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September 2004

To: Providers of OMAP Pharmaceutical Services

From: Joan M. Kapowich, Manager
OMAP Program and Policy

Subject: Pharmaceutical Program Rulebook Reissued

**Effective: October 1, 2004**

OMAP updated the Pharmaceutical Services Program Rulebook with the following administrative rule revisions:

OMAP revised OAR 410-121-0040 to add prior authorization for brand name drugs and to remove the prior authorization requirement from over-the-counter (OTC) drugs and drugs that have a reimbursement cost less than the prior authorization (PA) process fee. PA may be required on these two groups if OMAP determines there is a drug safety issue.

OMAP temporarily amended 410-121-0157 to reference the updated information regarding participating pharmaceutical companies to the Medicaid Drug Rebate Program, in compliance with federal regulations.

- If you are reading this letter on OMAP's website: (www.dhs.state.or.us/policy/healthplan/rules/), this Rulebook contains a complete set of administrative rules for this program, including revision(s).

- If you do not have web access and receive hardcopy of revisions, this letter is attached to the revised rule to be used as replacement in your Pharmaceutical Rulebook. Each rule is individually numbered for easy replacement.

If you have billing questions, contact a Provider Services Representative toll-free at 1-800-336-6016 or direct at 503-378-3697. TR561 10/1/04

# DEPARTMENT OF HUMAN SERVICES

# MEDICAL ASSISTANCE PROGRAMS

# DIVISION 121

# PHARMACEUTICAL SERVICES

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**410-121-0000 Foreword**

(1) The Pharmaceutical Services Oregon Administrative Rules are designed to assist providers in preparing claims for services provided to Office of Medical Assistance Programs (OMAP) 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 OMAP, 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) OMAP 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 OMAP rules are available on the Department of Human Services website.

Stat. Auth.: ORS 184

Stats. Implemented: ORS 414.065

4-1-04

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

(1) Pharmacies, rural health clinics, and other medical organizations may provide drug prescription services for fee-for-service OMAP clients and receive reimbursement from OMAP 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 OMAP;

(d) Have a current National Association of the Board of Pharmacy (NABP) number to bill OMAP; and

(e) Comply with OMAP pharmacy billing requirements.

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

(3) Nurse Practitioners licensed to dispense medications (OAR 851-050-0000) and Medical Doctors certified to dispense medications authorized by state law and their respective state licensing board to dispense medications (OAR 847-015-0025) may provide drug prescription services for fee-for-service OMAP clients. These providers may receive reimbursement from OMAP 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 provider with OMAP, including the dispensing certification or licensure; and

(d) Comply with OMAP pharmacy billing requirements.

(4) Licensed practitioners as noted in subsections (1) and (3) above, who practice in rural health clinics may provide drug prescription services for fee-for-service OMAP clients for an urgent medical condition as defined in ORS 414.325(6).

Statutory Authority: Chapter 409

Statutes Implemented: ORS 414.065

7-1-04

**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) Decisions concerning the clinical effectiveness of the prescription drugs are made by licensed health practitioners, informed by the latest peer-reviewed research;

(b) Decisions 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 has been determined 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, their drug will also be included 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/.

(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. Relative price will be determined using the methodology described in subsection (4);

(c) Drug classes and selected drug(s) for the drug classes will be reviewed annually:

(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) New drugs will not be added to the PDL until they have been reviewed by the HRC;

(C) All changes or revisions to the PDL will be made publicly, using the rulemaking process, and will be published on OMAP'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. These factors will be weighed 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 410-121-0180), in which DHS reviews that specific drug class;

(d) Once the cost of the benchmark drug is determined, the cost of the other FDA-approved drugs in the class will be recalculated using EAC for retail pharmacies in effect on the first of the month in which DHS reviews that specific drug class (OAR 410-121-0180), less average available rebate. Drugs with prices under the benchmark drug cost will be included on the PDL.

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

Table 121-0030-1, PMPDP PDL (updated effective 08/01/2004)

Stat. Auth.: ORS Chap. 409

Stats. Implemented: 414.065

8-1-04

**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.

**ANGIOTENSIN-CONVERTING ENZYME INHIBITORS (ACEIs)**

- (**)Enalapril (generic)
- Aceon
- Captopril (generic)
- Captopril/HCTZ (generic)
- Lisinopril (generic)
- Lotensin/HCTZ
- Monopril
- Monopril/HCTZ
- Uniretic

**BETA-BLOCKERS:**

- (**)Toprol XL
- Atenolol (generic)
- Bisoprolol (generic)
- Innopran XL
- Labetolol (generic)
- Metoprolol tartrate (generic)
- Nadolol (generic)
- Pindolol (generic)
- Propranolol (generic)
- Propranolol LA (generic)

**CALCIUM CHANNEL BLOCKERS**

Dihydropyridines

- (**) Norvasc
- Nicardipine (generic)
- Nifedipine (generic)
- Sular

Non-Dihydropyridines

- (**)Verapamil Sustained Action (SA) tablets (generic)
- Diltiazem (generic)
- Verapamil (generic

**ESTROGENS:**

- (**) Estradiol (oral)
- Cenestin
- Menest
- Ortho-Prefest
- Premarin (oral)
- Premphase
- Prempro

**HYPOGLYCEMICS, ORAL**

- (**) Glyburide (generic)
- Glipizide (generic
- Glyburide, micronized (generic)
- Tolbutamide (generic)

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

- (**) Naproxen (generic)
- Ibuprofen (generic)
- Piroxicam (generic)

**OPIOIDS, LONG-ACTING:**

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

**PROTON PUMP INHIBITORS**:

- Prilosec OTC

**SKELETAL MUSCLE RELAXANTS**

Antispasmodics for chronic neurological conditions:

- (**) Baclofen (generic)

Acute/chronic musculoskeletal spasms:

- (**)Cyclobenzaprine (generic)

**STATINS (CHOLESTEROL LOWERING MEDICATIONS):**

- (**) Lovastatin (generic)
- Altocor
- Lescol
- Lescol XL
- Lipitor
- Pravachol
- Zocor

**TRIPTAN DRUGS**

- (**) Maxalt
- Imitrex (all forms)
- Maxalt MLT
- Zomig
- Zomig ZMT

**URINARY INCONTINENCE DRUGS**

(**) Oxybutynin (tablets and liquid)

8-1-04

## 410-121-0033 Polypharmacy profiling

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

(2) OMAP 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 OMAP 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
2-1-2004

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

(1) Prior authorization (PA) will not be required when the prescription ingredient cost plus the dispensing fee is less than the PA processing fees as determined by the Office of Medical Assistance Programs.

(2) PA will not be required on over the counter (OTC) covered drugs when prescribed for covered diagnosis.

(3) PA will be required on (1) and (2) above if the Office of Medical Assistance Programs determines a potential client safety risk associated with the prescribed drug.

(4) Prescribing practitioners are responsible for obtaining PA for the following drugs and products:

(a) Isotretinoin (Accutane) and Retinoic Acid (Retin A);

(b) Growth hormone;

(c) Oral Nutritional supplements;

(d) Antihistamines (selected);

(e) Nasal inhalers (selected);

(f) Antifungals (selected);

(g) Weight reduction drugs;

(h) Excessive daily doses;

(i) Excessive drug therapy duration;

(j) Coal tar preparations;

(k) Topical antibiotics;

(l) Topical antivirals (selected);

(m) Topical testosterone;

(n) Dronabinol (marinol);

(o) Drugs with cosmetic indications;

(A) Emollients;

(B) Dermatologicals;

(C) Hair growth products;

(p) Proton Pump Inhibitors (PPI) after eight weeks of acute anti-ulcer therapy;

(q) Gabapentin (Neurontin);

(r) Triptan quantity limits;

(s) FluMist (Influenza Virus Vaccine Live, Intranasal).

(5) PA will be required for brand name drugs that have two or more generically equivalent products available.

(6) Psychotropic prescriptions for children under the age of six cannot be processed when a default 999999 provider number has been entered.

Stat. Auth.: ORS 409

Stats. Implemented: ORS 414.065

10-01-04

**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 the Pharmaceutical Services Supplemental Information on the Department of Human Services website.

(2) Receipt of approval of a PA:

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

(A) The PA is given for a specific date of service and an NDC number or product;

(B) The PA does 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. The pharmacy should also check whether the client is enrolled in a managed care plan. An enrollment may have taken place after PA was received;

(c) After a PA request is approved, the patient will be able to fill the prescription at any Medicaid pharmacy provider. 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 is available.

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

(a) Emergency dispensing for a 96-hour supply for clients without a PA pending;

(b) Emergency dispensing up to a seven-day supply, pending a submitted PA request for clients.

Stat. Auth.: ORS 409

Stats. Implemented: ORS 414.065

4-1-04

**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

4-01-04

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

(1) Drug Use Review (DUR) 4 in Oregon Medical Assistance Programs 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 which identifies an individual is confidential and may not be disclosed by the Oregon State Medical Assistance Programs DUR Board or the Retrospective DUR Council to any person other than health care providers appearing on a recipient's medication profile;

(b) Staff of the above-mentioned Board and Council may have access to identifying information to carry out intervention activities approved by Office of Medical Assistance Programs (OMAP), after signing an agreement to keep the information confidential. The identifying information may not be released to anyone other than DUR staff members of the Board or Council, or health care providers appearing on a recipient's medication profile. Identifying information is defined for the purposes of drug use review as names of prescribers, pharmacists and/or 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) Each dispensing pharmacist must offer to counsel each OMAP client receiving benefits (or the care giver of such individual), who presents a new prescription, unless the client refuses such counsel. Pharmacists must document these refusals:

(A) Counseling must be done in person, whenever practicable;

(B) 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 FCHPs;

(c) 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. Through this program the OMAP provides a professional drug therapy review for Medicaid clients:

(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 Oregon licensed physicians and pharmacists appointed by the Director of the OMAP. Members of this panel are referred to as council members;

(b)If therapy problems are identified by the review 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 OMAP approval.

(4) The Oregon State Medicaid DUR Board is a group of individuals who comprise an advisory committee to OMAP: (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;

(D) Medical quality assurance.

(b) The 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 Board is composed of five practicing pharmacists;

(A) five practicing physicians;

(B) two persons who represent people on Medical Assistance; and
(D) one person actively practicing dentistry.

(c) The retrospective DUR coordinator will attend board meetings in an ex officio capacity;

(d) Appointments to the Board are made by the OMAP Administrator:

(A) Nominations for 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 Board may be reappointed upon the completion of the his/her term.

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

(5) The 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;

(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 as part of retrospective DUR 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 program and its 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

4-1-04

**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 an OMAP provider number.

(4) See OAR 410-141-0065 for clients who are not required to be enrolled in the Pharmacy Management Program.

(5) A client who is enrolled with a pharmacy 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.

(6) Call the First Health Technical Help Desk for authorization to fill a prescription in the situations described in (5)(a) or (b) above.

Stat. Auth.: ORS 409

Stats. Implemented: ORS 414.065

4-1-04

**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 OMAP 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;

(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 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 that can stand repeated use and is primarily and customarily used to serve a medical purpose. Examples include wheelchairs, respirators, crutches, custom built orthopedic braces. Medical supplies are nonreusable items used in the treatment of illness or injury. Examples of medical supplies include diapers, syringes, gauze bandages, and tubing.

(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 specific 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 which is licensed and certified by DHS Seniors and People with Disabilities cluster as a Nursing Facility.

(12) Point-of-Sale (POS): A computerized, claims submission process for retail pharmacies which 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);

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

(14) Prescription Volume Survey: A survey used by pharmaceutical providers which determines the providers dispensing rate. This survey documents for each pharmacy the total prescriptions dispensed, the total prescriptions dispensed to OMAP clients, and if used, the types of unit dose system.

(15) 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 State Board of Pharmacy.

(16) Unit Dose Delivery System:

OMAP 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
4-1-04

**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

4-1-04

**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 Office of Medical Assistance Programs (OMAP) 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 OMAP for these prescriptions.

Stat.Auth.: ORS 409

Stats.Implemented: ORS 414.065

4-1-04

**410-121-0145 Prescription Requirements**

(1) OMAP 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.

(2) Each drug order or prescription filled for an OMAP client must be retained in the pharmacy's file at the pharmacy’s place of business.

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

Stat. Auth.: ORS 409

Stats. Implemented ORS 414.65

4-1-04

**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 Office of Medical Assistance Programs (OMAP) 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 OMAP 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 OMAP 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

4-15-04

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

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

(1) Drug Products for diagnosis 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, and are not approved by the Federal Drug Administration (FDA);

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

(8) Desi drugs;

(9) Drug Products and drug product quantities which do not meet OMAP guidelines.

Stat. Auth.: ORS 409

Stats. Implemented: ORS 414.065

4-1-04

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

(1) A pharmacy serving OMAP 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) OMAP 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 OMAP 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 OMAP 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 OMAP for a dispensing fee for each dispensing of legend drugs to eligible clients on an OMAP fee-for-service basis.

(3) The pharmacy must submit a written notification to OMAP of the agreement between the pharmacy and the nursing or community based care living facility. The notice must be received in OMAP 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 (OMAP 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 OMAP 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 OMAP through a completed Facility Dispensing Statement (OMAP 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 OMAP for repackaging/handling fees. There may only be one billing for each dispensing.

Stat. Auth.: ORS 409

Stats. Implemented ORS 414.65

4-1-04

**410-121-0150 Billing Requirements**

(1) When billing the Office of Medical Assistance Programs (OMAP) for pharmaceuticals, 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 paper claim.

(5) The prescribing physician's Medicaid Provider Identification (ID) Number is required on all claims. Use of the appropriate provider ID number is mandatory. Claims will deny for a missing or invalid Prescriber ID number. Exceptions to this include but are not limited to:

(a) Out-of-state providers;

(b) Mental Health providers working at county clinics which have no individual provider number;

(c) Inactive Medicaid providers contracted by managed care plans prescribing class seven (7) or eleven (11) drugs.

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

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

(8) Billing for Death With Dignity services:

(a) All Death With Dignity services must be billed directly to OMAP, even if the client is in a managed care plan;

(b) Prescriptions must be billed on an 5.1 Universal Claims Form paper claim form using an NDC number ;

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

(d) Claims for Death With Dignity services must be submitted on paper billing forms to OMAP at PO Box 992, Salem, Oregon 97308-0992.

Stat. Auth.: ORS 409

Stats. Implemented: ORS 414.065

4-1-04

**410-121-0155 Reimbursement**

Payment for fee-for-service pharmaceutical prescriptions 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) Centers for Medicaid and Medicare Services (CMS) federal upper limits (FUL) for payment; or

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

(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

(e) 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 Office of Medical Assistance Programs (OMAP) shall revise its estimated acquisition cost file twice monthly.

(3) Pharmacies must make available to OMAP any information necessary to determine the pharmacy's actual acquisition cost of pharmaceutical goods dispensed to OMAP 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 OMAP.

(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; or

(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
4-1-04

**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 Office of Medical Assistance Programs (OMAP) on all their drug products. OMAP will reimburse providers only for outpatient drug products manufactured or labeled by companies participating in this program.

(2) Names and Labeler Code numbers for participants in the Medicaid Drug Rebate Program are the responsibility of and maintained by CMS. OMAP receives this information from CMS in the form of numbered and dated Releases. OMAP includes in rule by reference, Release #132, dated June 22, 2004 and the OMAP Master Pharmaceutical Manufacturer's Rebate Lists, alphabetical and numeric, by manufacturer, updated July 19, 2004 and Release #133, dated August 13, 2004 and the OMAP Master Pharmaceutical Manufacturer's Rebate Lists, alphabetical and numeric, by manufacturer, updated August 24, 2004. This information is available on the Department of Human Services' website: www.dhs.state.or.us/policy/healthplan/rules/, and on the CMS website: www.cms.hhs.gov/medicaid/drugs/drughmpg.asp, or by contacting CMS.

(3) OMAP 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.

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

Stat. Auth.: ORS 409

Stats. Implemented: ORS 14.065

9/10/04 (T)

**410-121-0160 Dispensing Fees**

(1) Pharmacy providers must apply for an Office of Medical Assistance Programs (OMAP) review of their pharmacy dispensing fee level by completing a Pharmacy Prescription Survey (OMAP 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. OMAP will only accept the most recent two months worth of data; or

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

(A) This dispensing fee applies to clients identified on DHS case files as residing in a Long Term Care Facility;

(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

4-15-04

**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) Two billing methods are allowed:

(a) Use CMS-1500 when billing for vaccines administration. Use the appropriate CPT-code (90471 or 90472) for the administration plus the appropriate vaccine code(s) 90476-90749:

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

(B) The diagnosis code must be shown to the highest degree of specificity; or,

(b) Use the Point-of-Sale system when billing for vaccine administration. 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

4-1-04

**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 in Field 21 of the CMS-1500. The diagnosis code must be shown to the 5th digit on the CMS-1500 and OMAP 505.

(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 (and OMAP 505 if the client has Medicare coverage). Use Type of Service "S" and Procedure Code G0001.

Stat. Auth.: ORS 409

Stats. Implemented: ORS 414.065

4-1-04

**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 Office of Medical Assistance Programs; 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 OMAP Durable Medical Equipment and Medical Supplies Administrative Rules and Supplemental Information, and the OMAP Home Enteral/Parenteral Nutrition and IV Services Administrative Rules and Supplemental Information.

Stat. Auth.: ORS 409

Stats. Implemented: ORS 414.065

4-1-04

**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
6-1-03

**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 409
Stats. Implemented: ORS 414.065
2-1-99

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

(1) The 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. The development of the current Federal Upper Limit (FUL) listing has been accomplished by computer. 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 which CMS has determined to be equal to a 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. 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 at http://www.cms.hhs.gov/medicaid/drugs/drug10.asp. The FUL price listing will be updated approximately every six months.

(2) The most current CMS Federal Upper Limits for Drug Payments Listing, includes changes to Transmittal #37, Title XIX State Agency Letter Number 04-01, with changes to be effective March 20, 2004, and is available for downloading on OMAP's Website, (http://www.dhs.state.or.us/policy/healthplan/guides/pharmacy/). To request a hard copy, call OMAP.

Statutory Authority: ORS Chapter 409
Statutes Implemented: 414.065
5/14/2004 (T) 7/1/2004 (P)

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

(1)The Oregon maximum allowable cost, or the maximum amount that the Office of Medical Assistance Programs (OMAP) will reimburse for prescribed drugs, is determined by OMAP'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 OMAP. OMAC lists are generated monthly and each list indicates the amount, per product, that OMAP will reimburse to providers for products provided to OMAP clients during that particular month. For example: The OMAC list, January 1, 2003, includes the amounts OMAP will reimburse for products provided during the month of January 2003; the list, February 1, 2003, covers the month of February 2003, etc.

(3) OMAP includes in rule by reference the OMAC lists for February 1, 2002, March 1, 2002, April 1, 2002, July 1, 2002, August 1, 2002, September 1, 2002, October 1, 2002, November 1, 2002, December 1, 2002, January 1, 2003, February 1, 2003, March 1, 2003, April 1, 2003, May 1, 2003, June 1, 2003, July 1, 2003, August 1, 2003, September 1, 2003, October 1, 2003, November 1, 2003, and December 1, 2003.

(4) OMAP includes in rule by reference the OMAC lists for January 1, 2004, February 1, 2004, March 1, 2004, April 1, 2004, May 1, 2004, June 1, 2004, July 1,2004, August 1, 2004, September 1, 2004, October 1, 2004, November 1, 2004 and December 1, 2004.

(5) Current OMAC lists are available for review and/or downloading on OMAP's website:
http://www.dhs.state.or.us/policy/healthplan/guides/pharmacy/

Future lists, referenced in this rule, will be available and posted to OMAP's website upon receipt from First Health Services.

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

Stat. Auth.: ORS 184.750, ORS 184.770, ORS 411 & ORS 414
Stats. Implemented: ORS 414.065
2-1-2004

**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 OMAP. 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, OMAP 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 OMAP.

Stat. Auth.: ORS 409

Stats. Implemented: ORS 414.065

4-1-04

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

(1) Within 60 days after the end of each calendar quarter, the Office of Medical Assistance Programs (OMAP) 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) OMAP considers any failure to make timely payment in full of the amount due to be a dispute. Timely is defined by OMAP 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 OMAP 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 OMAP in letter form. Each letter will include an OMAP 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

4-1-04

**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 Office of Medcical Assistance Programs Web page on the Department of Human Services website.

Stat. Auth.: ORS 409

Stats. Implemented: ORS 414.065

4-1-04