

# Pharmaceutical Services Program Rulebook

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**DEPARTMENT OF HUMAN SERVICES**

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**DIVISION 121**

**PHARMACEUTICAL SERVICES**

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# Pharmaceutical Services Program Rulebook

## Update Information

July 1, 2007

DMAP updated this Rulebook with the following:

- **410-121-0030:** to reflect new additions and deletions of drugs to the Plan Drug List (PDL) list.
- **410-121-0040:** to delete references to drug criteria recommended by the U.S. Food and Drug Administration.
- **410-121-0145:** to revise prescription requirements for Over-the-Counter (OTC) Plan B drugs.
- **410-121-0150:** to revise billing requirements for OTC Plan B drug products and to clarify changes in billing requirements as a result of the National Provider Identifier (NPI).

All rules listed are amended to make housekeeping corrections.

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

## Other Provider Resources

DMAP has developed the following additional materials to help you bill accurately and receive timely payment for your services.

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### ■ 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](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](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**

(1) The Pharmaceutical Services Oregon Administrative Rules are designed to assist providers in preparing claims for services provided to Division of Medical Assistance Programs (DMAP) fee-for-service clients. The Pharmaceutical OARs must be used in conjunction with the General Rules for Oregon Medical Assistance Programs (OAR 410 Division 120).

(2) Pharmaceutical services delivered through managed care plans contracted with DMAP, under the Oregon Health Plan, are subject to the policies and procedures established in the Oregon Health Plan Administrative Rules (OAR 410 Division 141) and by the specific managed health care plans.

(3) DMAP endeavors to furnish medical providers with up-to-date billing, procedural information, and guidelines to keep pace with program changes and governmental requirements.

(4) Administrative rules and billing guidelines for Home Enteral/Parenteral Nutrition and IV services are included in OAR 410 Division 148. Administrative rules and billing guidelines for Durable Medical Equipment are included in OAR 410 Division 122.

(5) All DMAP rules are available on the Department of Human Services website.

Stat. Auth.: ORS 184

Stats. Implemented: ORS 414.065

1-1-07

## **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 414.324(6), may provide drug prescription services for fee-for-service Division of Medical Assistance Programs (DMAP) clients and receive reimbursement from DMAP by complying with all the following requirements:

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

(b) Meet all current licensing and regulatory requirements;

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

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

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

(f) Comply with DMAP pharmacy billing requirements.

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

Statutory Authority: Chapter 409

Statutes Implemented: ORS 414.065

1-1-07

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

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

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

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

(2) PMPDP Plan Drug List (PDL):

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

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

(c) For each selected drug class, the PDL will identify a drug(s) as the benchmark drug that DHS determines to be the most effective drug(s) available for the best possible price;

(d) The PDL will include other drugs in the class that are Medicaid reimbursable and which the Food and Drug Administration (FDA) has determined to be safe and effective if the relative cost is less than the benchmark drug(s). If pharmaceutical manufacturers enter into supplemental discount agreements with DHS that reduce the cost of their drug below that of the benchmark drug for the class, DHS will include their drug in the PDL;

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

(3) PMPDP PDL Selection Process:

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

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

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

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

(B) DHS will not add new drugs to the PDL until they have been reviewed by the HRC;

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

(4) Relative cost and best possible price determination:

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

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

(c) DHS will determine the benchmark drug based on (4)(b) and on the Estimated Acquisition Cost (EAC) on the first of the month (OAR 410-121-0155) in which DHS reviews that specific drug class;

(d) Once the cost of the benchmark drug is determined, DHS will recalculate the cost of the other FDA-approved drugs in the class using the EAC in effect for retail pharmacies on the first of the month in which DHS reviews that specific drug class less average available

rebate. DHS will include drugs with prices under the benchmark drug cost on the PDL.

(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.

Table 121-0030-1, PMPDP PDL.

Stat. Auth.: ORS Chap. 409

Stats. Implemented: 414.06

07-01-07

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

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

### **Plan Drug List (PDL)**

Note: (\*\*) This drug represents the benchmark drug for the class.

#### **ALZHEIMER'S DRUGS:**

- (\*\*)Aricept
- Namenda

#### **ANGIOTENSIN-CONVERTING ENZYME (ACE) INHIBITORS:**

- (\*\*)Enalapril (generic)
- Benzepiril (generic)
- Benzepiril-HCTZ (generic)
- Captopril (generic)
- Captopril-HCTZ (generic)
- Enalapril-HCTZ (generic)
- Lisinopril (generic)
- Lisinopril-HCTZ (generic)

#### **ANGIOTENSIN II RECEPTOR ANTAGONISTS (AIIRA):**

- (\*\*)Cozaar
- Avalide
- Avapro
- Atacand
- Atacand HCT
- Benicar
- Benicar HCT
- Diovan

- Diovan HCT
- Hyzaar
- Micardis
- Micardis HCT

### **BETA-BLOCKERS:**

- (\*\*) Metoprolol Succinate
- Acebutolol (generic)
- Atenolol (generic)
- Labetolol (generic)
- Metoprolol tartrate (generic)
- Nadolol (generic)
- Pindolol (generic)
- Propranolol (generic)

### **CALCIUM CHANNEL BLOCKERS:**

#### Dihydropyridines:

- (\*\*) Amlodipine (generic)
- Nicardipine (generic)
- Nifedipine (generic)
- Sular

#### Non-Dihydropyridines:

- (\*\*) Verapamil Sustained Action tablets (AB generic for Isoptin SR)
- Diltiazem IR (generic)
- Verapamil IR (generic)

### **ESTROGENS:**

#### Oral Products

- (\*\*) Estradiol (generic)

#### Transdermal Products

- (\*\*) Estradiol patch (generic)
- Alora
- Climara Pro
- Estraderm
- Menostar
- Vivelle, Vivelle-Dot

## Vaginal Products

(\*\*) Vagifem

- Estring
- Premarin

## **HYPOGLYCEMICS, ORAL:**

- (\*\*) Glyburide (generic)
- Glimepiride (generic)
- Glipizide (generic)

## **INHALED CORTICOSTEROIDS:**

### Low/Medium Potency

(\*\*) QVAR

- Aerobid, Aerobid-M
- Azmacort

### High Potency

(\*\*) Asmanex

- Flovent
- For Children <8 and unable to use inhaler: Pulmicort Respules

## **NEWER ANTIEMETICS**

- (\*\*) Ondansetron (generic)
- Emend (add-on therapy only)

## **NON-SEDATING ANTIHISTAMINES:**

(\*\*) Loratadine (generic)

## **NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAID):**

- (\*\*) Diclofenac sodium (generic)
- Ibuprofen (generic)
- Indomethacin (generic)
- Flurbiprofen (generic)
- Ketoprofen (generic)
- Meloxicam (generic)
- Naproxen (generic)

- Naproxen sodium (generic)
- Piroxicam (generic)

### **OPIOIDS, LONG-ACTING:**

- (\*\*) LA-Morphine Sulfate (generic)
  - Kadian
- Levorphanol (generic)
- Methadone HCL (generic)
- Oramorph SR

### **OVERACTIVE BLADDER DRUGS:**

(\*\*) Oxybutynin (tablets and syrup)

### **PROTON PUMP INHIBITORS:**

- (\*\*) Prilosec OTC
- Zegerid Packets

### **SKELETAL MUSCLE RELAXANTS:**

Antispasmodics for chronic neurological conditions:

- (\*\*) Baclofen (generic)
- Tizanidine

Acute/chronic musculoskeletal spasms:

(\*\*) Cyclobenzaprine (generic)

### **STATINS (CHOLESTEROL-LOWERING MEDICATIONS):**

Low/Medium Potency:

- (\*\*) Lovastatin (generic)
- Pravastatin (generic)

High Potency:

- Simvastatin (generic)

## **TRIPTAN DRUGS:**

(\*\*) Relpax

- Amerge
- Axert
- Imitrex
- Maxalt, Maxalt MLT
- Zomig, Zomig ZMT

### Nasal:

(\*\*) Zomig

- Imitrex

### Subcutaneous:

(\*\*) Imitrex

## **THIAZOLIDEDINES:**

(\*\*) Avandia

- Actos

## **410-121-0032 Supplemental Rebate Agreements**

(1) Supplemental Rebate Agreements are negotiated for specific drug products between the Division of Medical Assistance Programs (DMAP) and pharmaceutical manufacturers. Manufacturers may submit Supplemental Rebate offers for consideration to include their drug(s) on the Practitioner's-Managed Prescription Drug Plan (PMPDP) Plan Drug List (PDL), OAR 410-121-0030:

(a) Manufacturers must submit Supplemental Rebate Agreements on the agreement template approved by the Centers for Medicare and Medicaid Services (CMS). This template is available on the Department of Human Services Web site;

(b) "Supplemental Rebates" are DMAP and CMS approved discounts paid by manufacturers per unit of drug. These rebates are authorized by the Social Security Act section 42 USC 1396r-8(a)(1) and are in addition to federal rebates mandated by the Omnibus Budget Reconciliation Act (OBRA 90) and the federal rebate program;

(c) "Net Price" is the ingredient reimbursement amount minus the CMS Basic Rebate and CMS Consumer Price Index (CPI) Rebate minus the Supplemental Rebate;

(d) "CMS Basic Rebate" is the quarterly payment by a manufacturer pursuant to the manufacturer's CMS Medicaid Drug Rebate Agreement made in accordance with the Social Security Act, section 1927(c)(3), 42 USC 1396r-8 (c)(1), and 42 USC 1396r-8 (c)(3);

(e) "CMS CPI Rebate" is the quarterly payment by the manufacturer pursuant to the manufacturer's CMS Medicaid Drug Rebate Agreement, made in accordance with 42 USC 1396r-8 (c)

(2) Manufacturers may offer Supplemental Rebates by submitting the completed template to DMAP:

(a) Manufacturers will be allowed to submit Supplemental Rebate offers for drugs recommended for inclusion on the PDL by the Health Resources Commission;

(b) Drugs will be considered for addition to the appropriate PDL class when the Net Price is equal to or less than the benchmark drug estimated acquisition cost as determined in OAR 410-121-0030

(3) Manufacturers may submit a Supplemental Rebate Agreement offer by:

(a) Obtaining the CMS-approved template from the DHS website, and;

(b) Submitting the completed Supplemental Rebate Agreement with attachment B listing the drugs offered to DMAP. The manufacturers may submit up to three separate attachment B drug lists with the Supplemental Rebate Agreement offer.

(4) Acceptance of the offer:

(a) DMAP will notify the manufacturer of the acceptance of the offer(s);

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

Statutory Authority: ORS Chapter 409

Stats. Implemented: 414.065

1-1-07

### **410-121-0033 Polypharmacy profiling**

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

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

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

(a) Overuse of selected drug classes;

(b) Under-use of generic drugs;

(c) Therapeutic drug duplication;

(d) Drug to disease interactions;

(e) Drug to drug interactions;

(f) Inappropriate drug dosage;

(g) Drug selection for age;

(h) Duration of treatment;

(i) Clinical abuse or misuse.

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

Stat. Authority: ORS Chap. 409

Stats. Implemented: 414.065

1-1-07

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

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

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

(a) Each drug must be prescribed for conditions funded by OHP in a manner consistent with the Prioritized List of Health Services and its corresponding treatment guidelines, included within the client's benefit package of covered services, and not otherwise excluded or limited.

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

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

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

(5) PA is required for brand name drugs that have two or more generically equivalent products available. Criteria for approval are:

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

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

(6) PA will not be required:

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

(b) For over-the-counter (OTC) covered rugs when prescribed for conditions covered under OHP.

(7) Psychotropic prescriptions for children under the age of six cannot be processed when a default 999999 provider number has been entered. If such a default provider number is used, the drug may not be dispensed until PA has been obtained. The PA process will include providing the correct provider number.

Table 121-0040-1

Table 121-004-2

State Auth.: ORS Chap. 409  
Stats. Implemented: 414.065

7-1-07

**Table 121-0040-1**

Drugs Requiring Prior Authorization for Covered Diagnosis

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

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

Antihistamines, Selected	acrivas/pseudoephedrine certrizine certrizine/pseudoephedrine desloratadine fexofendadine fexofendadine/pseudoephedrine loratadine loratidine/pseudoephedrine	Semprex-D Zyrtec Zyrtec-D Clarinet Allegra Allegra-D Claritin Claritin-D	Allergic rhinitis is not a covered diagnosis unless it is complicated with other diagnoses (e.g. periorbital inflammation or other ocular complications; chronic sinusitis with 3 more episodes during past 12 months; sinus surgery, or frequent sinus procedures). Use must meet recommendations in Table 2.
Antiviral, Topical	acyclovir docosanol peniclovir	Zovirax Abreva Denavir	HSV infections are covered when complicated by an immunocompromised host.
Benign Prostatic Hypertrophy Drugs	alfuzosin dutasteride finasteride tamsulosin	Uroxatral Avodart Proscar Flomax	Treatment of enlarged prostate is not covered unless complicated by obstruction. The cosmetic use of these drugs for baldness is not covered.
Brand Drugs, Multi-Source	Various	Various	A covered diagnosis is required for use of a brand product when a generic is available.
Carisoprodol drugs	carisoprodol and all combination products	Soma, Soma Compound, various others	Any above the line diagnosis will be approved within dosing recommendations in Table 2.

Dronabinol	dronabinol	Marinol	Any covered diagnosis meeting the recommendations in Table 2 will be approved.
Gabapentin	gabapentin	Neurontin	Any covered diagnosis meeting the recommendations in Table 2 will be approved.
Growth Hormones	somatrem somatropin	Protropin Genotropin Humatrope Norditropin Nurotropin Nurotropin AQ Nurotropin Depot Saizen Serostim	Any covered diagnosis meeting recommendations in Table 2 will be approved.
Ketoralac	ketoralac	Toradol	Any covered diagnosis will be approved within the dosing recommendations in Table 2.
Laxative, selected	polyethylene glycol	Miralax	Any covered diagnosis will be approved.
Leukotriene receptor antagonists	montelukast	Singular	Allergic rhinitis is not a covered diagnosis unless it is complicated with other diagnoses (e.g. periorbital inflammation or other ocular complications; chronic sinusitis with 3 more episodes during past 12 months; sinus surgery, or frequent sinus procedures). Asthma is a covered diagnosis.

Nasal Inhalers	azelastine cromolyn beclomethasone budesonide flunisolide fluticasone mometasone triamcinolone	Astelin Nasal crom RA Beconase Rhinocort Nasalide Flonase Nasonex Nasacort	Allergic rhinitis is not a covered diagnosis unless it is complicated with other diagnoses (e.g. periorbital inflammation or other ocular complications; chronic sinusitis with 3 more episodes during past 12 months; sinus surgery, or frequent sinus procedures).
Nutritional Support, Enteral or oral	Nutritional bars, liquids, packets, powders, & wafers, and various others	Ensure, Ensure Plus, Nephro, Pediasure, Promod and various others	Diagnosis being treated must be a covered diagnosis and fall within the recommendations in Table 2.
Opioid Drugs, combination products (aka narcotics)	codeine/acetaminophen hydrocodone/acetaminophen dihydrocodone/acetaminophen/ caffeine oxycodone/acetaminophen propoxyphene/acetaminophen pentazocine/acetaminophen codeine/aspirin codeine/aspirin/caffeine oxycodone/aspirin pentazocine/aspirin propoxyphene/aspirin/caffeine various others	Tylenol with Codeine Vicodin, Lortab DHC Plus  Percocet Darvocet-N-100 Talacen Empirin with Codeine Fiorinal with Codeine Percodan Talwin Compound Darvon Compound Various others	Any covered pain diagnosis that is appropriate will be approved within dose recommendations in Table 2.
Oxycodone Extended Action	Oxycodone	OxyContin	Doses above 120mg/day require a prior authorization to insure the diagnosis is covered.

Psoriasis Drugs	alefacept efalizumab methoxsalen trioxsalen isotretinoin acitretin antralin tazarotene calcipotriene coal tar	Amevive Raptiva Psoralen, 8-MOP Trisoralen Accutane, Sotret Soriatane Psoriatec, Drithocrema Tazorac Dovonex Various	Only Stage III, IV psoriasis and psoriatic arthritis are covered. Stages I and II are not.  Other, non-experimental, covered diagnoses will be approved.
Sedatives	estazolam eszopiclone flurazepam quazepam ramelteon temazepam triazolam zaleplon zolpidem	Prosom Lunesta Dalmane Doral Rozerem Restoril Halcion Sonata Ambien	Chronic insomnia is not a covered diagnoses. Sleep disorders contributing to covered diagnoses (e.g. sleep apnea, bipolar affective disorder, depression, etc.) will be approved.
Stimulants	dextroamphetamine methamphetamine mixed amphetamines dexmethylphenidate methylphenidate	Dexedrine, Dextristat Desoxyn Adderall, Adderall XR Focalin Methylin, Metadate, Ritalin	Obesity is not a covered diagnoses. Use for ADHD, Narcolepsy and other covered diagnoses will be approved within the doses recommended in Table 2.
Testosterone, Topical	testosterone	Testoderm Androgel Androgem DHEA	Will be approved for covered diagnoses (e.g. Primary hypogonadism, Hypogonadotropic hypogonadism, AIDS related cachexia)
Weight Loss Drugs	orlistat sibutramine phentermine	Xenical Meridia Fastin	Obesity treatment is not a covered diagnosis. Only diagnoses that are covered will be approved.

**Table 121-0040-2**

## Drugs Requiring Prior Authorization for Medically Appropriate Use

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

<b>Drug Class</b>	<b>Drug Generic</b> (list is subject to market fluctuations)	<b>Drug Brand</b> (list is subject to market fluctuations)	<b>Use Criteria</b>
Actiq	Fentanyl	Actiq	Use restricted to the state adopted DUR Board recommendations on May 12, 2005.
Anti-emetics, selected	dolasteron granisetron ondansetron aprepitant	Anzemet Kytril Zofran Emend	Chronic use (>3 days/week) is restricted to indications that are supported by the medical evidence (e.g. nausea associated with chemotherapy)
Antihistamines, Selected	acrivas/pseudoephedrine certirzine certirzine/pseudoephedrine desloratadine fexofendadine fexofendadine/pseudoephedrine loratadine loratidine/pseudoephedrine	Semprex-D Zyrtec Zyrtec-D Clarinx Allegra Allegra-D Claritin Claritin-D	Use is restricted to covered diagnoses and therapy is recommended to include an asthma controller drug. Duplication with similar products (i.e. nasal inhalers) is not recommended.
Becaplermin	Becaplermin	Regranex	Use restricted to diabetic neuropathic ulcers.
Carisoprodol drugs	carisoprodol and all combination products	Soma, Soma Compound, various others	Carisoprodol is restricted to short-term use (56 tablets / 90days)

Dronabinol	dronabinol	Marinol	Dronabinol use is restricted to indications where the medical evidence supports its use (e.g. nausea associated with chemotherapy or cachexia)
Gabapentin	gabapentin	Neurontin	Gabapentin use is restricted to indications where the medical evidence supports its use (e.g. diabetic neuropathy, epilepsy, post-herpetic neuralgia).
Growth Hormones	somatrem somatropin	Protropin Genotropin Humatrope Norditropin Nurotropin Nurotropin AQ Nurotropin Depot Saizen Serostim	Growth hormone use is restricted to indications of documented hormone deficiency. Serostim may be approved for AIDS wasting within approved parameters.
Hepatitis C Drugs	Pegylated Interferon Ribavirin/Interferon A-2B Ribavirin	Peg-Intron Pegasys Rebetron Rebetol	Restricted to patient selection criteria the state adopted from DUR Board recommendations on May 25, 2004.
Ketoralac	ketoralac	Toradol	Ketoralac is restricted to short-term use (5 days every 60 days)
Leukotriene receptor antagonists	montelukast	Singular	Duplication with similar products (i.e. nasal inhalers, antihistamines) is not recommended. It is not indicated for

			COPD and other respiratory disorders without an asthma component.
Migraine Drugs (aka Triptans)	almotriptan eletriptan frovatriptan naratriptan rizatriptan sumatriptan zolmitriptan	Axert Relpax Frova Amerge Maxalt, Maxalt MLT Imitrex Zomig, Zomig ZMT	Monthly quantity limits are enforced based upon the state adopted DUR Board recommendations on May 31, 2005.
Nasal Inhalers	azelastine cromolyn beclomethasone budesonide flunisolide fluticasone mometasone triamcinolone	Astelin Nasalcrom RA Beconase Rhinocort Nasalide Flonase Nasonex Nasacort	Use is restricted to covered diagnoses and therapy is also recommended to include an asthma controller drug. Duplication with similar products (i.e. antihistamines) is not recommended.
Nutritional Support, Enteral or oral	Nutritional bars, liquids, packets, powders, & wafers, and various others	Ensure, Ensure Plus, Nephro, Pediasure, Promod and various others	These products are restricted to patients unable to take food orally in sufficient quantity to maintain adequate weight. Requires annual nutritional assessment to assess continued need.
Opioid Drugs, combination products (aka narcotics)	codeine/acetaminophen hydrocodone/acetaminophen dihydrocodone/acetaminophen n/caffeine oxycodone/acetaminophen propoxyphene/acetaminophen pentazocine/acetaminophen codeine/aspirin	Tylenol with Codeine Vicodin, Lortab DHC Plus  Percocet Darvocet-N-100 Talacen Empirin with Codeine Fiorinal with Codeine Percocet	Monthly quantity limits are enforced for acetaminophen or aspirin levels in these medications that the state adopted from DUR Board recommendations on May 1, 2003.

	codeine/aspirin/caffeine oxycodone/aspirin pentazocine/aspirin propoxyphene/aspirin/caffeine various others	Talwin Compound Darvon Compound Various others	
Polypharmacy	Various	Various	See: 410-121-0033
Proton Pump Inhibitors	esomeprazole lansoprazole lansoprazole w/naproxen omeprazole pantoprazole rabeprazole	Nexium Prevacid NaproPAC Prilosec Protonix Aciphex	PPI therapy beyond 8 weeks requires prior authorization. Chronic use is restricted to those who have failed H2-antagonist therapy or those with severe disease (e.g. Barrett's, ZE, etc.)
Sedatives	estazolam flurazepam quazepam temazepam triazolam	Prosom Dalmane Doral Restoril Halcion	Quantities are restricted to 15 doses/30days unless a covered diagnosis is provided.
Stimulants	dextroamphetamine methamphetamine mixed amphetamines dexmethylphenidate methylphenidate	Dexedrine, Dextristat Desoxyn Adderall, Adderall XR Focalin Methylin, Metadate, Ritalin	Doses greater than the recommended doses the state adopted from DUR Board recommendations on November 15, 2005 require prior authorization.

## **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 call the Managed Access Program (MAP) Help Desk to request the PA. The PA request may also be transmitted to the MAP Help Desk by FAX using the request form shown in the Pharmaceutical Services Supplemental Information on the Department of Human Services website.

(2) PA approval:

(a) If the PA request is approved, the MAP Help Desk will notify the pharmacy when the dispensing pharmacy information will be available.

(A) PA approvals are given for a specific date of service and for specific NDC numbers or products.

(B) PA approvals do not guarantee eligibility or reimbursement.

(b) It is the pharmacist'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.

(c) The pharmacy 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..

(d) 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. There is no need for a PA number.

(3) If the PA request has been denied, the MAP Help Desk will notify the pharmacy when the dispensing pharmacy information will be available.

(4) Emergency Need: The Pharmacist may request an emergent or urgent dispensing from First Health 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

Stats. Implemented: ORS 414.065

1-1-07

## **410-121-0061 Durable Medical Equipment and Medical Supplies**

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

Stat. Auth.: ORS 409

Stats. Implemented: ORS 414.065

1-1-07

## **410-121-0100 Drug Use Review**

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

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

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

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

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

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

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

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

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

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

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

(a) The criteria used in retrospective DUR are compatible with those used in prospective DUR. The drug therapy review is carried out by a panel of physicians and pharmacists who are licensed in Oregon and appointed by the DMAP Director. Members of this panel are referred to as council members.

(b) If therapy problems are identified by the Retrospective DUR Council, an educational letter is mailed to the prescribing provider, the dispensing provider, or both. Other forms of education are carried out under this program with DMAP approval.

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

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

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

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

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

(D) Medical quality assurance.

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

(A) Four practicing pharmacists;

(B) Five practicing physicians;

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

(D) One person actively practicing dentistry.

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

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

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

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

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

(e) Members of the DUR Board receive no compensation for their services, but subject to any applicable state law, shall be allowed actual and necessary travel expenses incurred in the performance of their duties.

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

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

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

(A) American Hospital Formulary Services Drug Information;

(B) US Pharmacopeia-Drug Information;

(C) American Medical Association Drug Evaluations;

(D) Peer-reviewed medical literature; or

(E) Drug DEX.

(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) The nature and scope of the DUR Board and the activities carried out by the DUR Board, including:

(i) A description of how pharmacies without computers 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 409

Stats. Implemented: ORS 414.065

1-1-07

## **410-121-0135 Pharmacy Management Program Requirements**

(1) The Pharmacy Management Program requires most fee-for-service clients to be enrolled in one pharmacy to receive their prescription drugs.

(2) The name and phone number of the pharmacy the client is required to use will be on the OMAP Medical Care ID. OMAP will only reimburse the pharmacy listed on the OMAP Medical Care ID.

(3) When no pharmacy is listed on the OMAP Medical Care ID, the client may have their prescriptions filled by any pharmacy that has a Division of Medical Assistance Programs (DMAP) provider number.

(4) Enrollment of an Oregon Health Plan (OHP) Client in a Pharmacy Management Program pharmacy shall be mandatory unless the OHP Client:

(a) Is a Prepaid Health Plan (PHP) DMAP member;

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

(c) Is an American Indian or Alaska Native with proof of Indian heritage;

(d) Is a child in the care and custody of the Department of Human Services;

(e) Is an inpatient or resident in a hospital, nursing facility, or other medical institution.

(5) Pharmacy Management Program 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.

(6) Pharmacy Management Program clients may receive drugs from a different pharmacy if:

(a) The client has an urgent need to fill a prescription and the enrolled pharmacy is not available; or

(b) The enrolled pharmacy does not have the prescribed drug in stock; or

(c) The client is out of the area (more than 50 miles) of their enrolled pharmacy;

(d) The client is using mail order home delivery in addition to their enrolled pharmacy.

(7) Call the Pharmacy Benefits Administrator Point of Sale Technical Help Desk for authorization to fill a prescription in the situations described in (5)(a-c) above.

Stat. Auth.: ORS 409

Stats. Implemented: ORS 414.065

1-1-07

## **410-121-0140 Definition of Terms**

(1) Actual Acquisition Cost: The net amount paid per invoice line item to a supplier. This net amount does not include separately identified discounts for early payment.

(2) Automated Information System (AIS): A computer system that provides on-line Medicaid eligibility information. AIS is accessed through the provider's touch-tone telephone by dialing 1-800-522-2508.

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

(4) Community Based Care Living Facility: For the purposes of the Division of Medical Assistance Programs (DMAP) Pharmacy Program, "community based care living facilities" include:

(a) Supportive Living Facilities;

(b) 24-Hour Residential Services;

(c) Foster Care;

(d) Semi-independent Living Programs; and

(e) Assisted Living and Residential Care Facilities.

(5) Compounded Prescriptions: 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. Compounded prescription is further defined to include the Oregon Board of Pharmacy definition of Compounding.

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

(7) 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.

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

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

(10) Managed Access Program (MAP): The Managed Access Program (MAP) is a system of determining, through a series of therapeutic and clinical protocols, which drugs require authorizations prior to dispensing.

(a) The drugs or categories of drugs requiring prior authorization (PA) are listed in OAR 410-121-0040.

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

(11) Nursing Facilities: The term "Nursing Facility" refers to an establishment that is licensed and certified by the DHS Seniors and People with Disabilities Division (SPD) cluster as a Nursing Facility.

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

(13) 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 a 34-day (See OAR 410-121-0146);

(b) Billing the agency for more than one dispensing fee when the prescription calls for one dispensing for the quantity dispensed;

(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.

(14) 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.

(15) Unit Dose Delivery System:

DMAP currently recognizes two types of unit dose dispensing systems in a nursing facility or community based living facility. Both the True and Modified Unit Dose delivery systems are described in OAR 410-121-0148.

Stat. Auth.: ORS 409

Stats. Implemented ORS 414.65

1-1-07

### **410-121-0143 Client Confidentiality**

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

Stat. Auth.: ORS 409.010 & ORS 409.110

Stats. Implemented: 414.065

1-1-07

## **410-121-0144 Notation on Prescriptions**

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

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

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

(a) "Diagnosis not covered ";

(b) "Excluded diagnosis"; or

(c) "Condition below the funding line".

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

(a) Below the funding line;

(b) An excluded service; or

(c) On the excluded list.

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

Stat. Auth.: ORS 409

Stats. Implemented: ORS 414.065

1-1-7

## **410-121-0145 Prescription Requirements**

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

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

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

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

(a) DMAP may reimburse a pharmacy for distributing over-the-counter Plan B emergency contraceptive drug products to women who are 18 years old and older and who are Medicaid eligible; and,

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

Stat. Auth.: ORS 409

Stats. Implemented ORS 414.65

7-1-07

## **410-121-0146 Dispensing Limitations**

(1) The quantity indicated by the prescriber on the prescription may not be reduced except when in conflict with the limitations below. The Division of Medical Assistance Programs (DMAP) will consider any form of prescription splitting, except as required below in this rule, as a billing offense and will take appropriate action as described in the General Rules.

(2) The following dispensing limitations apply to DMAP reimbursement:

(a) Dispensing, except as otherwise noted in this rule, is limited to the amount prescribed but not to exceed a 34-day supply of the drug. Exceptions to the 34-day supply limitation includes mail order pharmacy dispensed through DMAP contracted Mail Order Pharmacy and prescription in the drug classes listed below. These drug classes are limited to the amount prescribed by the physician, but not to exceed a 100-day supply of the drug. Exceptions (codes are from First Data Bank's Standard Therapeutic Classification Codes):

(A) Anticonvulsants, Code 48;

(B) Thyroid Preparation, Code 55;

(C) Rauwolfias, Code 70;

(D) Vasodilators, Coronary, Code 72;

(E) Vasodilators, Peripheral, Code 73;

(F) Digitalis preparations, Code 74;

(G) Xanthine derivatives, Code 75;

(H) Contraceptives, Topical, Code 36;

(I) Contraceptives, Oral, Code 63.

(b) After stabilization of a diabetic, a minimum of a one-month supply of Insulin should be provided per dispensing;

(c) For vaccines available in multiple dose packaging, a dispensing fee will be allowed for each multiple dose. When vaccines are administered at the pharmacy, refer to Administrative Rule 410-121-0185;

(d) For compounded prescriptions, components of the prescription shall be billed separately. Any reimbursement received from a third party for compounded prescriptions must be split and applied equally to each component.

Stat. Auth.: ORS 409

Stats. Implemented: ORS 414.065

1-1-07

## **410-121-0147 Exclusions and Limitations**

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

- (1) Drug Products for diagnoses below the funded line on the Health Services Commission Prioritized List;
- (2) Home pregnancy kits;
- (3) Fluoride for individuals over 18 years of age;
- (4) Expired drug products;
- (5) Drug Products from Non-Rebatable Manufacturers;
- (6) Drug products that are not assigned a National Drug Code (NDC) number;
- (7) Drug products that are not approved by the Federal Drug Administration (FDA);
- (8) Drug products dispensed for Citizen/Alien-Waived Emergency Medical client benefit type;
- (9) DESI drugs (*see* OAR 410-121-0420);
- (10) Medicare Part D covered drugs or classes of drugs for fully dual eligible clients;

Stat. Auth.: ORS 409

Stats. Implemented: ORS 414.065

1-1-07

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

(1) A pharmacy serving Division of Medical Assistance Programs (DMAP) clients in a nursing facility or a Community Based Care Living Facility must dispense medication in a manner consistent with that facility's system of use, i.e., bulk, unit dose or 30-day card system as set forth in ORS Chapter 441. (16) Unit Dose Delivery System:

(a) DMAP currently recognizes two types of unit dose dispensing systems:

(A) A True Unit Dose delivery system in a nursing facility or community-base care facility requires that:

(i) A pharmacy must deliver each client's medication a minimum of five days weekly, or delivery of medical carts every other day with service available seven days a week;

(ii) Resumption of the same medication after a "stop order" or discontinuance ("DC") order constitutes a new prescription;

(iii) The monthly billing period shall remain the same for all clients;

(iv) Small quantity prescriptions are allowed only when the monthly billing period is interrupted, e.g., hospitalization, new patient admit.

(B) A Modified Unit Dose delivery system in a nursing facility or community-based care facility requires that:

(i) A pharmacy must deliver each client's medication in a sealed single-or multi-dose package;

(ii) A pharmacy must dispense the greater of the quantity prescribed or a 30-day supply, except when short-term therapy is specified by the prescriber;

(iii) A pharmacy must bill DMAP for the date of dispensing within the timely filing limit;

(iv) Manufacturer's Unit Dose packaging of drugs is not reimbursable.

(b) Unit Dose dispensing is a 30-day blister pack, bingo or punch card containing multiple sealed single doses of medication:

(A) The pharmacy must have a system for dispensing and recovery of unused doses that has been approved by the State Board of Pharmacy;

(B) A 30-day card system that does not meet the requirements of the State Board of Pharmacy for recovery of unused doses, or for other reasons does not qualify for payment is not considered a True or Modified Unit Dose Delivery System.

(c) True and Modified Unit Dose providers must:

(A) Supply DMAP with a list of the nursing and community based care living facilities it will serve under this system;

(B) Sign an agreement to abide by the requirements of the program;

(C) Keep a separate, detailed Medication Administration Record (MAR) of all medications dispensed for each facility client served.

(2) Pharmacies that do not dispense through a unit dose or 30-day card system may bill DMAP for a dispensing fee for each dispensing of legend drugs to eligible clients on an DMAP fee-for-service basis.

(3) The pharmacy must submit a written notification to DMAP of the agreement between the pharmacy and the nursing or community based care living facility. The notice must be received in DMAP by the 15th of the month prior to the month the pharmacy initiates service to a facility. This notice must consist of the following:

(a) A completed Facility Dispensing Statement (DMAP 3063) signed by the pharmacist in charge, stating the dispensing method to be used for each qualified facility;

(b) The name, address, and telephone number of each facility served by the pharmacy.

(4) Pharmacies dispensing through a unit dose or 30-day card system must bill DMAP only for the medications actually dispensed. Only one dispensing fee will be reimbursed per medication dispensed in a 30-day period, for a medication ordered continuously for 30 days or more.

(5) The pharmacy must submit written notification to DMAP through a completed Facility Dispensing Statement (DMAP 3063) signed by the pharmacist in charge if at least one of the following situations arise:

(a) The percentage level of true or modified unit dose dispensings falls below the percentage level defined in OAR 410-121-0160;

(b) The dispensing system changes from unit dose either true or modified, to bulk dispensing or vice versa;

(c) The pharmacy discontinues providing services to a specific facility already on record as being served by the pharmacy.

(6) Pharmacies shall not bill DMAP for repackaging/handling fees. There may only be one billing for each dispensing.

Stat. Auth.: ORS 409

Stats. Implemented ORS 414.065

1-1-07

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Stat. Auth. ORS 409.010, ORS 409.050, and 2005 OR law, Ch. 754 (SB 1088)

Statutes Implemented: ORS 414.065

1-1-07

## **410-121-0150 Billing Requirements**

- (1) When billing the Division of Medical Assistance Programs (DMAP) for drug products, the provider must not bill in excess of the usual and customary charge to the general public.
- (2) The National Drug Code (NDC), as it appears on the package from which the prescribed medications are dispensed, must be indicated.
- (3) Actual metric decimal quantity dispensed, must be billed.
- (4) The provider must accurately furnish all information required on the 5.1 Universal Claims Form if submitting a paper claim.
- (5) The prescribing provider's Medicaid Provider Identification (ID) Number is mandatory on all fee-for-service client drug prescription claims. Claims will deny for a missing or invalid prescriber Medicaid Provider ID Number. Exceptions to this include, but are not limited to, the following:
  - (a) A miscellaneous Medicaid provider number of 999999 may be used for:
    - (A) Out-of-state prescribing providers; and
    - (B) Inactive Oregon Medicaid Providers;
  - (b) Prescribing providers who do not have a Medicaid Provider ID Number for billing, but who prescribe for fee-for-service prescriptions for clients under prepaid health plans (PHP), long-term care, or other capitated contracts are to be identified with the:
    - (A) Non-billing Provider ID Number assigned for prescription writing only;
    - (B) Clinic or facility Medicaid Provider ID Number until an individual Non-billing Provider ID Number is obtained; or
    - (C) Supervising physician's Provider ID Number when billing for prescriptions written by the physician assistant, physician students, physician interns, or medical professionals who have prescription writing authority.

(c) A miscellaneous Medicaid Provider ID Number– of 999999 may not be used for psychotropic prescriptions for children under the age of six.

(d) A Medicaid Provider ID number of BBBB BB must be used in order for a pharmacy to be reimbursed for distributing the emergency contraceptive drug product Plan B over-the-counter to women who are 18 years old or older and who are Medicaid eligible.

(6) When clients have private insurance, providers are required to bill the private insurance as primary and DMAP as secondary.

(7) When clients have Medicare prescription drug coverage, providers are required to bill Medicare as primary and DMAP as secondary.

(8) Billing for Death With Dignity services – Death With Dignity:

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

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

(c) Prescriptions must be billed on a 5.1 Universal Claims Form paper claim form using an NDC number.

(d) Claims must be submitted on paper billing forms to DMAP at PO Box 14165, Salem, Oregon 97308-0992.

Stat. Auth.: ORS 409

Stats. Implemented: ORS 414.065

7-1-07

## **410-121-0155 Reimbursement**

Payment for covered fee-for-service drug products will be the lesser of the usual and customary amount billed or the Estimated Acquisition Cost (EAC) of the generic form, minus any applicable copayments, plus a professional dispensing fee. Refer to OAR 410-120-1230 for client copayment details.

(1) EAC is the lesser of:

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

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

(c) Retail pharmacies: eighty-five percent of Average Wholesale Price (AWP) of the drug; or

(d) Unit dose or modified unit dose pharmacies: eighty-nine percent of AWP for long-term care clients in a nursing facility or community based living facility; or

(d) Contracted mail order pharmacy: seventy-nine percent of AWP for brand (trade) name drugs, forty percent of AWP for generic drugs and eighty-two percent of AWP for injectable drugs.

(2) The Division of Medical Assistance Programs (DMAP) shall revise its estimated acquisition cost file weekly.

(3) Pharmacies must make available to DMAP any information necessary to determine the pharmacy's actual acquisition cost of drug products dispensed to DMAP clients.

(4) Payment for trade name forms of multisource products will be the lesser of the amount billed or the EAC of the trade name form of the product, minus applicable copayments, plus a professional dispensing fee only if the prescribing practitioner has received a prior authorization for a trade name drug.

(5) Payment for individual special admixtures, fluids or supplies shall be limited to the lesser of:

(a) Eighty percent of the usual and customary charges to the general public;

(b) The amount Medicare allows for the same product or service;

(c) The amount the agency negotiates with an individual provider, less any amount paid or payable by another third party; or

(d) The amount established or determined by DMAP.

(6) No professional dispensing fee is allowed for dispensing:

(a) Condoms, contraceptive foams, suppositories, inserts, jellies, and creams;

(b) Pill splitters/cutters;

(c) Medical supplies and equipment; and

(d) Oral nutritional supplements.

(7) Over-the-counter contraceptive drugs and devices will be reimbursed at the lesser of billed amount or EAC, plus fifty percent of EAC;

(8) Oral nutritional supplements will be reimbursed at the lesser of billed amount or EAC, plus one third of EAC.

(9) Pill splitters/cutters with a National Drug Code (NDC) number will be reimbursed at the lesser of billed amount, or EAC. A practitioner prescription is not required. The limit is one per client in a twelve-month period.

Stat. Auth.: ORS 184.750, ORS 184.770, ORS 409, ORS 411 & ORS 414

Stats. Implemented ORS 414.065

1-1-07

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

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

(2) Documents in rule by reference: Names and Labeler Code numbers for participants in the Medicaid Drug Rebate Program are the responsibility of and maintained by CMS. DMAP receives this information from CMS in the form of numbered and dated Releases. Subsequently, DMAP produces and updates Master Pharmaceutical Manufacturer's Rebate Lists (Lists), alphabetical and numeric, by manufacturer. These lists are used by DMAP providers to bill for services. DMAP includes in rule by reference, the following CMS Releases and subsequent DMAP Master Pharmaceutical Manufacturer's Rebate Lists: Release #136, dated February 17, 2005 – Lists updated March 30, 2005; Release #137, dated May 13, 2005 and Lists updated June 23, 2005; Release #138, dated August 5, 2005, and Lists updated August 19, 2005, and Release #139, dated December 1, 2005 - Lists updated December 8, 2005; Release #140, dated March 15, 2006, and Lists updated March 17, 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.

All CMS Releases are available on the Department of Human Services' website:

[www.dhs.state.or.us/policy/healthplan/guides/pharmacy/main.html](http://www.dhs.state.or.us/policy/healthplan/guides/pharmacy/main.html), and on the CMS website: [www.cms.hhs.gov/medicaid/drugs/drughmpg.asp](http://www.cms.hhs.gov/medicaid/drugs/drughmpg.asp), and the subsequent DMAP Master Pharmaceutical Manufacturer's Rebate Lists, are available on the Department of Human Services' website: [www.dhs.state.or.us/policy/healthplan/guides/pharmacy/main.html](http://www.dhs.state.or.us/policy/healthplan/guides/pharmacy/main.html).

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

(4) DMAP contracts with First Health Services to manage the Medicaid Rebate Dispute Resolution program. Pharmacy providers must verify the accuracy of their Medicaid pharmacy claims with First Health Services 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

Stats. Implemented: ORS 414.065

1-1-07

## **410-121-0160 Dispensing Fees**

(1) Pharmacy providers must apply for a Division of Medical Assistance Programs (DMAP) review of their pharmacy dispensing fee level by completing a Pharmacy Prescription Survey (DMAP 3062) when one of the following situations occurs:

(a) The pharmacy initiates dispensing medications to clients in facilities and the most recent two months worth of dispensing data is available. DMAP will only accept the most recent two months worth of data;

(b) The pharmacy discontinues dispensing medications to clients in facilities. The pharmacy provider is required to notify DMAP within 60 days and complete a new Pharmacy Prescription Survey with the most recent two-months worth of dispensing data available. DMAP will only accept the most recent two months worth of data; or

(c) A completed Pharmacy Prescription Survey signed by the pharmacist in charge must be submitted to DMAP to initiate a review of dispensing fees.

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

(a) \$3.50 - Retail Pharmacies.

(b) \$3.91 - Institutional Pharmacies operating with a True or Modified Unit Dose Delivery System as defined by DMAP and that are enrolled with DMAP as an institutional pharmacy by sending a copy of its institutional pharmacy license with its provider application.

(A) This dispensing fee applies to prescriptions dispensed to clients identified on DHS case files as residing in a Long Term Care Nursing Facility or for clients covered by the Centers for Medicare and Medicaid Services community based waiver.

(B) All other dispensing fees for institutional pharmacies will be at the retail rate.

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

(3) The True or Modified Unit Dose Delivery System applies to those providers who give this service to over fifty percent of their patient population base associated with a particular Medicaid provider number.

Stat. Auth.: ORS 409

Stats. Implemented: ORS 414.065

1-1-07

## **410-121-0185 Pharmacy Based Immunization Delivery**

(1) A pharmacist may administer vaccines to persons who are over the age of eighteen as provided by ORS 689.205 and The Board of Pharmacy Administrative rule 855-041-0500.

(2) When billing for vaccines administration, use either the CMS-1500 or the Point Of Sale claims processing system:

(a) When using the CMS-1500 billing form: (A) Use the appropriate CPT-code (90471 and 90472) for the administration plus the appropriate vaccine 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) When using the Point-of-Sale system, use the National Drug Code (NDC), as it appears on the package from which the prescribed medications are dispensed. The administration fee for this service will be equivalent to those under 90471–90472.

Stat. Auth.: ORS 409

Stats. Implemented: ORS 414.065

1-1-07

## **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

Stats. Implemented: ORS 414.065

1-1-07

## **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 OMAP Medical Care Identification has been presented. In the absence of a valid Medical Care Identification, the provider should call the Automated Information System or contact the local branch office where the client is being served;

(c) All completed 5.1 Universal Claim Forms should be mailed to the Division of Medical Assistance Programs (DMAP); A paper claim must be used when the billed amount exceeds \$99,999;

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

Stat. Auth.: ORS 409

Stats. Implemented: ORS 414.065

1-1-07

## **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, carpjects), 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 409

Stats. Implemented: ORS 414.065

1-1-07

## **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.

(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 150 percent applied to the lowest price listed (in package sizes of 100 units, unless otherwise noted) in any of the published compendia of cost information of drugs.

(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 (contact Division of Medical Assistance Programs (DMAP) for most current website address). The FUL price listing will be updated approximately every six months.

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

(6) The most current CMS Federal Upper Limits for Drug Payments Listing includes changes to Transmittal #37, included in the January 20, 2005 Title XIX State Agency Letter, effective for February 14, 2005; the March 10, 2006 Title XIX State Agency Letter, effective for services rendered on or after April 10, 2006; the June 23, 2006 Title XIX State Agency Letter, effective for services rendered on or after July 23, 2006 and are available for downloading on the DMAP Website (contact DMAP for most current website address). To request a hard copy, call DMAP.

Statutory Authority: ORS Chapter 409.010, 409.110, 409.050

Statutes Implemented: 414.065

1-1-07

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

(1) The Oregon maximum allowable cost, or the maximum amount that the Division of Medical Assistance Programs (DMAP) will reimburse for prescribed drugs, is determined by DMAP's claims processing company, First Health Services. First Health Services determines the maximum allowable cost on selected multiple-source drug designation when a bioequivalent drug product is available from at least two wholesalers serving the State of Oregon.

(2) First Health Services generates and maintains all official OMAC lists and provides a copy of each list to DMAP. OMAC lists are generated monthly and each list indicates the amount, per product, that DMAP will reimburse to providers for products provided to DMAP clients during that particular month. For example: The OMAC list, January 1, 2003, includes the amounts DMAP will reimburse for products provided during the month of January 2003; the list, February 1, 2003, covers the month of February 2003, etc.

(3) DMAP includes in rule by reference the OMAC lists for January 1, 2005, February 1, 2005, March 1, 2005, April 1, 2005, May 1, 2005, June 1, 2005, July 1, 2005, August 1, 2005, September 1, 2005, October 1, 2005, November 1, 2005 and December 1, 2005.

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

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

(7) Current OMAC lists are available for review and/or downloading on DMAP's website:

[www.dhs.state.or.us/policy/healthplan/guides/pharmacy/](http://www.dhs.state.or.us/policy/healthplan/guides/pharmacy/). Future lists, referenced in this rule, will be available and posted to DMAP's website upon receipt from First Health Services.

(8) The OMAC list does not apply if a prescriber certifies that a singlesource (brand) drug is medically necessary.

Stat. Auth.: ORS 184.750, ORS 184.770, ORS 411 & ORS 414

Stats. Implemented: ORS 414.065

1-1-07

## **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) Since this ruling means the Federal funding for these drugs will be terminated, payment for drugs will not be made by the Division of Medical Assistance Programs (DMAP). The "Active Ingredient" and "Route" of administration columns are the major controlling factors regarding the FDA's less-than-effective drug determinations and CMS's reimbursement decisions regarding these drugs. The products' trade names, dosage forms and names of the producing firms are supplied for informational purposes. Thus, even though a drug's trade name, dosage form, is not shown on this list, if by its generic make up and route of administration it is identical, similar, or related to a drug on this list, no Federal Financial Participation (FFP) is available for such a drug. Therefore, DMAP will not reimburse for DESI drugs or dispensings of products that are identical, related, or similar.

(3) In accordance with current policy, Federal financial participation will not be provided for any drug on the FUL listing for which the FDA has issued a notice of an opportunity for a hearing as a result of the Drug Efficacy Study and Implementation (DESI) program and the drug has been found to be a less than effective or is identical, related or similar (IRS) to the DESI drug. The DESI drug listing is identified by the Food and Drug Administration or reported by the drug manufacturer for purposes of the Medicaid drug rebate program.

(4) The manufacturer has the responsibility of determining the DESI status of a drug product.

(5) DESI Less Than Effective Drug List is available for download on the Department of Human Services website. If you would like to request a hard copy of this list, please call DMAP.

Stat. Auth.: ORS 409

Stats. Implemented: ORS 414.065

1-1-07

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Stat. Auth.: ORS 409.010 & ORS 409.110

Stats. Implemented: ORS 414.065

1-1-07

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

(1) The all-inclusive rate for nursing facilities includes but is not limited to various drug products and OTC items. Please bill the nursing facility 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

Stats. Implemented: ORS 414.065

1-1-07