Title of Rule:	Preferred Drug List, Section 8.885
Rule Number:	MSB 07-06-01-B
Division / Contact / Phone:	Pharmacy Section / Tom Leahey / 303-866-2519

STATEMENT OF BASIS AND PURPOSE

1. Summary of the basis and purpose for the rule or rule change. (State what the rule says or does and explain why the rule or rule change is necessary).

   This rule establishes the Preferred Drug List program and its administration as directed by Executive Order D004 07.

2. An emergency rule-making is imperatively necessary

   ☐ to comply with state or federal regulation and/or

   ☐ for the preservation of public health, safety and welfare.

   Explain:

3. Federal authority for the Rule, if any:

   42 U.S.C. §1396r-8

4. State Authority for the Rule:

   25.5-1-301 through 25.5-1-303, C.R.S. (2006);
   25.5-5-506(3)(a), C.R.S. (2006)
   Excutive Order D004 07

Initial Review	**09/14/2007**	Final Adoption	**10/12/2007**
Proposed Effective Date	**11/30/2007**	Emergency Adoption	

DOCUMENT #05

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REGULATORY ANALYSIS

1. Describe the classes of persons who will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule.

   The following classes of persons may benefit and bear costs related to implementation of the PDL program: Medicaid fee-for-service clients, Medicaid providers, pharmacies and drug manufacturers.

2. To the extent practicable, describe the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.

   Medicaid clients may benefit from the PDL as it encourages providers to prescribe preferred drugs. Preferred drugs are generally the safest and most effective drugs within a drug class. Medicaid clients will continue to have access to non-preferred drugs. Clients using non-preferred drugs may need to obtain prior authorization. In these cases, clients may have to coordinate with their pharmacy and provider to assure that a prior authorization request is submitted to the Department's fiscal agent.

   Medicaid providers may benefit as the PDL encourages them to prescribe preferred drugs which are generally the safest and most effective drugs with a drug class. Providers will have to spend additional time submitting prior authorization requests on behalf of Medicaid clients.

   Pharmacies may have to spend additional time coordinating prior authorization requests among the client, provider, and the Department's fiscal agent.

   Drug manufacturers may have to enter into supplemental rebate agreements with the Department in order for their drug to be designated as a preferred drug. However, as a result of this designation, costs related to the supplemental rebates may be offset by an increase in the use of their drug by Medicaid clients. Some drugs may be designated as preferred without a drug manufacturer providing supplemental rebates to the Department. In this scenario, the drug manufacturer may also see an increase in the use of their drug. Drug manufacturers will not provide supplemental rebates for non-preferred drugs but may see a decline in a drug's use due to that designation.

3. Discuss the probable costs to the Department and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

   The PDL program will require three Department FTE, updates to the Department's pharmacy claim system and the processing of prior authorization requests. The Department estimates these costs to total $497,000 for FY 2007-2008. The Department may hire a contractor to

provide the clinical data required for P&T Committee evaluations since there is no cost-free source which provides sufficient data in an organized and understandable format. Also, the Department anticipates it would be more cost effective to hire a contractor rather than require the PDL staff to purchase, analyze and organize the clinical data. The Department cannot estimate exact cost savings for FY 2007-2008 since it will depend on which and when drug classes are included on the PDL.

4. Compare the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.

   The benefits are compliance with an Executive Order, clinically appropriate drug utilization by Medicaid clients and cost savings to the Department through use of preferred drugs.

   Inaction would mean the Department is out of compliance with an Executive Order D004 07.

5. Determine whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

   There are no less costly methods for achieving the purpose of the proposed rule. The Department believes that the PDL cannot be implemented without 3 FTE, a P&T Committee contractor, updates to the pharmacy claim system and the processing of prior authorization requests related to PDL implementation.

6. Describe any alternative methods for achieving the purpose for the proposed rule that were seriously considered by the Department and the reasons why they were rejected in favor of the proposed rule.

   Not applicable.

8.885 PREFERRED DRUG LIST

8.885.1 DEFINITIONS

Drug Class means a group of drugs that treat a particular disease or symptom and have the same mechanism of action.

Medical Director means the physician or physicians who advise the Department.

Non-preferred Drug means a drug that requires a prior authorization as described in 10 C.C.R. 2505-10, Section 8.834, before being payable by the Medical Assistance Program.

Preferred Drug means a drug that is payable by the Medical Assistance Program without first obtaining a prior authorization.

Preferred Drug List (PDL) means a list, applicable only to fee-for-service and primary care physician Medical Assistance Program non-Medicare clients, which identifies the Preferred and Non-preferred drugs within a drug class.

8.885.2 ESTABLISHING THE PREFERRED DRUG LIST

8.885.2.A. Notwithstanding 10 C.C.R. 2505-10, Section 8.830.G, to develop and maintain the PDL, the Department shall take the following steps:

1. Determine which drugs and Drug Classes shall be reviewed for inclusion on the PDL.

2. Refer selected drugs and Drug Classes to the Pharmacy and Therapeutics (P&T) Committee for clinical reviews performed without consideration of drug cost-effectiveness. The P&T Committee shall make recommendations pursuant to 10 C.C.R. 2505-10, Section 8.890.

3. Make recommendations to the Medical Director, or if that position is unfilled, the Executive Director, based on evaluations of relevant criteria, including but not limited to:

   a. Drug safety;

   b. Drug efficacy;

   c. The recommendations of the P&T Committee;

   d. Public comments received by the Department before a drug or drug class is reviewed at the relevant P&T Committee meeting;

   e. Cost-effectiveness;

   f. Scientific evidence, standards of practice and other relevant drug information for such evaluation; and

   g. Compliance with the Generic Mandate, 25.5-5-501 C.R.S. (2006) and Federal Upper Limits, 42 C.F.R. Sections 447.331-447.334.

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8.885.2.B. After the P&T Committee meets, the Medical Director, or if that position is unfilled, the Executive Director, shall review the recommendations of the P&T Committee and the Department and determine whether a reviewed drug is designated a Preferred Drug or a Non-preferred Drug.

8.885.2.C. After the Medical Director, or if applicable, the Executive Director, has designated a reviewed drug as Non-preferred, the Department shall refer that drug to the DUR Board for recommendations on prior authorization criteria.

8.885.2.D. After the DUR Board meets, the Medical Director, or if that position is unfilled, the Executive Director, shall review the recommendations of the P&T Committee, the DUR Board and the Department and determine the prior authorization criteria for Non-preferred Drugs.

8.885.2.E. The Department shall provide public notice of PDL updates at least thirty days before such changes take effect.

8.885.2.F. Drug Classes included on the PDL shall be reviewed annually.

8.885.3 NEW DRUGS

8.885.3.A. Notwithstanding any other provision of this section, a new drug entity, including new generic drugs and new drug product dosage forms of existing drug entities, in a Drug Class already included on the PDL:

1. Shall be automatically designated a Non-preferred Drug; unless

2. A preliminary evaluation by the Department finds that a new drug must be designated a Preferred Drug because it is medically necessary; or

3. The new drug must be designated a Preferred Drug in order to comply with the Generic Mandate, 25.5-5-501 C.R.S. (2006) and/or Federal Upper Limits, 42 C.F.R. Sections 447.331-447.334.

8.885.3.B. The Preferred or Non-preferred designation for a new drug shall continue until the relevant Drug Class is reviewed and the designation is changed pursuant to 10 C.C.R. 2505-10, Section 8.885.2.

8.885.4 EXCLUSION OF DRUGS, DRUG CLASSES OR INDIVIDUALS FROM THE PDL

8.885.4.A. The following exclusions are intended to promote good health outcomes and clinically appropriate drug utilization and to protect the most vulnerable Medical Assistance Program clients.

8.885.4.B. After reviewing the recommendations of the P&T Committee and the Department, the Medical Director, or if that position is unfilled, the Executive Director, may, notwithstanding any other provision of this section and to the extent allowed by federal and state law:

1. Exclude drugs or Drug Classes from consideration for inclusion on the PDL.

2. Determine continuity of care protocols that exempt Medical Assistance Program clients stabilized on specified Non-preferred Drugs from prior authorization requirements.

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3. Exclude specific Medical Assistance Program populations from prior authorization requirements for all Non-preferred Drugs.

8.885.4.C. Individual Medical Assistance Program clients may be exempted, on an annual basis, from prior authorization requirements for all Non-preferred drugs if:

1. A client meets clinical criteria recommended by the Department and P&T Committee and approved by the Medical Director, or if that position is unfilled, the Executive Director; and

2. A client's physician submits a care plan to the Department that details, among other things, the client's drug therapy and diagnoses.

8.885.5 OVER-THE-COUNTER DRUGS

8.885.5.A. Notwithstanding 10 C.C.R. 2505-10, Section 8.830.C, over-the-counter drugs that have been designated a Preferred Drug in compliance with the provisions of this section, shall be available without prior authorization.

8.885.6 SUPPLEMENTAL REBATES

8.885.6.A. The Department may enter into supplemental rebate agreements with drug manufacturers for Preferred Drugs. The Department may contract with a vendor and/or join a purchasing pool to obtain and manage the supplemental rebates.

8.885.7 ANNUAL REPORT

8.885.7.A. The Department shall prepare and publicly post an annual report that includes an estimate of cost savings generated by the PDL program.

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