Division of Medical Assistance Programs
Policy and Planning Section

Pharmaceutical Services Administrative Rulebook

Chapter 410, Division 121

Effective July 1, 2016

Table of Contents

410-121-0000 – Foreword and Definition of Terms 1

410-121-0021 – Organizations Authorized to Provide Pharmaceutical Prescription Services 7

410-121-0030 – Practitioner-Managed Prescription Drug Plan (T) 8

410-121-0032 – Supplemental Rebate Agreements 11

410-121-0033 – Polypharmacy profiling 12

410-121-0040 – Prior Authorization Required for Drugs and Products (T) 13

410-121-0060 – How to Get Prior Authorization for Drugs 16

410-121-0061 – Durable Medical Equipment, Medical Supplies, and Medical Surgical Services (Physician Administered Drugs) 18

410-121-0100 – Drug Use Review 19

410-121-0111 – Pharmacy & Therapeutics Committee 22

410-121-0135 – Pharmacy Management Program 24

410-121-0143 – Client Confidentiality 27

410-121-0145 – Prescription Requirements 28

410-121-0146 – Dispensing Limitations 29

Table 121-0146-1 – Maintenance Medications 31

410-121-0147 – Exclusions and Limitations 32

410-121-0148 – Dispensing in a Nursing Facility or Community Based Care Living Facility 33

410-121-0150 – Billing Requirements 34

410-121-0155 – Reimbursement 36

410-121-0157 – Participation in the Medicaid Drug Rebate Program 38

410-121-0160 – Dispensing Fees 39

410-121-0185 – Pharmacy Based Immunization Delivery 41

410-121-0190 – Medication Therapy Management Services and Clozapine Therapy Monitoring 42

410-121-0200 – Billing Forms 43
410-121-0220 – Instructions for Completion of the Prescription Drug Invoice..... 44
410-121-0280 – Billing Quantities, Metric Quantities and Package Sizes 45
410-121-0300 – CMS Federal Upper Limits for Drug Payments 46
410-121-0420 – DESI Less-Than-Effective Drug List 47
410-121-0580 – Oregon Medicaid and Pharmaceutical Manufacturers' Dispute Resolution Procedures 48
410-121-0625 – Items Covered in the All-Inclusive Rate for Nursing Facilities 50

410-121-0000 – Foreword and Definition of Terms

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

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

(3) Definition of Terms:

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

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

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

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

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

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

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

(h) CMS Consumer Price Index (CPI) Rebate: The quarterly payment by the manufacturer pursuant to the Manufacturer's CMS Medicaid Drug Rebate Agreement made in accordance with Section 1927(c)(2) of the Social Security act (42 U.S.C. 1396r-8(c)(2);

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

(A) The American Hospital Formulary Service drug information;

(B) The United States Pharmacopeia drug information;

(C) The American Medical Association drug evaluations;

(D) Peer-reviewed medical literature;

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

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

(A) Supportive Living Facilities;

(B) 24-Hour Residential Services;

(C) Adult Foster Care;

(D) Semi-Independent Living Programs;

(E) Assisted Living and Residential Care Facilities;

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

(G) Inpatient hospice;

(k) Compounded Prescription:

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

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

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

(m) Director: The Director of the Authority;

(n) Drug Order/Prescription:

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

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

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

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

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

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

(A) Habit-forming;

(B) Toxic or having potential for harm; or

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(A) Enforceable Physical Health Preferred Drug List: The list of drug products used to treat physical health diagnosis that the Division has identified which shall be exempt from client co-pays and may be subject to prior authorization (PA). Drugs prescribed that do not appear on the PDL (non-preferred products) shall be subject to both co-pays and PA as determined to be appropriate by the Division;

(B) Voluntary Mental Health Preferred Drug List: The list of drug products used to treat mental health diagnosis. These drugs are exempt from client co-pay. Any drug

prescribed for the treatment of mental health diagnosis shall be exempt from PA requirements by the Division;

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

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

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

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

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

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

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

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

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

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

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

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

(jj) 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;

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

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

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

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

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

Stat. Auth.: ORS 413.042, 414.065 & 414.325

Stats. Implemented: ORS 414.065

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

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

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

(b) Meet all current licensing and regulatory requirements;

(c) Be enrolled as a pharmacy provider with the Division;

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

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

(f) Comply with the Division pharmacy billing requirements.

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

Stat. Auth.: ORS 413.042

Stats. Implemented: ORS 414.065

410-121-0030 – Practitioner-Managed Prescription Drug Plan (T)

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

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

(b) Licensed health care practitioners also consider the client's health condition, personal characteristics, and the client's gender, race, or ethnicity.

(2) PMPDP Preferred Drug List (PDL):

(a) The PDL is the primary tool the Division uses to inform licensed health care practitioners about the results of the latest peer-reviewed research and cost effectiveness of prescription drugs;

(b) The PDL contains a list of prescription drugs that the Division, in consultation with the Drug Use Review (DUR)/Pharmacy & Therapeutics Committee (P&T), has determined represent the most effective drugs available at the best possible price;

(c) The PDL shall include drugs that are Medicaid reimbursable and the Food and Drug Administration (FDA) has determined to be safe and effective.

(3) PMPDP PDL Selection Process:

(a) The Division shall utilize the recommendations made by the P&T that result from an evidence-based evaluation process as the basis for selecting the most effective drugs;

(b) The Division shall ensure the drugs selected in section (3)(a) that are available for the best possible price and shall consider any input from the P&T about other FDA-approved drugs in the same class that are available for a lesser relative price. The Division shall determine relative price using the methodology described in section (4);

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

(A) The Division may evaluate more frequently if new safety information or the release of new drugs in a class or other information makes an evaluation advisable;

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

(C) The Division shall make all revisions to the PDL using the rulemaking process and shall publish the changes on the Division's Pharmaceutical Services provider rules website.

(4) Relative cost and best possible price determination:

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

(b) The Division may also consider dosing issues, patterns of use, and compliance issues. The Division shall weigh these factors with any advice provided by the P&T in reaching a final decision.

(5) Pharmacy providers shall dispense prescriptions in the generic form unless:

(a) The practitioner requests otherwise pursuant to OAR 410-121-0155;

(b) The Division notifies the pharmacy that the cost of the brand name particular drug, after receiving discounted prices and rebates, is equal to or less than the cost of the generic version of the drug.

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

(a) If the prescribing practitioner in their professional judgment wishes to prescribe a physical health drug not on the PDL, they may request an exception subject to the requirements of OAR 410-121-0040;

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

(c) Exceptions shall be granted when:

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

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

(7) Table 121-0030-1, PMPDP PDL dated July 1, 2016, is adopted and incorporated by reference and is found at: www.orpdl.org.

Stat. Auth.: ORS 413.032, 413.042, 414.065, 414.325, 414.330 to 414.414, 414.312, 414.316

410-121-0032 – Supplemental Rebate Agreements

(1) The Division of Medical Assistance Programs (Division) has a, Centers for Medicare and Medicaid Services (CMS) approved Supplemental Rebate Agreement. This template and instructions are available on the Oregon Health Authority's (Authority) web site at: www.oregon.gov/OHA/healthplan/pages/pharmacy-policy.aspx

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

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

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

(5) The Practitioner-Managed Prescription Drug List (PMPDP) also called the Preferred Drug List (PDL) consist of drugs after the Food and Drug Administration (FDA) has determined to be safe and effective and reimbursable as determined by the Centers for Medicaid and Medicare Services (CMS), and evaluated using an evidence-based review process by the Pharmacy & Therapeutics Committee (P&T) . If pharmaceutical manufacturers enter into supplemental rebate agreements with the SSDC, the Authority may include that drug on the PDL.

(6) Acceptance of the offer:

(a) The Division may accept an offer through the SSDC;

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

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

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

Stat. Auth.: ORS 409.025, 409.040, 409.110, 413.042 & 414.065 Stats. Implemented: ORS 414.065

410-121-0033 – Polypharmacy profiling

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

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

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

(a) Overuse of selected drug classes;

(b) Under-use of generic drugs;

(c) Therapeutic drug duplication;

(d) Drug to disease interactions;

(e) Drug to drug interactions;

(f) Inappropriate drug dosage;

(g) Drug selection for age;

(h) Duration of treatment;

(i) Clinical abuse or misuse.

(4) The Division Medical Director in conjunction with the Drug Use Review/Pharmacy & Therapeutics Committee will make final determinations on imposed drug prescription payment limitations relating to this policy.

Stat. Auth.: ORS 409.120, 413.042

Stats. Implemented: ORS 414.065

410-121-0040 – Prior Authorization Required for Drugs and Products (T)

(1) Prescribing practitioners shall obtain prior authorization (PA) for the drugs and categories of drugs requiring PA in this rule, using the procedures set forth 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 shall meet the following requirements for coverage:

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

(b) Each drug shall 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 Authority may require PA for individual drugs and categories of drugs to ensure that the drugs prescribed are indicated for conditions funded by OHP and consistent with the Prioritized List of Health Services and its corresponding treatment guidelines (see OAR 410-141-0480). The drugs and categories of drugs that the Authority requires PA for this purpose are found in the Oregon Medicaid Fee-for-Service Prior Authorization Approval Criteria (PA Criteria guide) dated July 1, 2016, adopted and incorporated by reference and found at:
http://www.oregon.gov/OHA/healthplan/pages/pharmacy-policy.aspx.

(4) The Authority 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 Pharmacy & Therapeutics Committee (P&T) and adopted by the Authority in this rule. The drugs and categories of drugs for which the Authority requires PA for this purpose are found in the Pharmacy PA Criteria Guide.

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

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

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

(c) PA criteria for all new drugs shall be reviewed by the DUR/P&T Committee.

(6) PA shall be obtained for brand name drugs that have two or more generically equivalent products available and that are not determined Narrow Therapeutic Index drugs by the DUR/P&T Committee:

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

(b) Manufacturers of immunosuppressant drugs used in connection with an organ transplant shall notify the Authority of patent expiration within 30 days of patent expiration for section (5)(a) to apply;

(c) Criteria for approval are:

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

(B) If section (6)(A) does not apply, the prescribing practitioner shall document that the use of the generically equivalent drug is medically contraindicated and provide evidence that either the drug has been used and has failed or that its use is contraindicated based on evidence-based peer reviewed literature that is appropriate to the client's medical condition.

(7) PA shall be obtained for non-preferred Preferred Drug List (PDL) products in a class evaluated for the PDL except in the following cases:

(a) The drug is a mental health drug as defined in OAR 410-121-0000;

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

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

(d) The prescription is a refill of an immunosuppressant.

(8) PA may not be required:

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

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

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

Stat. Auth.: ORS 413.032, 413.042, 414.065, 414.330 to 414.414, 414.312, 414.316

Stats. Implemented: 414.065, 414.334, 414.361, 414.371, 414.353, 414.354

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

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

(a) Call the Oregon Pharmacy Help Desk;

(b) FAX the request form shown in the Pharmaceutical Services Supplemental Information on the Oregon Health Authority's (Authority) web site to the Oregon Pharmacy Help Desk;

(c) Transmit the request electronically via the secure Medicaid Management Information Systems (MMIS) web portal.

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

(3) PA approval:

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

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

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

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

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

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

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

Stat. Auth.: ORS 409.025, 409.040, 409.110, 413.042 & 414.065

Stats. Implemented: ORS 414.065

410-121-0061 – Durable Medical Equipment, Medical Supplies, and Medical Surgical Services (Physician Administered Drugs)

Follow the guidelines in the Durable Medical Equipment and Medical Supplies (OAR 410 Division 122), Home Enteral/Parenteral Nutrition and IV Services (OAR chapter 410, division 148), and Medical Surgical Services (OAR chapter 410, division 130) administrative rules and supplemental information for billing and prior authorization of these medical supplies and services. This information is available on the Oregon Health Authority's web site.

Stat. Auth.: ORS 413.042

Stats. Implemented: ORS 414.065

410-121-0100 – Drug Use Review

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

(a) Information collected in a DUR program that identifies an individual is confidential;

(b) Staff of the Drug Use Review (DUR)/Pharmacy & Therapeutics (P&T) Committee and contractors may have access to identifying information to carry out intervention activities approved by the Division. The Division, DUR/P&T Committee or contractors shall adhere to all requirements of the Health Insurance Portability and Accountability Act (HIPAA) and all Division policies relating to confidential client information.

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

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

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

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

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

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

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

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

(a)The criteria used in retrospective DUR are compatible with those used in prospective DUR. Retrospective DUR criteria may include Pharmacy Management (Lock-In), Polypharmacy, and Psychotropic Use in Children. Drug therapy review is carried out by pharmacists with the Oregon State University College of Pharmacy, Drug Use Research and Management Program.

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

(4) The DUR/P&T Committee 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.

(b) The use of different types of education and interventions to be carried out or delegated by the P&T Committee and the evaluation of the results of this portion of the program; and

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

(A) DUR/P&T Committee Activities;

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

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

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

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

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

Stat. Auth.: ORS 413.042, 414.355, 414.360, 414.365, 414.370 & 414.380)

Stats. Implemented: ORS 414.065

410-121-0111 – Pharmacy & Therapeutics Committee

(1) Pursuant to Oregon Laws 2011, chapter 720 (HB 2100), the Drug Use Review Board (DUR Board) is abolished and the tenure of office for the members of the DUR Board expires. The legislature transferred the duties, functions and powers previously vested in the DUR Board to the Pharmacy and Therapeutics (P&T) Committee. This rule is retroactively effective on September 5, 2011, the date the P&T Committee was created and the DUR Board was abolished by HB 2100 and expires whenever the Oregon Health Authority (Authority) suspends the rule.

(2) Unless otherwise inconsistent with these administrative rules or other laws, any administrative rule or agency policy with reference to the DUR Board or a DUR Board volunteer, staff or contractor shall be considered to be a reference to the P&T Committee or a P&T Committee volunteer, staff or contractor. The current preferred drug list (PDL), prior authorization process, and utilization review process developed by the DUR Board remains in effect until such time as the Authority, after recommendations and advice from the P&T Committee, modifies them through the adoption of new administrative rules or policies and procedures.

(3) The P&T Committee shall advise the Oregon Health Authority (Authority) on the:

(a) Implementation of the medical assistance program retrospective and prospective programs, including the type of software programs to be used by the pharmacist for prospective drug use review and the provisions of the contractual agreement between the state and any entity involved in the retrospective program;

(b) Implementation of the Practitioner Managed Prescription Drug Plan (PMPDP);

(c) Adoption of administrative rules pertaining to the P&T Committee;

(d) Development of and application of the criteria and standards to be used in retrospective and prospective drug use review and safety edit programs in a manner that ensures that such criteria and standards are based on compendia, relevant guidelines obtained from professional groups through consensus-driven processes, the experience of practitioners with expertise in drug therapy, data and experience obtained from drug utilization review program operations. The P&T Committee must have an open professional consensus process, establish an explicit ongoing process for soliciting and considering input from interested parties, and make timely revisions to the criteria and standards based on this input and scheduled reviews;

(e) Development, selection and application of and assessment for interventions being educational and not punitive in nature for medical assistance program prescribers, dispensers and patients.

(4) The P&T Committee shall make recommendations to the Authority, subject to approval by the Director or the Director's designee, for drugs to be included on any PDL

adopted by the Authority and on the PMPDP. The P&T Committee shall also recommend all utilization controls, prior authorization requirements or other conditions for the inclusion of a drug on the PDL.

(5) The P&T Committee shall, with the approval of the Director or designee, do the following:

(a) Publish an annual report;

(b) Publish and disseminate educational information to prescribers and pharmacists regarding the P&T Committee and the drug use review programs, including information on the following:

(A) Identifying and reducing the frequency of patterns of fraud, abuse or inappropriate or medically unnecessary care among prescribers, pharmacists and recipients;

(B) Potential or actual severe or adverse reactions to drugs;

(C) Therapeutic appropriateness;

(D) Overutilization or underutilization;

(E) Appropriate use of generic products;

(F) Therapeutic duplication;

(G) Drug-disease contraindications;

(H) Drug-drug interactions;

(I) Drug allergy interactions;

(J) Clinical abuse and misuse.

(K) Patient safety

(6) Adopt and implement procedures designed to ensure the confidentiality of any information that identifies individual prescribers, pharmacists or recipients and that is collected, stored, retrieved, assessed or analyzed by the P&T Committee, staff of the P&T Committee, contractors to the P&T Committee or the Authority.

Stat. Auth.: ORS 413.042, 414.065, 414.355, 414.360, 414.365, 414.370, 414.380

Stats. Implemented: ORS 414.065

410-121-0135 – Pharmacy Management Program

(1) The Pharmacy Management Program promotes the appropriate use of quality pharmaceutical services by identifying and correcting overutilization of services.

(2) The Pharmacy Management Program limits some fee-for-service clients to receiving their prescription drugs through the following sources:

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

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

(c) A specialty pharmacy.

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

(a) Members enrolled in a Coordinated Care Organization;

(b) Clients with Medicare drug coverage in addition to OHP;

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

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

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

(a) Providers;

(b) Division staff; and

(c) Division contractors.

(5) Reasons for referring a client to the Division for potential enrollment in the Pharmacy Management Program shall be limited to factors that indicate possible overutilization or drug misuse, or that raise concern for patient safety. Those factors are:

(a) Use of three or more pharmacies during the prior six months;

(b) Fills prescriptions from more than one prescriber for the same or comparable medications; or

(c) Evidence that the client altered a prescription; or

(d) Exhibits behaviors or patterns of behavior that the Pharmacy and Therapeutics Committee has identified as indicative of intentional overutilization or misuse.

(6) Clients referred to the Division for potential enrollment in the Pharmacy Management Program shall be enrolled in the program only when a licensed pharmacist appointed by the Division conducts a review and concludes the individual utilized pharmaceutical items or services at a frequency or amount that is not medically necessary based on factors including, but not limited to, those described in subsection (5) of this rule.

(7) When the Division concludes enrollment in the Pharmacy Management Program is appropriate as described in subsection (6), the Division shall send the client a notice that provides the following information:

(a) The Division plans to require that the client use a designated pharmacy for a 12-month period;

(b) The specific date when the requirement will begin;

(c) An explanation of the reason for enrollment in the Pharmacy Management Program, and the benefits of enrollment in the Pharmacy Management Program; and

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

(A) A different designated pharmacy; and

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

(8) Changing the Pharmacy Management Program client’s enrolled pharmacy:

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

(A) Move out of area;

(B) Are reapplying for OHP benefits; or

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

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

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

(a) Is not available;

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

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

(10) Call the Oregon Pharmacy Help Desk for authorization to fill a prescription in the situations described in (9)(a)–(c) above.

(11) The client's appeal rights and the process for appealing a Division decision to enroll a client in the Pharmacy Management Program are found in OAR 410-120-1860. If the client requests an administrative hearing before the effective date of the client notice and requests that the services be continued, the Authority shall continue the services pursuant to OAR 410-120-1865.

Stat. Auth.: ORS 413.042 & 414.065

Stats. Implemented: ORS 414.065, OL 2013 Ch. 467 Sec. 2

410-121-0143 – Client Confidentiality

Pharmacists are responsible for maintaining the confidentiality of client information in compliance with Health Insurance Portability and Accountability Act (HIPAA) standards. Facilities shall provide adequate privacy for patient consultations.

Stat. Auth.: ORS 409.110 & 413.042

Stats. Implemented: 414.065

410-121-0145 – Prescription Requirements

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

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

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

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

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

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

Stat. Auth.: ORS 413.042, 414.065, 689.225, 689.305 & 689.508

Stats. Implemented ORS 414.065

410-121-0146 – Dispensing Limitations

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

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

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

(c) The quantity needed for Prescription Synchronization.

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

(3) The pharmacy may, at the client's direction, dispense less than the prescribed quantity of a maintenance medication in order to align the refill dates if the client has received the same dose for two months or more. (4) Unless otherwise specified in this rule, the Division will not reimburse claims for medications exceeding a 34-day supply.

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

(a) Ataractics, Tranquilizers — 07;

(b) Muscle Relaxants — 08;

(c) CNS Stimulants — 10;

(d) Psychostimulants, Antidepressants — 11;

(e) Amphetamine Preps — 12;

(f) Narcotic Analgesics — 40;

(g) Sedative Barbiturate — 46;

(h) Sedative Non-Barbiturate — 47.

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

(7) Except for medications listed in (5), claims for up to a 100-day supply of the following types of medications may be reimbursed to the Division's mail order pharmacy contractor, Indian Health mail order pharmacy providers, and 340B providers:

(a) A preferred PDL generic; and

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

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

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

(a) Have low probability for dosage or therapy changes due to side effects; and

(b) Are used most commonly to treat a chronic disease state and not considered curative or promoting recovery; and

(c) Are administered continuously rather than intermittently.

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

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

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

(13) Splitting prescriptions:

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

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

Stat. Auth.: ORS 413.042 & 414.065

Stats. Implemented: ORS 414.065

Table 121-0146-1 – Maintenance Medications

Drug Class (examples in parentheses)
ACE inhibitor/calcium channel blocker combos
ACE inhibitors (lisinopril)
ACE inhibitors/diuretic combos
Alpha/beta adrenergic blocking agents (carvedilol)
Alpha-glucosidase inhibitors (acarbose)
Antiarrythmics (quinidine)
Biguanides (metformin)
Contraceptives (does not require two previous fills)
Digitalis glycosides (digoxin, lanoxin)
Folic acid preparations
Hypotensive, sympatholytic (clonadine)
Hypotensive, vasodilators (prasozin)
Insulin release stimulant type (glipizide)
Insulin release stimulant/biguanide combo
Loop diuretics (furosemide)
Potassium replacement
Potassium sparing diuretics and combinations (spironolactone)
Prenatal vitamins
Thiazide and related diuretics (HCTZ)
Thyroid hormones (levothyroxine)

410-121-0147 – Exclusions and Limitations

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

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

(b) Home pregnancy kits;

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

(d) Expired drug products;

(e) Drug products from non-rebatable manufacturers, with the exception of selected oral nutritionals, vitamins, and vaccines;

(f) Active Pharmaceutical Ingredients (APIs) and Excipients as described by Centers for Medicare and Medicaid (CMS);

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

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

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

(j) Drug Efficacy Study Implementation (DESI) drugs (see OAR 410-121-0420);

(k) Medicare Part D covered drugs or classes of drugs for fully dual eligible clients (see OAR 410-121-0149, 410-120-1200, & 410-120-1210).

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

(3) Drugs requiring a skilled medical professional for safe administration will be billed by the medical professional's office; unless otherwise specified by the Division.

Stat. Auth.: ORS 413.042 & 414.065

Stats. Implemented: ORS 414.065 1-1-12

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

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

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

(2) An intermediate care facility is a facility providing regular health related care and services to individuals at a level above room and board, but less than hospital or skilled nursing levels ORS 442.015.

Stat. Auth.: 404.110, 413.042 & 414.065

Stats. Implemented: ORS 414.065

410-121-0150 – Billing Requirements

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

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

(A) The sum of charges for both the product cost and dispensing fee must not exceed a pharmacy's usual and customary charge for the same or similar service;

(B) When billing the Division for a prescription, the pharmacy shall bill the lowest amount accepted from any member of the general public who participates in the pharmacy provider's savings or discount program;

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

(c) Bill the actual metric decimal quantity dispensed;

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

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

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

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

(a) Non-billing NPI-assigned for prescription writing only;

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

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

(4) Billing for Death With Dignity services:

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

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

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

Stat. Auth.: ORS 413.042 & 414.065

Stats. Implemented: ORS 414.065

410-121-0155 – Reimbursement

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(c) The brand drug is listed on the Division's Preferred Drug List.

(7) No professional dispensing fee is allowed for dispensing pill splitters/cutters or diabetic supplies and glucose monitors which are exempt from co-payments under OHP General Rules.

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

(a) A practitioner prescription is required, and;

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

(9) A prescription is required for glucose monitors and related diabetic supplies.

(10) Payment for glucose monitors and related diabetic supplies billed with an NDC shall be reimbursed at a percentage of Medicare's rate for the HCPCS procedure code. The Division's reimbursement rates are listed in the DMAP fee schedule located at: www.oregon.gov/OHA/healthplan/pages/feeschedule.aspx

Stat. Auth.: ORS 184.750, 184.770, 413.042, & 414.065

Stats. Implemented: ORS 414.065

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 Patient Protection and Affordable Care Act (PPACA) enacted on March 23,2010 and the Health Care and Education Reconciliation Act of 2010, (HCERA) enacted on March 30, 2010, together called the Affordable Care Act, requires the Division to collect drug rebates for covered outpatient drugs dispensed to enrollees of Medicaid managed care organizations, (MCOs). The Medicaid Drug Rebate Program requires a drug manufacturer to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services for States to receive federal funding for outpatient drugs dispensed to Medicaid patients. The drug rebate program is administered by CMS's Center for Medicaid and State Operations (CMSO). Pharmaceutical companies participating in this program have signed agreements with CMS to provide rebates to the Division of Medical Assistance Programs (Division) on all their drug products. The Division will reimburse providers only for outpatient drug products manufactured or labeled by companies participating in this program.

(2) Documents in rule by reference: Names and Labeler Code numbers for participants in the Medicaid Drug Rebate Program are the responsibility of and maintained by CMS. The Division receives this information from CMS in the form of numbered and dated Releases. The Division includes in rule by reference, the CMS Releases online at http://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/program-releases.html.

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

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

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

Stat. Auth.: ORS 413.042 & 414.065

Stats. Implemented: ORS 414.065

410-121-0160 – Dispensing Fees

(1) Effective August 1, 2011 professional dispensing fees allowable for services shall be reimbursed as follows:

(a) All enrolled chain affiliated pharmacies shall be reimbursed at a rate of $9.68 per claim;

(b) Independently owned pharmacies in communities that are the only enrolled pharmacy within a fifteen (15) mile radius from another pharmacy shall be reimbursed at a dispensing fee of $14.01 per claim;

(c) All other enrolled independently owned pharmacies excluding those in 410-121-0160(b) shall be reimbursed based on an individual pharmacy's annual claims volume as follows:

(A) Less than 30,000 claims a year = $14.01;

(B) Between 30,000 and 49,999 claims per year = $10.14;

(C) 50,000 or more claims per year = $9.68.

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

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

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

(c) Completed surveys must be signed with a letter of attestation by the store owner or majority owner;;

(d) Pharmacies that fail to respond to the survey or do not include the letter of attestation shall default to the lowest dispensing tier;

(e) Once a tier is established for a calendar year, the pharmacy's dispensing fee shall remain in that tier until the next annual claims volume survey is conducted;

(f) Newly enrolled independent pharmacies shall be defaulted to the lowest dispensing tier until the next claims volume survey is conducted.

(3) All chain affiliated pharmacies shall be exempt from completing the annual claims volume survey.

Stat. Auth.: ORS 184.750, 184.770, 413.042, & 414.065

Stats. Implemented: ORS 414.065

410-121-0185 – Pharmacy Based Immunization Delivery

(1) When administering immunizations for adults (ages 19+) the pharmacy can bill either:

(a) Through Point-of-Sale (POS) using the appropriate National Drug Code (NDC) for the serum and the administration fee shall automatically be applied equivalent to Current Procedural Terminology (CPT) codes 90470-90474 ; or

(b) Bill on a CMS-1500, DMAP 505, or Provider Web Portal professional claim using the appropriate immunization CPT code for the serum; or

(c) Bill as a Provider Web Portal pharmacy claim.

(2) If billing as a professional claim, you must also include:

(a) A primary diagnosis to the highest degree of specificity, and;

(b) The appropriate CPT code for the serum, code ranges 90476-90749; and

(c) The appropriate CPT code for the administration, code ranges 90470-90474.

(3) Pursuant to ORS 689.205 and the Board of Pharmacy administrative rules 855-019-0270 through 855-019-0290; pharmacists may prescribe and administer vaccines to children who are from the age of 11 through 18 years of age only if the pharmacy is enrolled in the Vaccines for Children (VFC) Program. The Division will not reimburse providers the cost of privately purchased vaccination.

(4) If the pharmacy is enrolled in the VFC Program, then only the administration fee shall be reimbursed by the Division and must be billed on a professional claim. For detailed information on billing for the VFC Program, refer to Medical Surgical Services OAR 410-130-0255.

Stat. Auth.: ORS 413.042, & 414.065

Stats. Implemented: ORS 414.065

410-121-0190 – Medication Therapy Management Services and Clozapine Therapy Monitoring

(1) Clozapine monitoring protocol requires enhanced record keeping and reporting to the drug manufacturer's registry in order to dispense the medication. Dispensing pharmacy must meet all drug manufacturers requirements including data reporting.

(2) Clozapine monitoring includes documentation of client's diagnosis, dosage, dosage changes, appropriate laboratory reports (e.g. white blood cell counts), evaluation intervals, and submission of appropriate information to drug manufacturer to allow dispensing of medication;

(3) Clozapine monitoring is to be billed using appropriate Medication Therapy Management Services (MTMS) Current Procedural Terminology (CPT) code with the modifier TC appended. This is limited to no more than 5 units in 30 day time period per client, including the 30 day period from the date of discontinuation of clozapine therapy;

(4) Clozapine monitoring must be billed by a pharmacy;

(5) MTMS rendered outside of clozapine management must be performed by a licensed pharmacist and must be billed to appropriately reflect the performing provider. These encounters must be billed using the appropriate MTMS CPT code without the TC modifier.

Stat. Auth.: ORS 413.042 & 414.065

Stats. Implemented: ORS 414.065

410-121-0200 – Billing Forms

(1) Guidelines for using the Prescription Drug Invoice 5.1 Universal Claim Form:

(a) When a paper claim form is needed, this form is used to bill for all pharmacy services, home blood glucose monitors, and related diabetic supplies. These services must be billed with a National Drug Code (NDC);

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

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

(2) All other durable medical equipment and certain Enteral/Parenteral nutrition and IV services must be billed on the CMS-1500, using the billing instructions found in the Division's Durable Medical Equipment and Medical Supplies administrative rules (Division 122) and Supplemental Information, and the Division's Home Enteral/Parenteral Nutrition and IV Services Administrative rules (Division 148) and Supplemental Information. These services are billed with HCPCS procedure codes.

Stat. Auth.: ORS 413.042 & 414.065

Stats. Implemented: ORS 414.065

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 413.042, 414.034, & 414.065

Stats. Implemented: ORS 414.065

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 413.042, 414.034 & 414.065

Stat. Implemented: ORS 414.065

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

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

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

(3) The FUL drug listing is published in the State Medicaid Manual, Part 6, Payment for Services, Addendum A. The most current Transmittals and subsequent changes are posted to the CMS web site http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Federal-Upper-Limits.html.

Stat. Auth.: ORS 409.025, 409.040, 409.110, 413.042 & 414.065

Statutes Implemented: 414.065

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

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

(2) In accordance with Section 1903(i) (5) of the Social Security Act, federal funds participation (FFP) is not available for drugs deemed Less Than Effective (LTE) or Identical, Related of Similar (IRS) drugs for which the Food and Drug Administration (FDA) issued a Notice of Opportunity for a Hearing (NOOH) for all labeled indications. These drugs are also termed Drug Efficacy Study Implementation (DESI) drugs. the Division does not reimburse for drugs designated as less than effective or drugs identical, related, or similar to a DESI drug.

(3) A current list of LTE/IRS drugs is available at http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Medicaid-Drug-Rebate-Program-Data.html. The list is updated on approximately a quarterly basis by CMS after being reviewed for accuracy by the FDA.

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

Stat. Auth.: ORS 409.040, 413.042 & 414.325

Stats. Implemented: ORS 414.065

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

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

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

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

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

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

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

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

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

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

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

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

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

(5) Utilization/unit disputes shall be handled by a careful examination of paid claims data to determine the reasonableness of the reported units of products provided to Oregon recipients. If it is determined that the manufacturer is in error a letter notifying the manufacturer of the completed review and findings will be mailed to the

manufacturer and interest will accrue as set forth in the Rebate Agreement, Section V, Dispute Resolution.

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

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

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

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

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

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

Stat. Auth.: ORS 409.110 & 413.042

Stats. Implemented: ORS 414.065

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 over the counter items. The Division of Medical Assistance Programs (Division) requires that nursing facilities be billed for these items.

(2) The all-inclusive list is available for downloading in the Division of Medical Assistance Programs Web page on the Oregon Health Authority's (Authority) web site.

Stat. Auth.: ORS 409.025, 409.040, 409.110, 413.042 & 414.065

Stats. Implemented: ORS 414.065