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PERMANENT ADMINISTRATIVE RULES

8-3

I certify that the attached copies* are true, full and correct copies of the PERMANENT Rule(s) adopted on [Aug 3, 2007] by the
Date prior to or same as filing date

Department of Administrative Services, Oregon Prescription Drug Program

409

Agency and Division

Administrative Rules Chapter Number

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to become effective [August 3]. Rulemaking Notice was published in the [7-1-07] Oregon Bulletin.**
Date upon filing or later Month and Year

RULE CAPTION

Oregon Prescription Drug Program amends eligibility requirements, eligibility definition, program price, and contracting rules.

RULEMAKING ACTION

FILED

AUG 03 2007

**ARCHIVES DIVISION
SECRETARY OF STATE**

ADOPT: 409-030-0065

AMEND: 409-030-0000, 409-030-0005, 409-030-0010, 409-030-0020, 409-030-0040, 409-030-0050

Stat. Auth.: ORS 414.312 to 414.320

Stats. Implemented: ORS 414.312 to 414.318; Or Laws 2007 Chapter ____ (Senate Bill 362)

RULE SUMMARY

These rules implement Ballot Measure 44 passed by majority vote of the people of the State of Oregon on November 7, 2006.

These rules implement Senate Bill 362 signed into law by Governor Kulongoski on April 26, 2007.

These rules amend the contracting authority delegated to DAS SPO.

Lindsay A. Ball

Lindsay Ball, DAS Director

08-03-07

Authorized Signer

Printed name

Date

*With this original, file one photocopy of certificate, one paper copy of rules listed in Rulemaking Actions, and electronic copy of rules. **The Oregon Bulletin is published the 1st of each month and updates rules found in the OAR Compilation. For publication in Bulletin, rule and notice filings must be submitted by 5:00 pm on the 15th day of the preceding month unless this deadline falls on a weekend or legal holiday, when filings are accepted until 5:00 pm on the preceding workday.

ARC 930-2005

OHP 3-2007

STATEMENT OF NEED AND FISCAL IMPACT

A Notice of Proposed Rulemaking Hearing or a Notice of Proposed Rulemaking accompanies this form.

DAS/OHPR/Oregon Prescription Drug Program

409

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Administrative Rules Chapter Number

In the Matter of:

Amend: 409-030-0000, 409-030-0005, 409-030-0010, 409-030-0020, 409-030-0040, and 409-030-0050

Adopt: 409-030-0065

Rule Caption: (Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.)

Oregon Prescription Drug Program implements Ballot Measure 44 and Senate Bill 362.

Statutory Authority: ORS 414.312 to 414.320

Stats. Implemented: ORS 414.312 to 414.318; Or Laws 2007 Chapter ____ (Senate Bill 362)

Need for the Rule(s):

These rules implement Ballot Measure 44 and Senate Bill 362.

Documents Relied Upon, and where they are available:

Ballot Measure 44 and Senate Bill 362

Fiscal and Economic Impact, including Statement of Cost of Compliance:

The overall economic impact of these proposed rules includes, for the general public and for businesses, the legislative expectation that making the cost of drugs more affordable to people who are uninsured or underinsured and to public and private entities and labor unions could result in health care cost savings and in a healthier population, reduced emergency room visits and death. Improving health and reducing emergency room visits could reduce state and business subsidized care for the uninsured population. The potential economic magnitude of these positive economic effects from this rule change cannot be quantified at this time, but positive effects have been validated in publicly available information about the benefits of increasing access to health care for the underinsured. Anticipated specific fiscal and economic impacts are discussed below.

For the uninsured or underinsured part of the program:

The legislative expansion being implemented is intended to make prescription drugs more affordable for the general public, by adding individuals who have no insurance or who are underinsured. Individuals with Medicare drug coverage are eligible to participate. The Staff Measure Summary for Senate Bill 362 (3/27/07) noted that as of February 2007, "OPDP has enrolled approximately 12,500 people with an average savings of \$28 per prescription."

Eligible individuals are not charged a fee to enroll with OPDP. Individuals should experience no costs to enroll, since they can now do so by phone, online or by paper application. Senate Bill 362 removed the annual renewal process, so individuals will not experience any enrollment-related costs after their initial enrollment. At the point of sale, they must pay for their prescription drugs as an out-of-pocket cost. In most cases the price they pay using an OPDP card is reduced in comparison to the purchase price they would pay if the pharmacy did not apply the OPDP price. In some cases the pharmacy's usual cost may be less than the

OPDP price and in that case it will be charged instead of the OPDP price. The cost of administration is borne by the OPDP participants through a small per claim assessment (currently \$1 per claim) included in the program price at the time the prescription is purchased.

For group business (government, private entities and labor organizations):

The legislative expansion being implemented added private entities and labor organizations to the groups of entities that can participate in OPDP. Group enrollment is coordinated by OPDP's pharmacy benefit administrator. With these additions, it is anticipated that all types of private entities of all sizes may participate in OPDP. Participating groups should experience positive financial benefit from being able to participate in reduced drug costs for their group enrollees. In some cases, entities may be able to offer this benefit for the first time for their group enrollees. Private entities and labor unions that already provide prescription drug benefits for their enrollees will now have OPDP as one of their choices about how to arrange for drug benefit coverage. OPDP is unable to determine the extent of savings that may be obtained by participating entities or their enrollees. The cost of administration is borne by groups through a per claim assessment, potentially offset by rebates and credits based on their claims experience. Their group enrollees will be provided an OPDP card, which may be used at participating pharmacies to obtain their prescription drugs at the OPDP program price and in accordance with their group benefit plans.

State agencies, local governments, OHSU and special government bodies have been eligible to participate prior to the passage of Ballot Measure 44 and Senate Bill 362, although additional governmental entity participation may occur. (The Medicaid program is not eligible to participate.) To the extent that additional governmental entities can experience a reduction in their drug costs, the extent of such savings is speculative at this time.

Impact on pharmacies. Pharmacy participation remains voluntary. With approximately 70% of Oregon pharmacies opting into the program, more pharmacies see a benefit rather than a detriment to joining the network. Pharmacies collect a small dispensing fee to offset their dispensing costs, which is a normal practice for pharmacies. Pharmacies that would like to participate in OPDP must sign an agreement establishing the basic conditions of participation. That agreement establishes the discount rate that the pharmacy agrees to provide to OPDP enrollees. If ongoing OPDP negotiations with manufacturers are successful, this financial impact on pharmacies could be reduced. As the OPDP rate is expanded to a broader population of uninsured and underinsured and additional group enrollees, pharmacies will be selling more drugs at the OPDP rate. Increased sales volume at a reduced price could impact profit margin, but it may also provide an opportunity for an increase in non-pharmaceutical sales. The potential magnitude of the impact of selling more drugs at OPDP rates can't be quantified at this time, because of varying factors including the number of participating pharmacies and the wide range of wholesale acquisition costs that could impact the net financial effect on each pharmacy.

Impact on drug manufacturers and distributors. OPDP has no basis for evaluating the fiscal impact of these proposed rules on drug manufacturers and distributors. OPDP anticipates that affordable drugs may allow more individuals to obtain their prescriptions, potentially generating additional revenues for manufacturers and distributors. Discount drug prices are common in the health care industry, and OPDP expects to seek rebates or additional discounts from manufacturers. OPDP has no basis for evaluating the extent to which reduced sales prices for drugs, rebates and additional discounts could reduce revenues for manufacturers or distributors, or the potential for increased revenues due to increased sales volumes.

Impact on other health care sectors and the general public. The legislative expansions provide opportunities for the general public to participate in OPDP to achieve reduced out of pocket expense for prescription drugs. Individuals with health insurance and prescription drug coverage may not have a direct impact unless their sponsor or insurer chooses to provide their benefit through OPDP. However those individuals may

consider that they are underinsured for their prescription coverage and may join as the OPDP to take advantage of OPDP rates during periods of high deductible or to purchase drugs not covered by their carrier. Health insurers and workers compensation carriers may consider OPDP as a potential option for providing coverage; or consider ways to develop their own cost-savings within their competitive markets. Non-participating pharmacies avoid the OPDP discount impact, but also lose access to the OPDP enrollees for their pharmacy business. Hospitals, long-term care providers, and other health care providers are also affected by changes in health care costs. Healthier patients may mean fewer visits but better health outcomes if affordable drugs allow the patients to remain compliant with their prescribed drug regimes.

Estimate of number of small businesses subject to the proposed rule and identification of types of businesses and industries with small businesses subject to the proposed rule: Because of the changes made in Senate Bill 362, private entities and labor unions may participate in OPDP, which may include small businesses from every economic sector in the State. Because these are new eligibility types, OPDP is unable to determine the number of small businesses that may choose to participate. One type of small businesses subject to the proposed rule are pharmacies that are small businesses. Whether they are affected by the proposed rule depends on their voluntary decision to participate in the OPDP as a participating pharmacy.

Projected reporting, recordkeeping and other administrative activities required of small businesses for compliance: Small businesses that would like to participate in the group enrollment process will be required to provide information about their group enrollees to OPDP's third party administrator, distribute group enrollee identification cards, and participate in claims reimbursement processes that will be coordinated with OPDP's third party administrator.

Small businesses that are pharmacies that would like to participate as OPDP pharmacies must sign an agreement with OPDP and meet the recordkeeping requirements associated with the sale of the prescribed drugs in coordination with OPDP's third party administrator for claims administration. Since pharmacies already must comply with similar requirements for most other claims processes, it is not anticipated that these rules impose any significant additional burdens on small businesses that voluntarily choose to participate with OPDP.

Equipment, supplies, labor and administration required for small businesses: Small businesses that choose to participate in the group enrollment process will have some administration requirements in connection with the OPDP contract. If the small business already provides health insurance coverage, these OPDP administrative costs will be similar. If the small business is not experienced with group coverage, administration will include providing information about their group enrollees to OPDP, distributing group enrollee identification cards, and participating in claims reimbursement processes that will be coordinated with OPDP's third party administrator. Pharmacies that choose to participate already have the necessary point-of-sale equipment and staff to process pharmacy claims.

How were small businesses involved in the development of this rule?

These rules were developed to implement voter and legislative directive. There was no organized opposition to the ballot measure approved by 78% of the voters. Some small business owners including one pharmacist wrote arguments in favor of the ballot measure. Small businesses testified in favor of the legislative directive. The pharmacy association did not oppose the Ballot Measure or the Senate Bill.

Administrative Rule Advisory Committee consulted? No. If not, why not? The proposed rule implements voter and legislative directive. OPDP participated in legislative hearings and discussions with legislators about Senate Bill 362. The high level of public interest in this program has generated substantial input from interested stakeholders.

Cheryl Knotttingham
Signature

Cheryl Knotttingham DAS, DAR Coord.
Printed name

6/12/07
Date

Administrative Rules Unit, Archives Division, Secretary of State, 800 Summer Street NE, Salem, Oregon 97310. ARC 925-2005

409-030-0000

Definitions

- (1) Administrator -- The Administrator of the Oregon Prescription Drug Program.
- (2) Department -- The Department of Administrative Services acting by and through the Administrator of the Oregon Prescription Drug Program, the Office of Health Policy and Research, and any other office of the Department.
- (3) Contractor(s) -- One or more PBAs or TPAs authorized by the Oregon Prescription Drug Program (OPDP) to perform administrative duties of the program including but not limited to processing and paying claims, issuing I.D. cards and maintaining eligibility files.
- (4) Enrollee -- Any person who meets the eligibility requirements of the Oregon Prescription Drug Program according to ORS 414.312 (c) or (f) pays the applicable enrollment fee and is issued an enrollment card.
- (5) OPDP -- Oregon Prescription Drug Program
- (6) Participating Groups -- Agencies or institutions eligible to participate in the OPDP according to ORS 414.312(4) (a) (b) (d) (e) (g) or (h). Group Enrollee means any person who is issued an OPDP I.D. card through a Participating Group.
- (7) PDL -- Preferred Drug List
- (8) Pharmacy Benefit Administrator (PBA) -- An entity that, in addition to being a prescription drug claims processor, negotiates and executes contracts with pharmacies, manages preferred drug lists, negotiates rebates with prescription drug manufacturers and serves as an intermediary between the Administrator, prescription drug manufacturers and pharmacies.
- (9) Pharmacy providers -- Retail drug outlets that volunteer to participate in the Oregon Prescription Drug Program and that contract with the Department as a pharmacy provider.
- (10) Prescription drugs -- Drugs that must legally be prescribed by a practitioner authorized to prescribe drugs (legend drugs).
- (11) Prescription drug claims processor -- An entity that processes and pays prescription drug claims, transmits prescription drug prices and claims data between pharmacies and the OPDP and processes payments to pharmacies.
- (12) Program Price -- The reimbursement rates and prescription drug prices established by the Administrator of the Oregon Prescription Drug Program (OPDP), including program cost and the dispensing fee and all applicable manufacturers discounts and rebates.
- (13) Rebates -- Promotional or volume related refunds pre-arranged with manufacturers on certain prescription drugs used to reduce the cost to purchaser.

(14) Third Party Administrator (TPA) -- An entity that, in addition to being a prescription drug claim processor, facilitates program management including processing and paying prescription drug claims; transmitting prescription drug prices and claims and enrollment data between pharmacies and the OPDP and its groups; maintaining enrollment and issuing I.D. cards; and processing payments to pharmacies. The TPA could be contracted through the Department or PBAs.

Stat. Auth.: ORS 414.320

Stats. Implemented: ORS 414.312 - 414.320

409-030-0005

General Administration

(1) The purpose of these rules is to implement the Oregon Prescription Drug Program authorized in ORS 414.312 to 414.318.

(2) The Administrator will administer and implement the OPDP.

(3) The Administrator may enter into contracts with one or more PBAs or TPAs to assist in the administration of the OPDP.

(4) The Administrator, or designee, may:

(a) Negotiate price discounts and rebates on prescription drugs with prescription drug manufacturers;

(b) Purchase prescription drugs on behalf of Enrollees and Participating Groups;

(c) Contract with a prescription drug claims processor to adjudicate pharmacy claims and transmit program prices to pharmacies;

(d) Determine Program Prices and reimburse pharmacies for prescription drugs;

(e) Adopt and implement a Preferred Drug List for the program;

(f) Develop a system for allocating and distributing the operational costs of the program and any Rebates obtained to participants of the program; and

(g) Cooperate with any state or regional consortia in the bulk purchase of prescription drugs.

(3) The Administrator may adopt rules and develop forms to implement the OPDP.

(4) The Administrator is authorized to oversee the implementation of the OPDP, including review of Enrollee eligibility information, Participating Group information, and pharmacy provider compliance with the requirements of the program. The Administrator, or designee, may

review such records or other information, including health information, necessary to perform such oversight responsibilities.

Stat. Auth.: ORS 414.320

Stats. Implemented: ORS 414.312 - 414.320

409-030-0010

Pharmacy Providers

(1) To be a pharmacy provider under the Oregon Prescription Drug Program (OPDP), the pharmacy must contract with the Department of Administrative Services (Department) and the pharmacy provider must be licensed with the State of Oregon Board of Pharmacy as a pharmacy in Oregon.

(2) Signing the pharmacy provider contract constitutes agreement by the pharmacy provider to comply with all applicable state and federal laws and regulations, including these rules, and the terms and conditions of the contract. The contract authorizes the pharmacy to serve Enrollees in OPDP and outlines program compliance requirements.

(3) A contract may be issued to a qualified pharmacy provider upon:

(i) Completion and signing of the contract by the pharmacy provider or a person authorized by the pharmacy provider to bind the organization to compliance with these rules;

(j) Verification of pharmacy licensing with the Oregon Board of Pharmacy. Loss of the appropriate licensure will result in immediate termination of the OPDP contract; and

(k) Approval of the contract by the Department of Administrative Services.

(4) To contract for the OPDP, the pharmacy provider must agree to:

(a) Accept the Program Price in effect on the date of the transaction as established by the Administrator including but not limited to dispensing fees which may be charged to the Enrollee;

(b) Keep sufficient documentation of transactions to resolve disagreements with the Enrollee about the amount charged for the prescription drugs;

(c) Reimburse the Enrollee or Participating Group directly for overcharges as determined by Program Price in effect on the date of the transaction.

(d) Cooperate with the Contractor designated by the Administrator for claims processing, reimbursement, and such other tasks as necessary to administer the OPDP, including providing access to records.

(e) Agree to not charge Enrollees for costs incurred by the pharmacy provider for the electronic transmittal of the Program Price from the Department to the pharmacy.

(5) Advertising:

(a) A pharmacy provider may advertise that it participates in the OPDP;

(b) Advertising or marketing materials must be accurate and not misleading or confusing to Enrollees or to the public about participation in the OPDP or the savings offered by the pharmacy provider.

(c) The pharmacy provider must stop all advertisements pertaining to participation in the program if the Department suspends or terminates the contract.

(6) The Administrator may, at its discretion, suspend or remove a pharmacy provider from the OPDP if the pharmacy provider fails to comply with any material term or condition of its contract or these rules.

Stat. Auth.: ORS 414.320

Stats. Implemented: ORS 414.312 - 414.320

409-030-0020

Program Price

(1) The price for a prescription drug a pharmacy provider can charge an Enrollee under the Oregon Prescription Drug Program (OPDP) is the lesser of the following on the date of the transaction:

(a) The Program Price, or

(b) The pharmacy provider's usual and customary price, including program cost and dispensing fee.

(2) The Contractor will transmit the price of the prescription drugs to the pharmacy providers electronically.

(3) The OPDP is limited to prescription drugs prescribed in the name of and for the use by the Enrollee, except as otherwise provided in section (8) of this Rule.

(4) Prescription drug benefits will be outlined on Enrollee and Group Enrollee identification cards.

(5) The OPDP does not include prescriptions for over-the-counter drugs.

(6) The Administrator may establish different reimbursement rates or prescription drug prices for pharmacies in rural areas to maintain statewide access to the OPDP.

(7) Certain Participating Groups may receive the Program Price based on other reimbursement arrangements with OPDP, where the prescription drug is not being dispensed by a pharmacy provider to an individual Group Enrollee. Such reimbursement arrangements shall be approved and arranged by the PBA or TPA, as appropriate.

Stat. Auth.: ORS 414.320

Stats. Implemented: ORS 414.312 - 414.320

409-030-0040

Participating Groups and Small Entity Participating Groups

(1) The Administrator may establish processes, terms and conditions describing how the entities identified in ORS 414.312(4) may participate in the OPDP as a Participating Group, including such entities otherwise subject to ORS 731.036(6).

Stat. Auth.: ORS 414.320

Stats. Implemented: ORS 414.312 - 414.320

409-030-0050

Enrollment

(1) Participating Groups. Participating Groups will enroll for participation through the PBA or TPA chosen by the OPDP to administer the Participating Group's enrollment and claims processing.

(a) Eligibility for Group Enrollees of a Participating Group will be maintained electronically between the group and PBA or TPA.

(b) I.D. cards will be issued for Group Enrollees through the Participating Group at initial enrollment and renewals, and to individuals within the group between those times as needed.

(2) Individual Enrollees. Oregon who do not have prescription drug coverage or who are underinsured for prescription drug coverage and enrollees in the Senior Prescription Drug Assistance Program created under ORS 414.342 may be enrolled by the PBA or TPA.

(a) I.D. cards will be issued for Enrollees by the PBA or TPA.

(b) Individuals who are eligible for Medicare Part D prescription drug coverage may participate in the program.

(3) The OPDP may charge a nominal fee to participate in the program.

Stat. Auth.: ORS 414.320

Stats. Implemented: ORS 414.312 - 414.320

409-030-0060

Contracted Services

The Administrator of the Oregon Prescription Drug Program (OPDP) has procurement authority for goods and services to implement and administer ORS 414.312 to 414.318. The Administrator recognizes the benefits of statewide consistency and expertise when certain procurements under OPDP authority are instead procured for OPDP by the Department of Administrative Services. Therefore:

(1) OPDP adopts the public contracting rules in OAR Chapter 125 division 246 (General Provisions Related to Public Contracting) and division 247 (Public Procurements of Supplies and Services) (effective May 31, 2006) as the contracting rules that will apply to its procurements, except as otherwise provided in section (4) of this rule. The terms used in this rule will have the meaning set forth in the OAR 125 divisions 246 and 247.

(2) The Administrator of OPDP delegates procurement authority to the Chief Procurement Officer of the Department of Administrative Services for goods and services for OPDP, except as otherwise provided in section (4) of this rule. Procurements under this delegation shall be processed in accordance with OAR ch. 125, divisions 246 and 247.

(3) The Administrator of OPDP shall act as the agency's representative for each Contract. The Administrator may delegate in writing the representative's responsibilities to a designee. The agency's representative may participate with the Designated Procurement Officer assigned by the Chief Procurement Officer in all aspects of procurement.

(4) OPDP's mechanism for and administration of the enrollment of participating pharmacy providers or Participating Groups do not constitute procurements subject to this rule. The Administrator of OPDP may delegate to DAS on a case-by-case basis, by written agreement, procurement authority for such matters. Procurements under such a delegation shall be processed in accordance with OAR divisions 246 and 247.