may include that drug on the PDL.

(6) Acceptance of the offer:

(a) The Division 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) The Division 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: ORS 414.065

1-1-10

7-1-10 (Hk only)

410-121-0033 Polypharmacy profiling

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

(2) The Division 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 Division 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. Auth.: ORS 409.120 & 414.380
Stats. Implemented: ORS 414.065

2-1-10 (Stats only)

7-1-10 (Hk only)

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 Oregon Health Plan (OHP) in a manner consistent with the Oregon Health Services Commission's Prioritized List of Health Services Prioritized List of Health Services (OAR 410-141-0480 through 410-141-0520). If the medication is for a non-covered diagnosis, the medication shall 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 (Department) 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 that the Department requires PA for this purpose are found in the OHP Fee-For-Service Pharmacy PA Criteria Guide (Pharmacy PA Criteria Guide) dated Jan. 1, 2011, incorporated in rule by reference and found on our Web page at: http://www.dhs.state.or.us/policy/healthplan/guides/pharmacy/clinical.html.

(4) The Department 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 the Department requires PA for this purpose are found in the Pharmacy PA Criteria Guide.

(5) New drugs shall be evaluated when added to the weekly upload of the First DataBank drug file:

(a) If the new drug is in a class where current PA criteria applies, all associated PA criteria shall be required at time of the drug file load;

(b) If the new drug is indicated for a condition below the funding line on the Prioritized List of Health Services, PA shall be required to ensure that the drug is prescribed for a condition funded by OHP;

(c) PA criteria for all new drugs shall be reviewed at the next quarterly DUR Board meeting.

(6) 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 DUR 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 (6)(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.

(7) PA is required for non-preferred Preferred Drug List (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 to 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.

(8) 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 the Department;

(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.

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

Stats. Implemented: 414.065

1-1-11

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 Response (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

1-1-10

7-1-10 (Hk only)

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 chapter 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 (Stats only)

7-1-10 (Hk only)

410-121-0100 Drug Use Review

(1) Drug Use Review (DUR) in Division of Medical Assistance Programs (Division) 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;

(b) Staff of the DUR Board and contractors may have access to identifying information to carry out intervention activities approved by the Division. The Division, DUR Board or contractors shall adhere to all requirements of the Health Insurance Portability and Accountability Act (HIPAA) and all Division policies relating to confidential client information.

(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 Division 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. The Division 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 Division approval.

(4) The DUR Board is a group of individuals who comprise an advisory committee to the Division:

(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 Division 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

7-1-10

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 (Division) mail order pharmacy contractor; and

(c) A specialty pharmacy.

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

(a) Prepaid Health Plan (PHP) Division 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 (Department);

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

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

(a) Providers;

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

(c) Department staff; and

(d) Department contractors.

(4) Reasons for referring a client to the Division 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 the Division identifies a client meeting the criteria in subsection (4) that is appropriate for the Pharmacy Management Program, the Division will send the client a notice that provides the following information:

(a) The Division 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 the Division'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 the Division;

(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, the Division 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 Division 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, 414.065
Stats. Implemented: ORS 414.065

1-1-10

7-1-10 (Hk only)

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

410-121-0145 Prescription Requirements

((1) Division of Medical Assistance Programs (Division) 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 Division 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) The Division 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, the Division 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 414.065, 689.225, 689.305 & 689.508
Stats. Implemented ORS 414.065

5-15-10

7-1-10 (Hk only)

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.

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

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

(a) Division 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, 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.

(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) 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).

Stat. Auth.: ORS 409.050 & 414.065
Stats. Implemented: ORS 414.065

4-1-10 (T) 7-1-10 (P)

410-121-0147 Exclusions and Limitations

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

(1) Drug products for diagnoses below the funded line on the Health Services Commission Prioritized List or an excluded service under Oregon Health Plan (OHP) coverage.

(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) Except for selected oral nutritional supplements, vitamins, and vaccines.

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

(10) DESI drugs (*see* OAR 410-121-0420).

(11) Medicare Part D covered drugs or classes of drugs for fully dual eligible clients.

(12) 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, the Division 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 & 414.065

Stats. Implemented: ORS 414.065

7-1-10

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

A pharmacy serving Division of Medical Assistance Programs 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.

(1) 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.

(2) 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.: 409.050, 404.110 & 414.065
Stats. Implemented: ORS 414.065

2-10-10 (Stats only)

7-1-10 (Hk only)

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

(1) This rule is a 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. The Division shall 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 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 the Division 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 Medicare's Point-of-Sale Solution.

(3) If all the criteria in subsection (2) are met, then the Division shall consider paying the claim or a portion of the claim, as follows:

(a) The pharmacy must contact the Department’s 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) The Division’s payment authorization shall be limited to not greater than a one-month supply; and

(d) The Division's reimbursement amount shall 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 the Division 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 & 409.050
Statutes Implemented: ORS 414.065

1-1-11

410-121-0150 Billing Requirements

(1) When billing the Division of Medical Assistance Programs (Division) 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 the Division as secondary;

(e) When clients have Medicare prescription drug coverage, bill Medicare as primary and the Division 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 NPI-assigned 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 the Division, 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 Division Supplemental Information for Pharmaceutical Services.

Stat. Auth.: ORS 409.050, 414.065
Stats. Implemented: ORS 414.065

7-1-09
7-1-10 (Hk only)

410-121-0152 Pharmacy Participation in Annual Claims and Acquisition Cost Surveys

(1) Annual Claims Volume Survey:

(a) In order to establish which tier of reimbursement for professional dispensing fees that enrolled pharmacies will receive beginning January 1, 2011 under the Division's transition to an acquisition cost based reimbursement methodology for the ingredient cost of filling prescriptions, all enrolled pharmacy providers must:

(A) Complete a claims volume survey between the period of October 22, 2010 and November 12, 2010. Enrolled pharmacies must return the completed survey to the Division or its contractor by U.S. mail or electronic mail;

(B) Submit the total number of claims processed by each individually-enrolled pharmacy outlet during the previous 12 months. This shall include the total volume of claims paid from all payer types and the total dollar amount for all claims processed during this period;

(b) Independently owned pharmacies shall be required to submit a signed letter of attestation by the store owner or majority owner with the completed survey stating that all information provided is true and accurate;

(c) Individual pharmacies that are chain affiliated, or their parent company may respond to the survey at either the individual store level or corporate office. In either case, the completed survey must be accompanied by a letter of attestation by a corporate officer stating that all information provided is true and accurate;

(d) Pharmacies that fail to respond to the survey or do not include the letter of attestation shall default to the lowest tiered dispensing fee that has been proposed by the Division, effective January 1, 2011;

(e) Pharmacies that fail to submit the completed survey and attach the letter of attestation prior to November 12, 2010 shall not be allowed to reverse and re-bill claims to receive a higher dispensing fee;

(f) Once a tier is established for a calendar year, the pharmacy's dispensing fee shall remain at that tier until the next annual claims volume survey conducted by the Division or its contractor.

(2) Actual Acquisition Cost Survey:

(a) To establish the basis for changes to be effective January 1, 2011 to the current definition of Actual Acquisition Cost as defined in 410-121-0000 (3) (a), the Division shall require all enrolled pharmacies to complete an ingredient cost survey between the dates of October 22, 2010 and November 12, 2010 and return it to the Division or its contractor;

(b) The results of the survey shall be used to establish ingredient cost reimbursement, beginning January 1, 2011. Survey information may be completed and submitted as follows:

(A) Regardless of ownership type, ingredient cost surveys may be completed at the individual store level, their parent company if applicable, or by the pharmacy's authorized wholesaler;

(B) In the event the enrolled pharmacy prefers the survey be completed by their wholesaler, the pharmacy shall be responsible for giving the wholesaler permission and authorization to provide the Division with the completed survey;

(C) If the enrolled pharmacy has their wholesaler complete the survey, it is the enrolled pharmacy's responsibility to ensure their wholesaler completes and returns the survey to the Division or its contractor;

(c) Neither the Division nor its contractor shall be responsible for ensuring that a pharmacy's wholesaler completes the survey and neither shall be responsible for facilitating communications between the pharmacy and its wholesaler for the purpose of completing the survey.

Stat. Auth: ORS 409.050, 413.042 & 414.065; OR Laws 2009, chapter 595, sections 10-23

Other Authority: ORS 291.261, Or. Laws 2009; chapter 901; OAR 943-001-0010-943-001-0015; OAR 407-043-0010

Stats. Implemented: ORS 414.065

10-18-10(T)

410-121-0155 Reimbursement

(1) The Division shall pay the lesser of the provider's usual charge to the general public for a drug or the estimated acquisition cost (EAC) plus a dispensing fee. The EAC is defined by the Division as the lesser of:

(a) The Average Actual Acquisition Cost (AAAC) of the drug;

(b) In cases where no AAAC is available, the Division will reimburse at Wholesale Acquisition Cost (WAC);

(c) The Federally Mandated Upper Limit (FUL) for certain multiple source drugs as established and published by CMS;

(d) 340B covered entities and federally qualified health centers or their contracted agents that fill Medicaid patient prescriptions with drugs purchased at the prices authorized under Section 340B of the Public Health Service Act must bill Medicaid for the actual acquisition cost.

(2) The Division shall revise its EAC file weekly. Pharmacies must make available to the Division, or its contractor, any information necessary to determine the pharmacy's actual acquisition cost of drug products dispensed to the Division's clients.

(3) The AAAC shall serve as the basis for reimbursement. Individual pharmacies are required to participate in an AAC survey conducted by the Division, or its contractor, not more than one time per every 18 to 24-month period. Pharmacies that do not respond to AAC survey requests may be subject to disenrollment as providers for the Oregon Health Plan.

(4) If a provider is unable to purchase a particular drug product at the AAAC the provider shall report this to the Division or its contractor for further review through a dispute resolution process. Providers may submit inquiries via telephone, facsimile, via electronic mail, or the contractor's secure web site:
http://or.mslc.com/RequestRateReview.aspx

(a) The Division or its contractor will respond to all inquiries or complaints with 24 hours and resolve the issue within 5 business days;

(b)The pricing dispute resolution process shall include the Division or its contractor verifying the accuracy of pricing to ensure consistency with marketplace pricing and drug availability;

(c) Price adjustments shall be made during the next weekly pricing update.

(5) 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.

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

(a) Shall be the EAC of the trade name form, minus applicable copayments, plus a professional dispensing fee;

(b) The Division shall only pay if the prescribing practitioner has received a prior authorization for the trade name drug.

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

(8) Payment for pill splitters/cutters with a National Drug Code (NDC) number shall be the lesser of the billed amount or the EAC, and:

(a) A practitioner prescription is not required;

(b) The Division shall 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
Stats. Implemented: ORS 414.065

1-1-11

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

(1 (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 (Division) on all their drug products. The Division 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. The Division receives this information from CMS in the form of numbered and dated Releases. The Division includes in rule by reference, the following CMS Releases and subsequent the Division 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 the Division 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) The Division 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

7-1-10 (Hk only)

410-121-0160 Dispensing Fees

(1) Effective January 1, 2011 professional dispensing fees allowable for services shall be based on an individual pharmacy's annual claims volume as follows:

(a) Less than 49,999 claims a year = $14.01;

(b) Between 50,000 and 69,999 claims per year = $10.14;

(c) 70,000 or more claims per year = $9.68;

(2) All Division enrolled pharmacies shall be required to complete an annual survey that collects claim volumes from enrolled pharmacies and other information from the previous 12 month period to determine the appropriate dispensing fee reimbursement:

(a) Claims volume shall be stated by total OHP covered prescriptions and claims from all payer types;

(b) Survey activities shall be conducted by either the Division or its contractor and must be completed and returned by pharmacies within 14 days of receipt;

(c) Complete surveys must be signed with a letter of attestation by:

(A) The store owner or majority owner for independent pharmacies;

(B) The Pharmacy manager and the store manager or a corporate officer for chain pharmacies.

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

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

1-1-11

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. The Division of Medical Assistance Programs (Division) will not reimburse the providers the cost of a privately purchased vaccination.

(3) Providers must 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 90470–90474.

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

Stats. Implemented: ORS 414.065

7-1-10

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 Code 36415.

Stat. Auth.: ORS 409.010 & 414.065
Stats. Implemented: ORS 414.065

2-1-10 (Stats only)

7-1-10 (Hk only)

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 the Department 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 (Division)

(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 Division's Durable Medical Equipment and Medical Supplies administrative rules and Supplemental Information, and the Division's Home Enteral/Parenteral Nutrition and IV Services Administrative rules and Supplemental Information.

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

Stat. Auth.: ORS 409.050 & 414.065
Stats. Implemented: ORS 414.065

12-1-08

7-1-10 (Hk only)

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 (Stat lines only)

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

410-121-0420 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. the Division 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
Stats. Implemented: ORS 414.065

2-1-10 (Stats only)

7-1-10 (Hk only)

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 (Division) 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) The Division considers any failure to make timely payment in full of the amount due to be a dispute. Timely is defined by the Division 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 the Division 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 the Division in letter form. Each letter will include a Division 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 & 409.110
Stats. Implemented: ORS 414.065

1-1-07

7-1-10 (Hk only)

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. The Division 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

7-1-10 (Hk only)