

Enrolled
Senate Bill 819

Sponsored by Senator CLARNO; Senators L BEYER, BROWN, BURDICK, CASTILLO, CORCORAN, DUNCAN, HARTUNG, MESSERLE, METSGER, MINNIS, Representatives NELSON, NOLAN, C WALKER

CHAPTER

AN ACT

Relating to Oregon Health Plan; creating new provisions; amending ORS 414.325; and declaring an emergency.

Be It Enacted by the People of the State of Oregon:

SECTION 1. The Legislative Assembly finds that:

- (1) The cost of prescription drugs in the Oregon Health Plan is growing and will soon be unsustainable;
- (2) The benefit of prescription drugs when appropriately used decreases the need for other expensive treatments and improves the health of Oregonians; and
- (3) Providing the most effective drugs in the most cost-effective manner will benefit both patients and taxpayers.

SECTION 2. It is the policy of the State of Oregon that a Practitioner-managed Prescription Drug Plan will ensure that:

- (1) Oregonians have access to the most effective prescription drugs appropriate for their clinical conditions;
- (2) Decisions concerning the clinical effectiveness of prescription drugs are made by licensed health practitioners, are informed by the latest peer-reviewed research and consider the health condition of a patient or characteristics of a patient, including the patient's gender, race or ethnicity; and
- (3) The cost of prescription drugs in the Oregon Health Plan is managed through market competition among pharmaceutical manufacturers by publicly considering, first, the effectiveness of a given drug and, second, its relative cost.

SECTION 3. (1) The Department of Human Services shall adopt a Practitioner-managed Prescription Drug Plan for the Oregon Health Plan. The purpose of the plan is to ensure that enrollees of the Oregon Health Plan receive the most effective prescription drug available at the best possible price.

(2) Before adopting the plan, the department shall conduct public meetings and consult with the Health Resources Commission.

(3) The department shall consult with representatives of the regulatory boards and associations representing practitioners who are prescribers under the Oregon Health Plan and ensure that practitioners receive educational materials and have access to training on the Practitioner-managed Prescription Drug Plan.

(4) Notwithstanding the Practitioner-managed Prescription Drug Plan adopted by the department, a practitioner may prescribe any drug that the practitioner indicates is medically necessary for an enrollee as being the most effective available.

(5) An enrollee may appeal to the department a decision of a practitioner or the department to not provide a prescription drug requested by the enrollee.

(6) This section does not limit the decision of a practitioner as to the scope and duration of treatment of chronic conditions, including but not limited to arthritis, diabetes and asthma.

SECTION 4. The President of the Senate and the Speaker of the House of Representatives shall designate an appropriate interim legislative committee or legislative commission to:

(1) Receive regular reports on the development and implementation of the Practitioner-managed Prescription Drug Plan;

(2) Review the impact of the implementation of the Practitioner-managed Prescription Drug Plan, including but not limited to a review of whether the program realizes any savings, whether there is an increase in physician and hospital costs for individuals receiving medical assistance, and whether there is an impact on the ability of an individual receiving medical assistance to obtain prescribed drugs; and

(3) Report its findings and recommendations periodically to the Emergency Board and to the Seventy-second Legislative Assembly.

SECTION 5. ORS 414.325 is amended to read:

414.325. (1) As used in this section, "legend drug" means any drug requiring a prescription by a practitioner, as defined in ORS 689.005.

(2) A licensed practitioner may prescribe such drugs under this chapter as the practitioner in the exercise of professional judgment considers appropriate for the diagnosis or treatment of the patient in the practitioner's care and within the scope of practice. Prescriptions shall be dispensed in the generic form pursuant to ORS 689.515, 689.854 and 689.857 and pursuant to rules of the [division] Department of Human Services unless the practitioner prescribes otherwise and an exception is granted by the [division] department.

(3) [Except as provided in subsections (4) and (5) of this section, the division shall place no limit on the type of legend drug that may be prescribed by a practitioner, but] The department shall pay only for drugs in the generic form if the federal Food and Drug Administration has approved a generic version of a particular brand name drug that is chemically identical to the brand name drug according to federal Food and Drug Administration rating standards, unless an exception has been granted by the [division] department.

(4) [Notwithstanding subsection (3) of this section,] An exception must be applied for and granted before the [division] department is required to pay for minor tranquilizers and amphetamines and amphetamine derivatives, as defined by rule of the [division] department.

(5)[(a)] Notwithstanding subsections (1) to (4) of this section, [and except as provided in paragraph (b) of this subsection, the division] the department is authorized to:

[(A)] (a) Withhold payment for a legend drug when federal financial participation is not available; and

[(B)] (b) Require prior authorization of payment for drugs [which] that the [division] department has determined should be limited to those conditions generally recognized as appropriate by the medical profession.

[(b) The division may not require prior authorization for therapeutic classes of non-sedating antihistamines and nasal inhalers, as defined by rule by the division, when prescribed by an allergist for treatment of any of the following conditions, as described by the Health Services Commission on the funded portion of its prioritized list of services:]

[(A) Asthma;]

[(B) Sinusitis;]

[(C) Rhinitis; or]

[(D) Allergies.]

(6) Notwithstanding subsection (3) of this section, the department may not limit legend drugs when used as approved by the federal Food and Drug Administration to treat mental illness, HIV and AIDS, and cancer.

SECTION 5a. If House Bill 2497 becomes law, section 5 of this 2001 Act (amending ORS 414.325) is repealed and ORS 414.325, as amended by section 1, chapter _____, Oregon Laws 2001 (Enrolled House Bill 2497), is amended to read:

414.325. (1) As used in this section:

(a) "Legend drug" means any drug requiring a prescription by a practitioner.

(b) "Pharmacy network" means a group of pharmacies using a shared database or employing other electronic means to access prescription information of enrollees from multiple points of service.

(c) "Practitioner" has the meaning given that term in ORS 689.005.

(2) A licensed practitioner may prescribe such drugs under this chapter as the practitioner in the exercise of professional judgment considers appropriate for the diagnosis or treatment of the patient in the practitioner's care and within the scope of practice. Prescriptions shall be dispensed in the generic form pursuant to ORS 689.515, 689.854 and 689.857 and pursuant to rules of the Department of Human Services unless the practitioner prescribes otherwise and an exception is granted by the department.

(3) [Except as provided in subsections (4) and (5) of this section, the department shall place no limit on the type of legend drug that may be prescribed by a practitioner, but] **The department shall pay only for drugs in the generic form if the federal Food and Drug Administration has approved a generic version of a particular brand name drug that is chemically identical to the brand name drug according to federal Food and Drug Administration rating standards, unless an exception has been granted by the department.**

(4) [Notwithstanding subsection (3) of this section,] An exception must be applied for and granted before the department is required to pay for minor tranquilizers and amphetamines and amphetamine derivatives, as defined by rule of the department.

(5)(a) Notwithstanding subsections (1) to (4) of this section [and except as provided in paragraph (b) of this subsection], the department is authorized to:

(A) Withhold payment for a legend drug when federal financial participation is not available; and

(B) Require prior authorization of payment for drugs [which] that the department has determined should be limited to those conditions generally recognized as appropriate by the medical profession.

[(b) The department may not require prior authorization for therapeutic classes of non-sedating antihistamines and nasal inhalers, as defined by rule by the department, when prescribed by an allergist for treatment of any of the following conditions, as described by the Health Services Commission on the funded portion of its prioritized list of services:]

[(A) Asthma;]

[(B) Sinusitis;]

[(C) Rhinitis; or]

[(D) Allergies.]

[(c)] (b) Notwithstanding subsections (1) to (4) of this section and [paragraphs (a) and (b)] paragraph (a) of this subsection, the department may require prior authorization of payment for drugs for individuals whose prescription drug use exceeded 15 drugs in the preceding six-month period.

(6) Notwithstanding subsection (3) of this section, the department may not limit legend drugs when used as approved by the federal Food and Drug Administration to treat mental illness, HIV and AIDS, and cancer.

[(6)] (7) When a practitioner prescribes a legend drug under this chapter, the practitioner shall write on the prescription:

(a) The diagnosis code for the condition on the prioritized list of services covered for payment for which the legend drug is being prescribed; and

(b) The practitioner's Office of Medical Assistance Programs provider number.

[(7)(a)] (8)(a) At the time of enrollment or reenrollment in a fee-for-service payment system, an enrollee shall designate a primary pharmacy or pharmacy network to dispense legend drugs covered by the medical assistance program.

(b) The department shall adopt rules establishing procedures that allow an enrollee to:

(A) Obtain a legend drug at a pharmacy other than a designated primary pharmacy or pharmacy network; and

(B) Change a designation of a primary pharmacy or pharmacy network.

[(8)] (9) The department shall adopt rules that:

(a) Establish procedures to ensure that a primary pharmacy or pharmacy network will receive notice when an enrollee obtains a legend drug at another pharmacy; and

(b) Allow payment at the point of sale to a pharmacy other than a primary pharmacy or pharmacy network for a legend drug obtained by an enrollee as described in subsection [(7)(b)(A)]

(8)(b)(A) of this section.

SECTION 6. ORS 414.325, as amended by section 5 of this 2001 Act, is amended to read:

414.325. (1) As used in this section, "legend drug" means any drug requiring a prescription by a practitioner, as defined in ORS 689.005.

(2) A licensed practitioner may prescribe such drugs under this chapter as the practitioner in the exercise of professional judgment considers appropriate for the diagnosis or treatment of the patient in the practitioner's care and within the scope of practice. Prescriptions shall be dispensed in the generic form pursuant to ORS 689.515, 689.854 and 689.857 and pursuant to rules of the Department of Human Services unless the practitioner prescribes otherwise and an exception is granted by the department.

(3) **Except as provided in subsections (4) and (5) of this section, the department shall place no limit on the type of legend drug that may be prescribed by a practitioner, but the department shall pay only for drugs in the generic form [if the federal Food and Drug Administration has approved a generic version of a particular brand name drug that is chemically identical to the brand name drug according to federal Food and Drug Administration rating standards,] unless an exception has been granted by the department.**

(4) **Notwithstanding subsection (3) of this section, an exception must be applied for and granted before the department is required to pay for minor tranquilizers and amphetamines and amphetamine derivatives, as defined by rule of the department.**

(5)(a) **Notwithstanding subsections (1) to (4) of this section and except as provided in paragraph (b) of this subsection, the department is authorized to:**

[(a)] (A) Withhold payment for a legend drug when federal financial participation is not available; and

[(b)] (B) Require prior authorization of payment for drugs that the department has determined should be limited to those conditions generally recognized as appropriate by the medical profession.

(b) **The department may not require prior authorization for therapeutic classes of non-sedating antihistamines and nasal inhalers, as defined by rule by the department, when prescribed by an allergist for treatment of any of the following conditions, as described by the Health Services Commission on the funded portion of its prioritized list of services:**

(A) Asthma;

(B) Sinusitis;

(C) Rhinitis; or

(D) Allergies.

[(c)] **Notwithstanding subsection (3) of this section, the department may not limit legend drugs when used as approved by the federal Food and Drug Administration as the primary treatment for mental illness, HIV and AIDS and cancer.]**

SECTION 6a. If House Bill 2497 becomes law, section 6 of this 2001 Act (amending ORS 414.325) is repealed and ORS 414.325, as amended by section 5a of this 2001 Act, is amended to read:

414.325. (1) As used in this section:

(a) "Legend drug" means any drug requiring a prescription by a practitioner.

(b) "Pharmacy network" means a group of pharmacies using a shared database or employing other electronic means to access prescription information of enrollees from multiple points of service.

(c) "Practitioner" has the meaning given that term in ORS 689.005.

(2) A licensed practitioner may prescribe such drugs under this chapter as the practitioner in the exercise of professional judgment considers appropriate for the diagnosis or treatment of the patient in the practitioner's care and within the scope of practice. Prescriptions shall be dispensed in the generic form pursuant to ORS 689.515, 689.854 and 689.857 and pursuant to rules of the Department of Human Services unless the practitioner prescribes otherwise and an exception is granted by the department.

(3) **Except as provided in subsections (4) and (5) of this section, the department shall place no limit on the type of legend drug that may be prescribed by a practitioner, but the department shall pay only for drugs in the generic form [if the federal Food and Drug Administration has approved a generic version of a particular brand name drug that is chemically identical to the brand name drug according to federal Food and Drug Administration rating standards,] unless an exception has been granted by the department.**

(4) **Notwithstanding subsection (3) of this section, an exception must be applied for and granted before the department is required to pay for minor tranquilizers and amphetamines and amphetamine derivatives, as defined by rule of the department.**

(5)(a) **Notwithstanding subsections (1) to (4) of this section and except as provided in paragraph (b) of this subsection, the department is authorized to:**

(A) Withhold payment for a legend drug when federal financial participation is not available; and

(B) Require prior authorization of payment for drugs that the department has determined should be limited to those conditions generally recognized as appropriate by the medical profession.

(b) **The department may not require prior authorization for therapeutic classes of non-sedating antihistamines and nasal inhalers, as defined by rule by the department, when prescribed by an allergist for treatment of any of the following conditions, as described by the Health Services Commission on the funded portion of its prioritized list of services:**

(A) Asthma;

(B) Sinusitis;

(C) Rhinitis; or

(D) Allergies.

[(b)] (c) **Notwithstanding subsections (1) to (4) of this section and [paragraph (a)] paragraphs (a) and (b) of this subsection, the department may require prior authorization of payment for drugs for individuals whose prescription drug use exceeded 15 drugs in the preceding six-month period.**

[(6) *Notwithstanding subsection (3) of this section, the department may not limit legend drugs when used as approved by the federal Food and Drug Administration to treat mental illness, HIV and AIDS, and cancer.*]

[(7)] (6) **When a practitioner prescribes a legend drug under this chapter, the practitioner shall write on the prescription:**

(a) **The diagnosis code for the condition on the prioritized list of services covered for payment for which the legend drug is being prescribed; and**

(b) **The practitioner's Office of Medical Assistance Programs provider number.**

[(8)(a)] (7)(a) **At the time of enrollment or reenrollment in a fee-for-service payment system, an enrollee shall designate a primary pharmacy or pharmacy network to dispense legend drugs covered by the medical assistance program.**

(b) The department shall adopt rules establishing procedures that allow an enrollee to:
(A) Obtain a legend drug at a pharmacy other than a designated primary pharmacy or pharmacy network; and

(B) Change a designation of a primary pharmacy or pharmacy network.

[(9)] (8) The department shall adopt rules that:

(a) Establish procedures to ensure that a primary pharmacy or pharmacy network will receive notice when an enrollee obtains a legend drug at another pharmacy; and

(b) Allow payment at the point of sale to a pharmacy other than a primary pharmacy or pharmacy network for a legend drug obtained by an enrollee as described in subsection [(8)(b)(A)] (7)(b)(A) of this section.

SECTION 7. The amendments to ORS 414.325 by section 6 of this 2001 Act become operative on January 2, 2007.

SECTION 7a. If House Bill 2497 becomes law, section 7 of this 2001 Act is amended to read:

Sec. 7. The amendments to ORS 414.325 by section [6] 6a of this 2001 Act become operative on January 2, 2007.

SECTION 8. This 2001 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2001 Act takes effect on its passage.

Passed by Senate July 6, 2001

Received by Governor:

.....M.,....., 2001

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Secretary of Senate

Approved:

.....M.,....., 2001

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President of Senate

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Governor

Passed by House July 7, 2001

Filed in Office of Secretary of State:

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Speaker of House

.....M.,....., 2001

.....
Secretary of State

PMPDP Plan Drug List (PDL):

- The PDL is the primary tool that the Department of Human Services (DHS) has developed to inform licensed health care practitioners about the results of the latest peer-reviewed research and cost effectiveness of prescription drugs.
- The PDL is a listing of prescription drugs for selected classes that DHS, in consultation with the Health Resources Commission (HRC), has determined represents effective drug(s) available at the best possible price.
- For each selected drug class, the PDL will identify a drug(s) as the benchmark drug that has been determined to be the most effective drug(s) available for the best possible price. The PDL will include other drugs in the class that are Medicaid reimbursable and which the FDA has determined to be safe and effective if the relative cost is less than the benchmark drug(s). If pharmaceutical manufacturers enter into supplemental discount agreements with DHS that reduces the cost of their drug below that of the benchmark drug for the class, their drug will also be included in the PDL. A copy of the PDL is available on the web at www.omap.hr.state.or.us.

PMPDP Plan Drug List (PDL) Selection Process:

- DHS will utilize the recommendations made by the HRC, which result from an evidence-based evaluation process, as the basis for identifying the most effective drug(s) within a selected drug class.
- DHS will determine the drug(s), identified in the paragraph above, that is available for the best possible price; and considering any input from the HRC, other FDA approved drug(s) in the same class that are available for a lesser relative price. Relative price will be determined using the methodology described in subsection below (Relative Cost and Best Possible Cost Determination).
- Drug classes and selected drug(s) for the drug classes will be reviewed annually or more frequently if in the discretion of DHS, new safety information or the release of new drugs in a class or other information makes this advisable. New drugs will not be added to the PDL until they have been reviewed by the HRC. All changes or revisions to the PDL will be made publicly, using the rulemaking process, and will be published in OMAP's Pharmaceutical Services provider guide.

Relative Cost and Best Possible Price Determination

- DHS will determine the relative cost of all drugs in each selected class that are Medicaid reimbursable and that the FDA has determined to be safe and effective.
- DHS will first determine the benchmark drug based on the Average Wholesale Price (AWP) on the first of the month in which DHS reviews that specific drug class.
- Once the cost of the benchmark drug is determined, the costs of other FDA approved drugs in the class will be recalculated using AWP, Oregon Maximum Allowable Cost (OMAC) and/or Federal Upper Limits in effect on the first of the month in which DHS reviews that specific drug class (OAR410-121-0180), less average rebate. Drugs with prices under 105% of the benchmark drug price will be included on the PDL.
- DHS will consider price, rebate, and the stability of both, over a period of time in determining the cost effectiveness. DHS may also consider dosing issues, patterns of use and compliance issues. These factors will be weighed with any advice provided by the Health Resources Commission in reaching a final decision.

PMPDP Reimbursement

OMAP will only reimburse for the prescription drugs specifically listed in the PMPDP categories on the Plan Drug List(s). OMAP will only reimburse for drugs not listed in the PMPDP categories by using the exception process.

PMPDP Plan Drug List (PDL) Exception Process

- If the prescribing practitioner, in his/her professional judgement, wishes to prescribe a drug not on the PDL, he/she may request an exception, subject to the requirements of OAR 410-121-0040. The prescribing practitioner must certify in his/her handwriting, or, if the prohibition was communicated by telephone, or electronic transmission, the pharmacist's handwriting, one of the following phrases or notations: No substitution; N.S.; Brand medically necessary; Brand necessary; Medically necessary; D.A.W. (Dispense As Written); or notations with similar meaning. Preprinted, stamped or a box to check is unacceptable.
- Regardless of the PDL, prescriptions shall be dispensed in the generic form unless practitioner requests otherwise subject to the regulations outlined in OAR 410-121-0155.

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

Table 121-0030-1 – PMPDP Plan Drug List (PDL):

- **Long-Acting Opioids:**

- All drugs listed below were evaluated by the Health Resources Commission using an evidence-based review process. No evidence was found to support one drug as more effective or safe than the others on the list.
- All drugs listed below can be prescribed without an exception. Medicaid eligible drugs not listed below can be prescribed using the exception process in the PMPDP.

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

(**) LA-Morphine Sulfate (generic)
Dolophine HCL
Methadone HCL (generic)
Methadose
Levo-Dromoran
Levorphanol (generic)
Kadian
Oramorph SR
Duragesic

- **Proton Pump Inhibitors:**

- All drugs listed below were evaluated by the Health Resources Commission using an evidence-based review process. No evidence was found to support one drug as more effective or safe than the others on the list.
- All drugs listed below can be prescribed without an exception. Medicaid eligible drugs not listed below can be prescribed using the exception process described in the PMPDP.

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

(**) Protonix
Aciphcx
Prevacid

■ **Statins (Cholesterol Lowering medications):**

- All drugs listed below were evaluated by the Health Resources Commission using an evidence-based review process. No evidence was found to support one drug as more effective or safe than the others on the list.
- All drugs listed below can be prescribed without an exception. Medicaid eligible drugs not listed below can be prescribed using the exception process in the PMPDP (OAR 410-121-0030(6)).

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

(**) Lovastatin
Mevacor
Pravachol

■ **Non-Steroidal Anti-Inflammatory drugs:**

- All drugs listed below were evaluated by the Health Resources Commission using an evidence-based review process. No evidence was found to support one drug as more effective or safe than the others on the list.
- All drugs listed below can be prescribed without an exception. Medicaid eligible drugs not listed below can be prescribed using the exception process in the PMPDP (OAR 410-121-0030(6)).

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

(**) Naproxen
Ibuprofen
Piroxicam
Salsalate

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

Prescribing practitioners are responsible for obtaining prior authorization for the following drugs and products:

- Isotretinoin (Accutane) and Retinoic Acid (Retin A);
- Growth hormone;
- Oral Nutritional supplements;
- Antihistamines (selected);
- Nasal inhalers (selected);
- Antifungals (selected);
- Weight reduction drugs;

- Excessive daily doses;
- Coal tar preparations;
- Topical antibiotics;
- Topical antivirals (selected);
- Topical testosterone;
- Drugs with cosmetic indications;
 - ◆ Emollients;
 - ◆ Dermatologicals;
 - ◆ Hair growth products;
- Proton Pump Inhibitors: Prior authorization is required after the initial eight weeks of acute antiulcer therapy when dosages exceed the chart below:
 - ◆ Drug: Axid (nizatidine); Acute Daily Dosage - > 151 mg;
 - ◆ Drug: Nexium (esomeprazole); > 19 mg;
 - ◆ Drug: Previcid (lansoprazole); Acute Daily Dosage - > 14 mg;
 - ◆ Drug: Prilosec (omeprazole); Acute Daily Dosage - > 9 mg;
 - ◆ Drug: Protonix (pantoprazole); Acute Daily Dosage - > 39 mg;
- Over-the-counter medications not mentioned above are limited to two prescriptions per therapeutic class per month;
- Psychotropic prescriptions for children under 6, cannot be processed when a default 999999 provider number has been entered.

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

The prescribing practitioner will request prior authorization (PA) through the following procedure:

- A prescriber electing to order a drug requiring PA may have any licensed medical personnel in their office call the Managed Access Program (MAP) Help Desk (1-800-344-9180) to request PA. The PA request may also be transmitted to the MAP Help Desk by FAX (1-800-250-6950) using the request form shown in the Appendices of the Pharmaceutical Services guide;
- The MAP Help Desk is available 24-hours a day, seven days per week. The MAP pharmacist will ask for some or all of the following information, depending upon the class of the drug requested:

- ◆ Client name and recipient ID number;
- ◆ Diagnosis IDC-9-CM;
- ◆ Drug name, strength, size and quantity of medication;
- ◆ Medical justification for use of selected drug;
- ◆ Pharmacy name and phone number (if available).

Pharmacists shall:

- When the request is approved, the MAP Help Desk will notify the pharmacy when the dispensing pharmacy information is available. It is the pharmacist's responsibility to check whether the drugs are covered, whether the client is eligible, and to note restrictions such as date ranges and quantities before dispensing any medications that require prior authorization. The pharmacy should also check whether the client is enrolled in a managed care plan. An enrollment may have taken place after PA was received;
- PA is given for a specific date of service and an NDC number or product;
- Able to fill the prescription at any Medicaid pharmacy provider. There is no need for a PA number;
- Emergency dispensing will be prior authorized for a seven-day supply for clients not enrolled in a managed care plan;
- If the PA request has been denied, the MAP Help Desk will notify the pharmacy when the dispensing pharmacy information is available.

PA does not guarantee eligibility or reimbursement.

410-121-0061 Durable Medical Equipment and Medical Supplies

Follow the guidelines in the Durable Medical Equipment and Medical Supplies (DME) and Home Enteral/Parenteral Nutrition and IV Services guides for billing and prior authorization of these items and services.

Medical supplies for home enteral/parenteral nutrition and IV services are listed in the Home Enteral/Parenteral Nutrition and IV Services guide.

Bill Medicare first for these services for qualified clients.

Use the HCFA-1500 or OMAP 505 billing forms, as outlined in the above guides.

PROPOSED

Practitioner Managed Prescription Drug Plan List (PMPDP) (Administrative Rule 410-121-0030)

Table 121-0030-1

Plan Drug List (PDL)

Long-Acting Opioids:

All drugs listed below were evaluated by the Health Resources Commission using an evidence-based review process. No evidence was found to support one drug as more effective or safe than the others on the list.

All drugs listed below can be prescribed without an exception. Medicaid eligible drugs not listed below can be prescribed using the exception process (OAR 410-121-0030(6)).

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

(**) LA- MORPHINE SULFATE (generic)

DOLOPHINE HCL

METHADONE HCL (generic)

METHADOSE

LEVO-DROMORAN

LEVORPHANOL (generic)

KADIAN

ORAMORPH SR

DURAGESIC

Proton Pump Inhibitors:

All drugs listed below were evaluated by the Health Resources Commission using an evidence-based review process. No evidence was found to support one drug as more effective or safe than the others on the list.

All drugs listed below can be prescribed without an exception. Medicaid eligible drugs not listed below can be prescribed using the exception process (OAR 410-121-0030(5)).

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

(**) PROTONIX

ACIPHEX

PREVACID

Statins (Cholesterol Lowering medications):

All drugs listed below were evaluated by the Health Resources Commission using an evidence-based review process. No evidence was found to support one drug as more effective or safe than the others on the list.

All drugs listed below can be prescribed without an exception. Medicaid eligible drugs not listed below can be prescribed using the exception process (OAR 410-121-0030(5)).

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

(**) LOVASTATIN
MEVACOR
PRAVACHOL

Non-Steroidal Anti-Inflammatory drugs:

All drugs listed below were evaluated by the Health Resources Commission using an evidence-based review process. No evidence was found to support one drug as more effective or safe than the others on the list.

All drugs listed below can be prescribed without an exception. Medicaid eligible drugs not listed below can be prescribed using the exception process (OAR 410-121-0030(5)).

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

(**) NAPROXEN
IBUPROFEN
PIROXICAM
SALSALATE

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850



Center for Medicaid and State Operations

SMDL #02-014

September 18, 2002

Dear State Medicaid Director:

This letter is to clarify issues related to supplemental drug rebate agreements and prior authorization of Medicaid covered outpatient drugs. A number of States have sought CMS approval of supplemental drug rebate agreements between a State and drug manufacturers with respect to Medicaid covered outpatient prescription drugs. Some of these States subject covered outpatient drugs to prior authorization as a means of encouraging drug manufacturers to enter into separate or supplemental rebate agreements for covered drugs purchased by Medicaid recipients.

Medicaid Supplemental Drug Rebate Agreements

States may enter separate or supplemental drug rebate agreements as long as such agreements achieve drug rebates equal to or greater than the drug rebates set forth in the Secretary's national rebate agreement with drug manufacturers, which is published at 56 F.R. 7049 (1991). The drug rebate statute, at section 1927(a)(1) of the Social Security Act (Act), provides that "the Secretary may authorize a State to enter directly into agreements with a manufacturer." Also, section 1927(a)(4) of the Act provides that any drug rebate agreement between a State and drug manufacturers and in effect on November 5, 1990, may constitute a rebate agreement in compliance with the statute if CMS determines that any such agreement "provides for rebates that are at least as large as the rebates otherwise required under this section." CMS accordingly believes that Congress intended that States that seek CMS approval under section 1927(a)(1) to enter directly into agreements with manufacturers must ensure that any such agreement will achieve drug rebates that are at least equal to the rebates set forth in the Secretary's rebate agreements with manufacturers.

We remind States that supplemental drug rebates must be "considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance" as required by section 1927(b)(1)(B) of the Act.

Prior Authorization Requirements Related to Supplemental Rebate Agreements

PA nego
States may subject covered outpatient prescription drugs to prior authorization as a means of encouraging drug manufacturers to enter into separate or supplemental rebate agreements for covered drugs purchased by Medicaid recipients. Section 1927(d)(1)(A) of the Act permits States to subject any covered outpatient drug to a requirement of prior authorization as long as the State complies with the requirements set forth in section 1927(d)(5). A prior authorization program used to negotiate drug discounts for the Medicaid program is consistent with those provisions as well as the paramount purpose of the drug rebate provisions which is to reduce the costs to the Medicaid program for prescription drugs.

*
A prior authorization program does not need to comply with the requirements for restrictive formularies. The formulary provisions of section 1927(d)(4) were added to the drug rebate provisions in 1993 to give States additional authority to implement restrictive formularies. Congress passed paragraph (d)(4) expressly stating that “[a] prior authorization program established by a State under [section 1927(d)(5)] is not a formulary subject to the requirements of this paragraph.”* Furthermore, since concerns related to drug use, monitoring, waste, fraud or abuse are separately and independently addressed by the procedures authorized by sections 1927(d)(6) and 1927(g), a prior authorization program need not be limited to those concerns. The Act affords States broad authority and flexibility to implement a prior authorization program in order to secure cost savings for the Medicaid program.

The operation of a prior authorization program used to negotiate drug discounts for the Medicaid population is a significant component of a State plan. We would therefore expect that a State that does not currently have an approved prior authorization State plan amendment, and that seeks to undertake such a program, would submit to CMS for review a State plan amendment incorporating the program’s prior authorization requirements, while simultaneously seeking CMS’s authorization for its proposed separate or supplemental rebate agreement. A State that has an approved State plan amendment governing prior authorization requirements, but which seeks for the first time to use its prior authorization authority to negotiate drug discounts for the Medicaid program, must amend its State plan to refer to the separate or supplemental rebate agreement and submit its proposed rebate agreement for CMS authorization.

* Of course, the formulary provisions of section 1927(d)(4) continue to apply if a State chooses to make judgments about the therapeutic advantages of a drug excluded from a formulary, and the State plan must permit coverage of any such drug pursuant to a prior authorization program that complies with section 1927(d)(5).

Maine Issue

Non-Medicaid Supplemental Rebates and Medicaid Prior Authorization

A number of States secure prescription drug benefits, rebates, or discounts for non-Medicaid populations by linking such benefits to a Medicaid prior authorization program. The Act does not preclude States from negotiating prices, including manufacturer discounts and rebates for non-Medicaid drug purchases. However, the establishment of a prior authorization program for Medicaid covered drugs to secure drug benefits, rebates, or discounts for non-Medicaid populations is a significant component of a State plan and we would therefore expect that a State would submit such a program for CMS review under the State plan process. Similarly, the use of any pre-existing prior authorization program to secure drug benefits, rebates, or discounts for non-Medicaid populations would constitute a "[m]aterial change[] in State law, . . . policy, or in the State's operation of the Medicaid program" and we would therefore expect that a State would submit a plan amendment to CMS for review. (See section 430.12(c)(1)(ii) of the regulations.) In submitting such a State plan amendment, the State should be prepared to demonstrate through appropriate evidence that the prior authorization program will further the goals and objectives of the Medicaid program. A State could make such a demonstration by submitting appropriate evidence that its prior authorization requirement is designed to increase the efficiency and economy of the Medicaid program. A State could demonstrate that its prior authorization requirement furthers Medicaid goals and objectives by submitting appropriate evidence that the requirement sufficiently benefits the Medicaid population as a whole by making available to financially needy individuals medically necessary prescription drugs, thereby improving their health status and making it less likely that they will become Medicaid eligible.

If you have any questions regarding CMS policy relating to supplemental drug rebate agreements or prior authorization programs, please direct them to Larry Reed at (410) 786-3325 or Deirdre Duzor at (410) 786-4626.

Sincerely,

/s/

Dennis G. Smith
Director

cc:

CMS Regional Administrators

CMS Associate Regional Administrators
for Medicaid and State Operations

Page 4 – State Medicaid Director

Lee Partridge
Director, Health Policy Unit
American Public Human Services Association

Joy Wilson
Director, Health Committee
National Conference of State Legislatures

Matt Salo
Director of Health Legislation
National Governors Association

Brent Ewig
Senior Director, Access Policy
Association of State and Territorial Health Officials

Trudi Matthews
Senior Health Policy Analyst
Council of State Governments

Jim Frogue
Acting Director, Health and Human Services Task Force
American Legislative Exchange Council

Ryan, Robin

From: Sweet, Richard
Sent: February 25, 2003 4:57 PM
To: Ryan, Robin
Cc: Wischnewski, Marne; de Felice, David Patrick

Robin:

Marne and I talked with Rep. Underheim and there were some things he wanted included in the draft:

- 1. DHFS would have the discretion to phase in the PDL with different groups of people. (He thought that if this were done, the public benefit programs would go first, then the private sector/uninsured, then public employees.)**
- 2. DHFS would use bids to determine which drugs are on the PDL (after they're determined to be safe and effective), but wouldn't be locked in to using the bid procedure; e.g. they could use negotiation.**
- 3. DHFS would be able to use: (1) a broader PDL (i.e more than one or two drugs) combined with prior authorization; or (2) a narrower PDL, with no prior authorization requirements, but monitoring of prescribing patterns and penalizing by the Medical Examining Board of physicians who routinely prescribe drugs not on the PDL without medical justification.**

Dave, are these changes okay with Spencer?

Dick Sweet

**Senior Staff Attorney
Wisconsin Legislative Council
(608)266-2982
richard.sweet@legis.state.wi.us**

2/25/03 mtg.

Dick Sweet, Darcy (Citizen Action) Maine Wischniewski
(Underheim), & Dave de Felice (Coggs)

Same bill for Reps. Underheim & Coggs

Preferred drug list not a restrictive formulary
- so just use prior authorization committee
to make safety & efficacy decisions - don't
need a board appointed by Governor to
make determinations

Prior auth. com. (PAc) will classify drugs
based on efficacy & safety - then bid
for lowest cost drug -

DHFS may contract out bidding responsibility

~~Program~~ Prescription Drug Assistance Program (PDA)
for the uninsured
- don't limit eligibility to those
under 400% pov.
use 2001 AR 857

Preferred Drug List
use for: public assistance programs
PDA
state & loc. gov. employees
private sector
can have DHFS phase in
start w/ public assist. progs
PDA & st. employees
then private sector

Not asking for a fed. waiver to
extend MA to more people for
prescrip drugs - i.e. not like Maine

Allow PBC to use lists from other states
in developing preferred drug list for Wis.

DHFS can contract out bid process

Standards for making PDL - review literature.
- use VT, if anything good

have PBC review determinations periodically

use Indiana provision for approval of
new single source drugs for PDL
- 60 days

don't cover over the counter drugs on PDL

allow DHFS to include more than just
lowest-cost drug in each therapeutic
class - can include others that are
reasonably close in cost

"enforcement" of PDL - allow patient to get
drug if prescribed - but penalize doc. for
off-list prescriptions

do include fed MA per auth. regs - i.e.
must respond to request for PRT in
24 hours & give 72 hour supply in
emergency situations

put all AIDS/HW drugs on PDZ

PDZ

pharmacist voluntarily participates
don't spell out formula for setting
amt. pharmacist can charge - let
DHFS decide

allow persons on M'care who have
supplemental ins. to be eligible for PDZ
start with \$20 enrollment fee
(same as Senior Care)

enrollment fee - for admin costs
rebates - for further discounts?
LADL

NO. 127. AN ACT RELATING TO PRESCRIPTION DRUG COST
CONTAINMENT AND AFFORDABLE ACCESS.

(H.31)

It is hereby enacted by the General Assembly of the State of Vermont:

Sec. 1. 33 V.S.A. chapter 19, subchapter 5 is added to read:

Subchapter 5. Prescription Drug Cost Containment

§ 1997. DEFINITIONS

As used in this subchapter:

(1) “Board” or “drug utilization review board” means the drug utilization review board established by the commissioner in connection with the Medicaid program.

(2) “Commissioner” means the commissioner of prevention, assistance, transition, and health access.

(3) “Department” means the department of prevention, assistance, transition, and health access.

(4) “Health benefit plan” means a health benefit plan with prescription drug coverage offered or administered by a health insurer, as defined by subdivision 9402(7) of Title 18, and the out-of-state counterparts to such plans.

The term includes, but is not limited to:

(A) any state public assistance program with a health benefit plan that provides coverage of prescription drugs;

(B) any health benefit plan offered by or on behalf of the state of Vermont or any instrumentality of the state providing coverage for government employees and their dependents that agrees to participate in the program; and

(C) any insured or self-insured health benefit plan that agrees to participate in the program.

(5) "Participating health benefit plan" means a health benefit plan that has agreed to participate in one or more components of the pharmacy best practices and cost control program.

(6) "Program" or "the pharmacy best practices and cost control program" means the pharmacy best practices and cost control program established by this subchapter.

(7) "State public assistance program", includes, but is not limited to, the Medicaid program, the Vermont health access plan, the Vermont health access plan-pharmacy, VScript and VScript-Expanded, the state children's health insurance program, the state of Vermont AIDS medication assistance program, the General Assistance program, the pharmacy discount plan program, and the out-of-state counterparts to such programs.

§ 1998. PHARMACY BEST PRACTICES AND COST CONTROL

PROGRAM ESTABLISHED

(a) The commissioner of prevention, assistance, transition, and health access shall establish a pharmacy best practices and cost control program

designed to reduce the cost of providing prescription drugs, while maintaining high quality in prescription drug therapies. The program shall include:

(1) A preferred list of covered prescription drugs that identifies preferred choices within therapeutic classes for particular diseases and conditions, including generic alternatives.

(A) The commissioner, and the commissioner of banking, insurance, securities, and health care administration shall implement the preferred drug list as a uniform, statewide preferred drug list by encouraging all health benefit plans in this state to participate in the program.

(B) The commissioner of personnel shall use the preferred drug list in the state employees health benefit plan only if participation in the program will provide economic and health benefits to the state employees health benefit plan and to beneficiaries of the plan, and only if agreed to through the bargaining process between the state of Vermont and the authorized representatives of the employees of the state of Vermont. The provisions of this subdivision do not authorize the actuarial pooling of the state employees health benefit plan with any other health benefit plan, unless otherwise agreed to through the bargaining process between the state of Vermont and the authorized representatives of the employees of the state of Vermont.

(C) The commissioner shall encourage all health benefit plans to implement the preferred drug list as a uniform, statewide preferred drug list by inviting the representatives of each health benefit plan providing prescription

drug coverage to residents of this state to participate as observers or nonvoting members in the commissioner's drug utilization review board, and by inviting such plans to use the preferred drug list in connection with the plans' prescription drug coverage;

(2) Utilization review procedures, including a prior authorization review process;

(3) Any strategy designed to negotiate with pharmaceutical manufacturers to lower the cost of prescription drugs for program participants, including a supplemental rebate program;

(4) Education programs, including a counterdetailing program, designed to provide information and education on the therapeutic and cost-effective utilization of prescription drugs to physicians, pharmacists and other health care professionals authorized to prescribe and dispense prescription drugs;

(5) Alternative pricing mechanisms, including consideration of using maximum allowable cost pricing for generic and other prescription drugs;

(6) Alternative coverage terms, including consideration of providing coverage of over-the-counter drugs where cost-effective in comparison to prescription drugs, and authorizing coverage of dosages capable of permitting the consumer to split each pill if cost-effective and medically appropriate for the consumer;

(7) A simple, uniform prescription form, designed to implement the preferred drug list, and to enable prescribers and consumers to request an

exception to the preferred drug list choice with a minimum of cost and time to prescribers, pharmacists and consumers; and

(8) Any other cost containment activity adopted by rule by the commissioner that is designed to reduce the cost of providing prescription drugs while maintaining high quality in prescription drug therapies.

(b) The commissioner shall implement the pharmacy best practices and cost control program for Medicaid and all other state public assistance program health benefit plans to the extent permitted by federal law.

(c)(1) The commissioner may implement the pharmacy best practices and cost control program for any other health benefit plan within or outside this state that agrees to participate in the program.

(2) The commissioner of prevention, assistance, transition, and health access, and the secretary of administration shall take all steps necessary to enable Vermont's participation in joint prescription drug purchasing agreements with any other health benefit plan or organization within or outside this state that agrees to participate with Vermont in such joint purchasing agreements.

(3) The commissioner of personnel shall take all steps necessary to enable the state of Vermont to participate in joint prescription drug purchasing agreements with any other health benefit plan or organization within or outside this state that agrees to participate in such joint purchasing agreements, as may

be agreed to through the bargaining process between the state of Vermont and the authorized representatives of the employees of the state of Vermont.

(4) The actions of the commissioners and the secretary shall include:

(A) active collaboration with the Northeast Legislative Association on Prescription Drugs in the Association's efforts to establish a Prescription Drug Fair Price Coalition;

(B) active collaboration with the Pharmacy RFP Issuing States initiative organized by the West Virginia Public Employees Insurance Agency;

(C) the execution of any joint purchasing agreements or other contracts with any participating health benefit plan or organization within or outside the state which the commissioner determines will lower the cost of prescription drugs for Vermonters while maintaining high quality in prescription drug therapies; and

(D) with regard to participation by the state employees health benefit plan, the execution of any joint purchasing agreements or other contracts with any health benefit plan or organization within or outside the state which the commissioner determines will lower the cost of prescription drugs and provide overall quality of integrated health care services to the state employees health benefit plan and the beneficiaries of the plan, and which is negotiated through the bargaining process between the state of Vermont and the authorized representatives of the employees of the state of Vermont.

(5) The commissioner and the commissioner of personnel may renegotiate and amend existing contracts to which their departments are parties if such renegotiation and amendment will be of economic benefit to the health benefit plans subject to such contracts, and to the beneficiaries of such plans. Any renegotiated or substituted contract shall be designed to improve the overall quality of integrated health care services provided to beneficiaries of such plans.

(6) The commissioners and the secretary shall report quarterly to the health access oversight committee and the joint fiscal committee on their progress in securing Vermont's participation in such joint purchasing agreements.

(7) The commissioner, the commissioner of personnel, the commissioner of banking, insurance, securities and health care administration, and the secretary of human services shall establish a collaborative process with the Vermont Medical Society, pharmacists, health insurers, consumers, employer organizations and other health benefit plan sponsors, the Northeast Legislative Association on Prescription Drug Pricing, pharmaceutical manufacturer organizations, and other interested parties designed to consider and make recommendations to reduce the cost of prescription drugs for all Vermonters.

(d) A participating health benefit plan other than a state public assistance program may agree with the commissioner to limit the plan's participation to

one or more program components. The commissioner shall supervise the implementation and operation of the pharmacy best practices and cost control program, including developing and maintaining the preferred drug list, to carry out the provisions of the subchapter. The commissioner may include such insured or self-insured health benefit plans as agree to use the preferred drug list or otherwise participate in the provisions of this subchapter. The purpose of this subchapter is to reduce the cost of providing prescription drugs while maintaining high quality in prescription drug therapies.

(e) The commissioner of prevention, assistance, transition, and health access shall develop procedures for the coordination of state public assistance program health benefit plan benefits with pharmaceutical manufacturer patient assistance programs offering free or low cost prescription drugs, including the development of a proposed single application form for such programs. The commissioner may contract with a nongovernmental organization to develop the single application form.

(f)(1) The drug utilization review board shall make recommendations to the commissioner for the adoption of the preferred drug list. The board's recommendations shall be based upon considerations of clinical efficacy, safety, and cost-effectiveness.

(2) The board shall meet at least quarterly. The board shall comply with the requirements of subchapter 2 of chapter 5 of Title 1 (open meetings) and subchapter 3 of chapter 5 of Title 1 (open records).

(3) To the extent feasible, the board shall review all drug classes included in the preferred drug list at least every 12 months, and may recommend that the commissioner make additions to or deletions from the preferred drug list.

(4) The program shall establish board procedures for the timely review of prescription drugs newly approved by the federal Food and Drug Administration, including procedures for the review of newly-approved prescription drugs in emergency circumstances.

(5) Members of the board shall receive per diem compensation and reimbursement of expenses in accordance with section 1010 of Title 32.

§ 1999. CONSUMER PROTECTION RULES; PRIOR AUTHORIZATION

(a)(1) The pharmacy best practices and cost control program shall authorize pharmacy benefit coverage when a patient's health care provider prescribes a prescription drug not on the preferred drug list, or a prescription drug which is not the list's preferred choice, if either of the circumstances set forth in subdivision (2) or (3) of this subsection applies.

(2)(A) The program shall authorize coverage under the same terms as coverage for preferred choice drugs if the prescriber determines, after consultation with the pharmacist, or with the participating health benefit plan if required by the terms of the plan, that:

(i) the preferred choice has not been effective, or with reasonable certainty is not expected to be effective, in treating the patient's condition; or

(ii) the preferred choice causes or is reasonably expected to cause adverse or harmful reactions in the patient.

(B) The prescriber's determination concerning whether the standards established in this subdivision (2) have been demonstrated shall be final.

(3) The program shall authorize coverage if the patient agrees to pay any additional cost in excess of the benefits provided by the patient's health benefit plan which is participating in the program. The provisions of this subdivision (3) shall not apply to the extent that they may be inconsistent with any federal Medicaid laws and regulations. The provisions of this subdivision (3) shall not affect implementation by a participating health benefit plan of tiered copayments or other similar cost sharing systems.

(b) The program or any participating health benefit plan shall provide information on how prescribers, pharmacists, beneficiaries, and other interested parties can obtain a copy of the preferred drug list, whether any change has been made to the preferred drug list since it was last issued, and the process by which exceptions to the preferred list may be made.

(c) For HIV and AIDS-related medications used by individuals with HIV or AIDS, the preferred drug list and any utilization review procedures shall not be more restrictive than the drug list and the application of the list used for the state of Vermont AIDS medication assistance program.

(d) The program's prior authorization process shall not apply to prescription drugs prescribed for the treatment of severe and persistent mental illness including schizophrenia, severe depression, or bipolar disorder.

(e)(1) The prior authorization process shall be designed to minimize administrative burdens on prescribers, pharmacists, and consumers. The provisions of this section shall apply to the program's prior authorization process, except to the extent that different prior authorization rules are established in section 2004 of this title.

(2) The prior authorization process shall ensure real-time receipt of requests, by telephone, voice mail, facsimile, electronic transmission, or mail on a 24-hour basis, seven days a week.

(3) The prior authorization process shall provide an in-person response to emergency requests by a prescriber with telephone answering queues that do not exceed 10 minutes.

(4) Any request for authorization or approval of a drug that the prescriber indicates, including the clinical reasons for the request, is for an emergency or urgent condition shall be responded to in no more than four hours from the time the program or participating health benefit plan receives the request.

(5) In emergency circumstances, or if the response to a request for prior authorization is not provided within the time period established in subdivision (4) of this subsection, a 72-hour supply of the drug prescribed shall

be deemed to be authorized by the program or the participating health benefit plan, provided it is a prescription drug approved by the Food and Drug Administration, and provided, for drugs dispensed to a Medicaid beneficiary, it is subject to a rebate agreement with the Centers for Medicare and Medicaid Services.

(6) The program or participating plan shall provide to participating providers a prior authorization request form for each enrolled beneficiary, known to be a patient of the provider, designed to permit the prescriber to make prior authorization requests in advance of the need to fill the prescription, and designed to be completed without unnecessary delay. The form shall be capable of being stamped with information relating to the participating provider, and if feasible at least one form capable of being copied shall contain known patient information.

(f) The program's prior authorization process shall require that the prescriber, not the pharmacy, request a prior authorization exception to the requirements of this section. The program may exempt a prescriber from the need to secure prior authorization for a specific drug category if the program determines that the prescriber has written a minimum number of scripts in that category, and the prescriber prescribes prescription drugs on the preferred drug list at or above the minimum threshold for that category.

Shaw to
Name