Title of Rule:	Revision to the Pharmacy Rule for Mail Order Delivery of Drugs, Section 8.800
Rule Number:	MSB 08-12-02-A
Division / Contact / Phone:	Pharmacy Benefits 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).

   Senate Bill 08-090 authorizes mail order delivery of maintenance medications under specified circumstances for Medicaid clients. This rule revision implements the legislation.

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:

4. State Authority for the Rule:

   25.5-1-301 through 25.5-1-303, C.R.S. (2008);
   25.5-5-505(1) C.R.S. (2008)

Initial Review	**01/09/2009**	Final Adoption	**02/13/2009**
Proposed Effective Date		Emergency Adoption	**04/01/2009**

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.

   Medicaid clients who meet the requirements of the proposed rule revision will benefit by having access to mail order delivery of maintenance medications. Mail order pharmacies may benefit from an increase in dispensed drugs for the qualifying clients. Pharmacies that do not provide a mail order service may see a corresponding decline in drugs dispensed for qualifying clients.

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

   The Department does not have sufficient data to quantify how many clients will qualify and actually use mail order pharmacies, or which pharmacies will be affected.

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 Department expects to implement and enforce the proposed rule revision using existing resources. The authorizing legislation decreased the medical services premiums appropriation by $279,272 based on the expectation that some drug claims, previously paid entirely by Medicaid, will first be billed to third-party insurance and Medicaid will be the payer of last resort. Otherwise, the Department does not anticipate a significant effect on state revenues.

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

   The proposed rule revision facilitates access to drugs for qualifying Medicaid clients and ensures the Department is compliant with state law. Failure to implement the proposed rule revision would cause the Department to be noncompliant with state law and may adversely impact access to drugs for vulnerable clients and clients with third-party insurance that requires the use of mail order pharmacies.

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

   Not applicable.

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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.

8.800 PHARMACEUTICALS

Prescribed drugs within certain limitations are a benefit of the Medical Assistance program.

DEFINITIONS

.01 Retail Pharmacy is a pharmacy whose sole pharmacy purpose is to provide drugs and related services to non hospitalized people and is not subsidized by any governmental entity.

.02 Institutional Pharmacy is a pharmacy for which a majority of the overhead costs are included in the inpatient rate and whose primary function is to provide drugs and services to hospitalized patients and others receiving health care provided by the facility within which the pharmacy is located with which the pharmacy is associated.

.03 Government Pharmacy is a pharmacy whose primary function is to provide drugs and services to a facility whose operating funds are appropriated directly from a governmental body.

.04 Dispensing Physician is a duly licensed physician who prepares, dispenses and instructs patients to self administer medication on a regular basis.

.05 Legend Drug is a drug bearing the statement: "Caution Federal Law Prohibits Dispensing without a Prescription."

.06 Over the Counter Drug (O.T.C.) is a drug that can be purchased without a physician's prescription.

.07 Prescribed Drug is a drug which is ordered by a physician to be used by a patient to treat a disease or condition.

.08 Usual and Customary Charge is the reimbursement amount the general public is requested by the provider to pay for a good or service.

.09 Reimbursement Charge is the amount of payment requested for a provided benefit service. It shall be the lesser of the provider's usual and customary charge or any amount the provider will accept from any other third party program or from the public in the form of discounts, special rebates, incentives, or coupons.

.10 Part D Eligible Individual has the same meaning as defined in 10 C.C.R. 2505-10, Section 8.1000.1.

.11 Physical Hardship means any physiological disorder or condition, cosmetic disfigurement, or anatomical loss affecting one or more of the following body systems: neurological, musculoskeletal, special sense organs, respiratory (including speech organs), cardiovascular, reproductive, digestive, genitourinary, hemic and lymphatic, skin, and endocrine; or, any mental or psychological disorder, such as mental retardation, organic brain syndrome, emotional or mental illness, and specific learning disabilities.

.12 Mail Order Pharmacy means any pharmacy that delivers drugs primarily by mail.

.13 Maintenance Medication means any drug, as determined by the Department, which is used to treat a chronic illness or symptoms of a chronic illness.

.14~~1~~ Medicare Part D means the prescription drug benefit provided to Part D eligible individuals pursuant to the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA).

.15~~2~~ Medicare Part D Drugs means prescription drugs defined at 42 U.S.C. Sections 1395w-102 and 141 and 42 C.F.R. Section 423, *et seq.*

8.820 CONDITIONS OF PARTICIPATION

.01 A pharmacy provider must be duly licensed or certified by the appropriate regulatory body in the state in which it is located.

.02 Any pharmacy or dispensing physician whether in-state or out-of-state who wishes to submit claims for payment must submit an application for participation to the Division. The Division will review the application and notify the submitting provider whether or not they are accepted as a provider and, if accepted, the effective date. An application may be denied, terminated or not renewed for any of the grounds set forth in 8.051 or 8.130. An accepted application for participation must be on file with the Division of Medical Assistance before any reimbursement for any item or service will be made.

.03 An out-of-state pharmacy may participate and receive payment for dispensed drugs only if the recipient has been injured or suffered a disease or illness while temporarily absent from Colorado. The State will then reimburse for drugs dispensed on an emergency basis only. Chronic or maintenance drugs are not a benefit in such cases. Exceptions to this requirement are for those pharmacies located in towns outside but bordering the State of Colorado that~~mat~~ provide regular services to Colorado recipients; or, those pharmacies who provide dru~~a~~gs for foster care children or other recipients that permanently reside in other states and are wards of the State of Colorado; or, Mail Order Pharmacies that mail Maintenance Medications to recipients meeting the requirements of 10 C.C.R. 2505-10 Section 8.821.

8.821 MAIL ORDER DELIVERY OF DRUGS

8.821.A. Mail order delivery of a Maintenance Medication by a Mail Order Pharmacy is a pharmacy benefit when:

1. A client has been informed that a local pharmacy may be able to provide the same services as a Mail Order Pharmacy; and

2. A client, or a client's physician, declares in writing that the client has:

   a. A Physical Hardship that prohibits the client from obtaining a Maintenance Medication from a local pharmacy; or

   b. Third-party insurance that requires the client to obtain a Maintenance Medication from a Mail Order Pharmacy.

8.850 BASIS FOR REIMBURSEMENT

Benefit drugs shall be reimbursed at the lesser of the Medicaid allowable reimbursement charge, or the provider's reimbursement.

The Medicaid allowable reimbursement charge is the sum of the ingredient cost of the drug dispensed and the provider's dispensing fee.

8.850.01 DISPENSING FEE

The dispensing fee is a pre-determined amount paid to a provider for dispensing a prescription. It is established and periodically adjusted within appropriated funds based upon the results of a cost survey which is designed to measure actual costs of filling prescriptions. The results of the survey shall be reported to the Medical Services Board at the next regular meeting following delivery of the report to the Department of Health Care Policy and Financing.

The pharmacy dispensing fee for retail pharmacies shall be $4.00.

Institutional pharmacies shall receive a dispensing fee of $ 1.89.

The dispensing fee for a Maintenance Medication delivered via mail by a Mail Order Pharmacy shall be $4.00.

Governmental pharmacies that have the cost of dispensing covered as part of an all-inclusive Medicaid payment shall receive no fee.

Dispensing physicians shall not receive a dispensing fee unless their offices or sites of practice are located more than 25 miles from the nearest participating pharmacy. In the latter case, a fee of $ 1.89 will be paid.

.02 INGREDIENT COST

Ingredient cost for retail pharmacies and Mail Order Pharmacies (estimated acquisition cost) is the price of the drug actually dispensed as defined in (c) below or the M.A.C. or the high volume E.A.C., whichever is less.

Benefit drugs dispensed in unit of use (unit dose) packaging will be reimbursed based upon the bulk package size of 100 or pints or if not available in those sizes, the most common size which most closely matches the standard sizes defined above.

The ingredient cost for institutional and government pharmacies is defined as the actual cost of acquisition for the drug dispensed or the M.A.C., or the high volume E.A.C., whichever is less.

A. Maximum Allowable Cost (M. A. C.)

The state M.A.C. is the maximum ingredient cost allowed by the Department for certain multiple-source drugs. The establishment of a MAC. is subject, but not limited to, the following considerations:

1. multiple manufacturers;

2. broad wholesale price span;

3. availability of drugs to retailers at the selected cost;

4. high volume of Medicaid recipient utilization;

5. bioequivalence or interchangeability.

When Federal M.A.C. limits for multiple source drugs are announced, they will be adopted if they are less than state M.A.C. or if no state M.A.C. exist.

Section II of the ColoRx shall identify the generic drugs subject to M.A.C.

The ingredient cost of any drug subject to M.A.C. shall be limited to M.A.C. or wholesale price as determined by the Department, whichever is less. Exceptions which will allow reimbursement greater than M.AC. for a drug entity are obtained through the prior authorization mechanism. An exception will be granted if the patient's response to the generic drag is not therapeutic, an allergic reaction is involved, or any similar situation exists.

If a recipient requests a brand name for a prescription which is subject to M.A.C., then he/she may pay the ingredient cost difference between the M.A.C. and brand name drug. The recipient must sign the prescription stating that he/she is willing to pay the difference in ingredient cost to the pharmacy. The pharmacy will be paid M.A.C. plus a dispensing fee or reimbursement charges whichever is lower.

B. High Volume Estimated Acquisition Cost (E.A.C.)

Reimbursement for single source drugs or certain multiple source drugs which are most frequently prescribed will be based upon average wholesale prices or direct manufacturers' prices for package sizes containing quantities greater than 100 dosage units or less if not available in 100's. Basis for inclusion in the high volume estimated acquisition cost list includes but is not limited to:

1. Single source manufacturers;

2. High volume Medicaid recipient utilization;

3. Interchangeability problems with multiple source drugs;

4. Package sizes in excess of 100;

These drugs will be identified in Section III of the ColoRx.

C. Drug Pricing

A drug pricing file will be maintained and updated monthly by the Department. The modified average wholesale price of a drug as determined by the Department, State M.A.C., and Federal Upper Limit (FUL), will be the basis for setting the prices in the drug pricing file.

Modified average wholesale price shall be defined as the average wholesale price less 13.5%, effective July 1, 2002 for name-brand drugs. For generic drugs, modified average wholesale price shall be defined as the average wholesale price less 35%, effective July 1, 2002. The average wholesale price will be determined by the Department and placed in the drug pricing file as follows:

1. By subtracting 13.5% from the average wholesale price for name-brand drugs and 35% from the average wholesale price for generic drugs, as determined by the Department.

2. If the average wholesale price cannot be determined by the Department, then the distributors' or manufacturers' prices will be used to estimate average wholesale price to be modified and used in the drug pricing file as the price of the drug.

The following pricing methodologies are used, noting that the pricing methodology resulting in the lowest price will be used:

1. Average wholesale price (AWP) minus 13.5% for name-brand drugs

2. Average wholesale price (AWP) minus 35% for generic drugs

3. Direct price plus 18%

4. State M.A.C., pharmacy acquisition cost of generic drugs available in the state market place plus 18%.

5. Federal Upper Limit (FUL)

Any pharmacy, not including out-of-state Mail Order Pharmacies, which is the only pharmacy within a twenty mile radius may submit an invoice to the Department for the difference in price between AWP minus 13.5% and AWP minus 12% for name-brand drugs and AWP minus 35% and AWP minus 12% for generic drugs. The invoice shall be submitted to the Department, within 30 days of sale, and shall contain all the information set forth in Section 8.840 as well as the difference between prices as set forth above and documentation that the pharmacy is the only pharmacy available within a twenty mile radius. The pharmacy shall be reimbursed for the difference between pricing methodologies.

Information on current pricing may be obtained by contacting: the Rates Section, Medical Assistance Office at the Department.