

Certificate and Order for Filing
TEMPORARY ADMINISTRATIVE RULES
A Statement of Need and Justification accompanies this form.

I certify that the attached copies* are true, full and correct copies of the TEMPORARY Rule(s) adopted on upon filing by the
Date prior to or same as filing date.

Oregon Health Authority (OHA), Division of Medical Assistance Programs (Division) 410
Agency and Division Administrative Rules Chapter Number

Darlene Nelson 503-945-6927 503-947-5221 dar.l.nelson@state.or.us
Rules Coordinator Telephone Fax email

Communications Unit, 3rd Fl., DHS Bldg., 500 Summer St. NE-E35, Salem, Or. 97301-0177
Address

to become effective upon filing **through** 3/15/2012 .
Date upon filing or later A maximum of 180 days including the effective date.

RULEMAKING ACTION

Rule Filing Caption: Legislatively mandated implementation of Pharmacy & Therapeutics Committee.

ADOPT: 410-121-0110

AMEND: 410-121-0000, 410-121-0033, 410-121-0040 and 410-121-0100

Statutory Authority: ORS 409.025, 409.040, 409.110, 413.042, 414.065, 414.325, 414.355, 414.360, 414.365, 414.370, 414.380, Or Law 2011, chapter 720 (HB 2100)

Other Authority: None.

Statutes Implemented: 414.065; Or Law 2011, chapter 720 (HB 2100)

Subject Matter: The Division temporarily adopted OAR 410-121-0110 and amended 410-121-0000, 410-121-0040 and 410-121-0100 in order to comply with State and Federal mandates in regards to the Pharmacy & Therapeutics (P&T) Committee. New legislation abolished the Drug Use Review (DUR) Board, which performed the Federal requirements in the past. These rule revisions are retroactively effective to September 5, 2011 until it expires or the Division suspends the rule, whichever comes first.

410-121-0000: Multiple definitions added to clarify text in other rules assisting the P&T Committee operations.

410-121-0033: Update references to the abolished DUR Board and replace with P&T Committee.

410-121-0040: Update references to the abolished DUR Board and replace with P&T Committee.

410-121-0100: Remove information relating to the abolished DUR Board and replace with information about the new P&T Committee.

410-121-0110: Rule adopted to transfer and define duties from the abolished DUR Board to the P&T Committee.

The Division intends to permanently adopt rule revisions through the standard rule process which will allow for input from stakeholders and the public.

Authorized Signers: Judy Mohr Peterson 9-29-2011
Judy Mohr Peterson, Jean Phillips or Sandy Wood Date

Secretary of State
Statement of Need and Justification

A Certificate and Order for Filing Temporary Administrative Rules accompanies this form.

Oregon Health Authority (OHA), Division of Medical Assistance Programs (Division) 410
Agency and Division Administrative Rule Chapter Number

In the Matter of: The temporary amendment of rules that govern payment for the **Pharmaceutical Services Program**. The Division temporarily adopted 410-121-0110 and amended OAR 410-121-0000, 410-121-0033, 410-121-0040 and 410-121-0100.

Rule Filing Caption: Legislatively mandated implementation of Pharmacy & Therapeutics (P&T) Committee

Statutory Authority: ORS 409.025, 409.040, 409.110, 413.042, 414.065, 414.325, 414.355, 414.360, 414.365, 414.370, 414.380, Or Law 2011, chapter 720 (HB 2100)

Other Authority: None

Statutes Implemented: 414.065; Or Law 2011, chapter 720 (HB 2100)

Need for Rule(s): The **Pharmaceutical Services Program's** administrative rules govern Division payments for services provided to certain clients. The Division temporarily adopted OAR 410-121-0110 and amended 410-121-0000, 410-121-0033, 410-121-0040 and 410-121-0100 in order to comply with State and Federal mandates in regards to the Pharmacy & Therapeutics (P&T) Committee. New legislation abolished the Drug Use Review (DUR) Board, which performed the Federal requirements in the past. These rule revisions are retroactively effective to September 5, 2011 until it expires or the Division suspends the rule, whichever comes first.

410-121-0000: Multiple definitions added to clarify text in other rules assisting the P&T Committee operations.

410-121-0033: Update references to the abolished DUR Board and replace with P&T Committee

410-121-0040: Update references to the abolished DUR Board and replace with P&T Committee.

410-121-0100: Remove information relating to the abolished DUR Board and replace with information about the new P&T Committee.

410-121-0110: Rule adopted to transfer and define duties from the abolished DUR Board to the P&T Committee.

The Division intends to permanently adopt rule revisions through the standard rule process which will allow for input from stakeholders and the public.

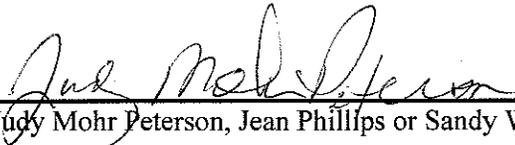
Justification of Temporary Rule(s): The Authority finds that time delays associated with the permanent rulemaking process vs. the temporary or emergent process will result in serious prejudice to the public interest by potentially resulting in non-compliance with both state and federal drug review obligations under Or Law 2011, chapter 720 (House Bill 2100) and 42 U.S.C.1396r-8, and result in serious prejudice to clients in Oregon's Medicaid Program by delaying the reassessment and update of preferred drug lists and prior authorization requirements. Effective September 5, 2011, the DUR Board that previously satisfied these federal and state requirements was abolished and replaced with the P&T Committee. The P&T Committee is charged with assessing the appropriateness, utilization, duplication, contraindications, interactions, dosage

and duration of treatment, abuse or misuse, and allergies in regards to Medicaid covered drugs. The State must retroactively adopt administrative rules to the effective date the legislature transferred the duties, functions and powers from the DUR Board to the P&T Committee to avoid a gap in the performance of these federal and state obligations, or delay the assessment and update of preferred drug lists and prior authorization requirements. Failure to comply with these requirements may put the State at risk for losing Federal Match dollars for reimbursement of drugs to OHP clients.

Documents Relied Upon, and where these can be viewed or obtained: Or Law 2011, chapter 720 (HB 2100): <http://www.leg.state.or.us/11reg/measpdf/hb2100.dir/hb2100.en.pdf>

Other Agencies affected:

Authorized Signers:

 9-29-2011
Judy Mohr Peterson, Jean Phillips or Sandy Wood Date

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);

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

(df) Average Net Price: The average of net price (definition below) of all drugs in an identified Preferred Drug List (PDL) (definition below) class or group;

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

(fh) 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;

(gi) 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));

(j) 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;

(hk) 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;

- (h) 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);

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

- (j) Director: The Director of the Authority;

- (k) Drug Order/Prescription:
 - (A) A medical practitioner's written or verbal instructions for a patient's medications; or
 - (B) A medical practitioner's written order on a medical chart for a client in a nursing facility;

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

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

(rn) 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;

(es) 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;

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

(qu) 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";

(fv) 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;

(~~sw~~) 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;

(~~tx~~) 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";

(~~uy~~) 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;

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

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

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

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

(~~ydd~~) Preferred Drug List (PDL): A PDL consists of prescription drugs in selected classes that the Authority, in consultation with the Health Resources Commission (HRC), has determined represent the most

effective drug(s) available at the best possible price. (See details for the Division's PMPDP PDL in OAR 410-121-0030):

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

(B) Voluntary Mental Health Preferred Drug List: The list of drug products used to treat mental health diagnosis. These drugs are exempt from client co-pay. Any drug prescribed for the treatment of mental health diagnosis shall be exempt from PA requirements by the Division;

(zee) 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;

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

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

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

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

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

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

(bhh) 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;

(~~ee~~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;

(~~dd~~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;

(~~ee~~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;

(~~ff~~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;

(~~gg~~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;

(~~hh~~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.

Stat. Auth.: ORS 409.025, 409.040, 409.110, 413.042, 414.065 &
414.325

Stats. Implemented: ORS 414.065

410-121-0033 Polypharmacy profiling

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

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

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

(a) Overuse of selected drug classes;

(b) Under-use of generic drugs;

(c) Therapeutic drug duplication;

(d) Drug to disease interactions;

(e) Drug to drug interactions;

(f) Inappropriate drug dosage;

(g) Drug selection for age;

(h) Duration of treatment;

(i) Clinical abuse or misuse.

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

Stat. Auth.: ORS 409.120, 413.042 & 414.380

Stats. Implemented: ORS 414.065

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

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

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

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

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

(3) The Oregon Health Authority (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 OHP Fee-For-Service Pharmacy PA Criteria Guide (PA Criteria Guide) dated Jan. 1, 2011, incorporated in rule by reference and found on our Web page at:

<http://www.dhs.state.or.us/policy/healthplan/guides/pharmacy/clinical.html>

(4) The 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 Drug Use Review (DUR) Board and

adopted by the Authority in this rule (see OAR 410-121-0100 for a description of the DUR program). 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 at the next quarterly DUR Board Pharmacy & Therapeutics (P&T) Committee meeting.

(6) PA is required for brand name drugs that have two or more generically equivalent products available and that are NOT determined Narrow Therapeutic Index drugs by the Oregon DUR Board P&T Committee:

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

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

(c) Criteria for approval are:

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

(B) If (6)(A) does not apply, the prescribing practitioner must document that the use of the generically equivalent drug is medically

contraindicated, and provide evidence that either the drug has been used and has failed or that its use is contraindicated based on evidence-based peer reviewed literature that is appropriate to the client's medical condition.

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

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

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

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

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

(8) PA may not be required:

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

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

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

Stat. Auth.: ORS Chap. 409.110, 413.042, 414.065, and 414.334

Stats. Implemented: 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 ~~DUR Board~~ 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 Board~~ 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 Board is a group of individuals who comprise an advisory committee to the Division:~~

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

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

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

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

~~(D) Medical quality assurance;~~

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

~~(A) Four practicing pharmacists;~~

~~(B) Five practicing physicians;~~

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

~~(D) One person actively practicing dentistry;~~

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

~~(d) Appointments to the DUR Board are made by the Division Director;~~

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

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

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

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

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

(5) The DUR Board 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. ~~Criteria and standards will be consistent with the following compendia:~~

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

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

~~(C) Drug DEX Information System;~~

~~(D) Peer-reviewed medical literature; or~~

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

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

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

(A) DUR Board 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 physician visits and hospitalizations.

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

Stats. Implemented: ORS 414.065

410-121-0110 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 on March 15, 2012 or whenever the Oregon Health Authority (Authority) suspends the rule, whichever comes first.

(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 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.

(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, Or Law 2011, chap. 720 (HB 2100)

Stats. Implemented: ORS 414.065, Or Law 2011, chap. 720 (HB 2100)