THIS PAGE NOT FOR PUBLICATION

Title of Rule:	Changes to Provider Reimbursement Rates for the Old Age Pension Health and Medical Care Program
Rule Number:	MSB 09-01-15-A
Division / Contact / Phone:	State Programs and Federal Financing Division / Cindy Arcuri / X3996

SECRETARY OF STATE
RULES ACTION SUMMARY AND FILING INSTRUCTIONS

SUMMARY OF ACTION ON RULE(S)

1. Department / Agency Name: Health Care Policy and Financing / Medical Services Board
2. Title of Rule: MSB 09-01-15-A, Changes to Provider Reimbursement Rates for the Old Age Pension Health and Medical Care Program
3. This action is an adoption of: an amendment
4. Rule sections affected in this action (if existing rule, also give Code of Regulations number and page numbers affected):

   Sections(s) 8.941.1 and 8.941.9, Colorado Department of Health Care Policy and Financing, Staff Manual Volume 8, Medical Assistance (10 CCR 2505-10).
5. Does this action involve any temporary or emergency rule(s)? Yes
   If yes, state effective date:
   Is rule to be made permanent? (If yes, please attach notice of hearing). Yes

PUBLICATION INSTRUCTIONS*

Please replace current text from *§8.941.1 GENERAL DESCRIPTION - OLD AGE PENSION HEALTH CARE PROGRAM AND OLD AGE PENSION HEALTH CARE SUPPLEMENTAL PROGRAM* through the end of §8.941.1.G. with the new text attached. Also, please replace current text from *§8.941.9 REIMBURSEMENT TO PROVIDERS* through the end of the section with new text attached.

This change is effective 06/30/2009.

*to be completed by MSB Board Coordinator

THIS PAGE NOT FOR PUBLICATION

Title of Rule:	Changes to Provider Reimbursement Rates for the Old Age Pension Health and Medical Care Program
Rule Number:	MSB 09-01-15-A
Division / Contact / Phone:	State Programs and Federal Financing Division / Cindy Arcuri / X3996

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).

   Effective January 9, 2009, an emergency rule was adopted that allowed increases for specific provider rates in order for the Old Age Pension Health and Medical Care Program to reimburse providers closer to the program's statutory spending limits. However, in order to meet projected State budget reduction targets, in accordance with Section 8.941.9, the Executive Director of the Department lowered reimbursement rates for this program back to their former levels, effective February 1, 2009. Current budget strategies accommodate the restoration of reimbursement rates to the higher levels approved on January 9, 2009. This proposed rule increases reimbursement rates to those higher levels effective April 15, 2009.

   This current proposed rule also adds in clarifying language under Section 8.941.1(E) relating to the authority of the Executive Director of the Department to increase reimbursement rates to providers within constitutional and statutory limits. The language added is identical to the language added under the emergency rule adopted by the Medical Services Board at its January 9, 2009 Board meeting. The language is added here again in MSB 09-01-15-A since the emergency rule adopted in January, MSB 08-11-21-B, will not be in effect permanently.

   The proposed rule also deletes language under 8.941.1(B) that limits inpatient hospital benefits for Old Age Pension Health and Medical Care Program recipients who receive inpatient hospital services from providers of the Colorado Indigent Care Program. This restriction is no longer necessary for budgetary purposes.

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:

Initial Review		Final Adoption	**05/08/2009**
Proposed Effective Date	**04/10/2009**	Emergency Adoption	**04/10/2009**

DOCUMENT #01

3. Federal authority for the Rule, if any:

   Not applicable. This is a state-only program.

4. State Authority for the Rule:

   25.5-1-301 through 25.5-1-303, C.R.S. (2008);
   25.5-2-1-1. C.R.S. (2008); Colorado Constitution, Article XXIV

THIS PAGE NOT FOR PUBLICATION

Title of Rule:	Changes to Provider Reimbursement Rates for the Old Age Pension Health and Medical Care Program
Rule Number:	MSB 09-01-15-A
Division / Contact / Phone:	State Programs and Federal Financing Division / Cindy Arcuri / X3996

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 persons affected by this proposed rules are the recipients and providers of medical care for the Old Age Pension Health and Medical Care Program. Changes to reimbursement rates and benefits directly impact providers and may indirectly affect client access to care.

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 rule will adjust payment rates based on the Medicaid reimbursement as follows:

Service Type	Rates Effective 01/09/09 - 01/31/09	Rates Effective 02/0/09 - 04/14/09	Proposed Rates Effective 04/15/09
Pharmacy	75%	70%	75%
Inpatient Hospital	10%	10%	10%
Outpatient Services	65%	60%	65%
Practioner/Physician	65%	60%	65%
Emergency Dental	65%	60%	65%
Laboratory and X-Ray	65%	60%	65%
Medical Supply	65%	60%	65%
Hospice and Home Health	65%	60%	65%
Emergency Transportation	65%	60%	65%

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 is implementing these rate changes in order to better manage the Old Age Pension Health and Medical Care Program's expenditures within statutory and constitutional spending authority limits The provision under Section 8.941.1 allowing the Executive Director to increase reimbursement rates without advance approval from the Medical Services Board was approved in January 2009, under a previous emergency rule, MSB # 08-11-21-B and is made permanent in this current rule, 09-01-05-A. There are no administrative costs associated with changing authorized reimbursement rates for Old Age Pension Health

and Medical Care Program providers within the State's Medicaid Management Information System.

Unexpended moneys from this program revert to the Supplemental Old Age Pension Health and Medical Care Fund. The Department estimates that even with this increase in provider reimbursement rates, the balance of this reserve fund will sufficiently cover State budgetary needs, should the General Assembly appropriate funds from this Supplemental Old Age Pension Health and Medical Care Fund to the General Fund.

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

   Inaction on Section 8.941.9 would result in needlessly low reimbursement rates to providers, which in turn could negatively affect participation in the program and potentially limit client access to health care services. Inaction would also result in noncompliance with the intent of the Long Bill appropriations for FY 2008-09. Inaction in section 9.941.1 (B.) might also unnecessarily restrict client access to inpatient hospital services.

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

   At this time, the most efficient means to financially manage the program is to modify reimbursement rates.

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.

   The Department has modeled numerous rate change and expenditures scenarios. This proposal does not eliminate benefits for recipients and provides an equitable benefit to health care providers.

8.941.1 GENERAL DESCRIPTION - OLD AGE PENSION HEALTH CARE PROGRAM AND OLD AGE PENSION HEALTH CARE SUPPLEMENTAL PROGRAM

In accordance with the Constitution of Colorado, Title XXIV, Section 7, and the Colorado Social Services Act, an Old Age Pension Health Care Program is established to provide necessary medical care for the Old Age Pension recipients who do not qualify for Medicaid under Title XIX of the Social Security Act and Colorado statutes. The State Department is designated as the single State agency to administer the program.

The Old Age Pension Health Care Supplemental Program is authorized by Colorado Revised Statues, Section 26-2-117, C.R.S. The funding for this program cannot be accessed until all funds in the Old Age Pension Health Care Program are exhausted.

A. The Old Age Pension Health Care Program and the Old Age Pension Health Care Supplemental Program provide optional benefits to clients who qualify for (State only) OAP-A and (State only) OAP-B pensions who do not qualify for Federal Financial Participation in the Colorado Medicaid Program. These cases are coded with Supplemental Income Status Code (SISC) C.

B. Under the Old Age Pension Health Care Program and the Old Age Pension Health Care Supplemental Program, only the following State funded benefits are provided: physician and practitioner services, inpatient hospital, outpatient services, lab and x-ray, emergency transportation, emergency dental, pharmacy, home health services and supplies, and Medicare cost sharing. ~~As of January 1, 2004 the inpatient hospital benefit is suspended until October 15, 2004.~~

~~Effective October 15, 2004, the inpatient hospital benefit is restored at those hospitals which participate under the Colorado Indigent Care Program. Services to the clients covered under the Old Age Pension Health Care Program and the Old Age Pension Health Care Supplemental Program are limited to those inpatient services available under the Colorado Indigent Care Program.~~

Effective January 1, 2006, Medicare Part D prescription drugs provided pursuant to the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (defined at 42 U.S.C. Sections 1395w-102 and 141 and 42 C.F.R. Section 423, et seq.) shall not be a benefit for those individuals who are eligible for both Medicare and the Old Age Pension Health Care Program or the Old Age Pension Health Care Supplemental Program. The pharmacy drug benefit under the Old Age Pension Health Care Program and the Old Age Pension Health Care Supplemental Program shall follow Medicaid regulations, as specified under 8.830.

For the benefits listed above, the Old Age Pension Health Care Program and the Old Age Pension Health Care Supplemental Program shall only be used to provide clients with health care services determined to be medically necessary by the health care provider.

C. All other medical benefits not listed in paragraph B are excluded under the Old Age Pension Health Care Program and the Old Age Pension Health Care Supplemental Program. Inpatient care in an institution for tuberculosis or mental diseases, skilled and intermediate nursing facility services, and home and community based services are also excluded.

D. The Old Age Pension Health Care Program and the Old Age Pension Health Care Supplemental Program eligibility shall not be retroactive. Eligibility shall begin with the date of application or date eligibility is established, whichever is later.

E. The Executive Director of the Department of Health Care Policy and Financing, under the direction of the State Medical Services Board, shall manage the Old Age Pension Health and Medical Care fund and the supplemental Old Age Pension Health and Medical Care fund to assure that

utilization controls and other mechanisms are in place in order to hold expenditures within the constitutional and statutory limits.

Should the Executive Director, at any time during the course of a fiscal year, determine that expenditures will exceed the available funds, he/she shall take action to reduce expenditures as needed by reducing, suspending, or eliminating payments for covered benefits.

The Executive Director shall consider reducing, suspending or eliminating benefits, individually or in any combination, based upon the shortest duration of time and considering the least impact on the client. The Executive Director shall report to the Board whenever such action is required, specifying the dollar impact, length of time for the reduction, and the number of clients and providers affected. In addition, the Executive Director shall report to the Board on the feasibility of other cost reduction options.

Should the Executive Director, at any time during the course of a fiscal year, determine that expenditures will be less than the available funds, he/she may take action to increase expenditures up to constitutional and statutory limits by modifying the reimbursement methodology for covered benefits. In addition, the Executive Director shall report to the Board whenever such action is taken.

F. Counties shall provide information to Old Age Pension Health Care Program clients regarding the disposal of excess resources in order to qualify for the Medicaid program. Such information shall include advisements concerning the prohibition of transfer of assets without fair consideration.

G. If Medicare pays for a medical service that is a non-benefit for this group, the co-insurance and deductible will not be paid by the Old Age Pension Health Care Program or the Old Age Pension Health Care Supplemental Program.

8.941.9 REIMBURSEMENT TO PROVIDERS

As of July 1, 2007, the Old Age Pension Health Care Program and the Old Age Pension Health Care Supplemental Program will reimburse inpatient hospital services at 10% of the appropriate Medicaid reimbursement. [Eff 07/30/2007]

As of ~~January 9, 2009~~April 15, 2009, providers of physician and practitioner services; outpatient services (including outpatient hospitals, federal qualified health centers, rural health centers and dialysis centers); emergency dental services, independent laboratory and x-ray services; medical supply services; hospice and home health services; and emergency transportation services will be reimbursed at 65% of the appropriate Medicaid reimbursement. As of ~~January 9, 2009~~April 15, 2009, pharmacy claims are reimbursed at 75% of the appropriate Medicaid reimbursement.

In accordance with 8.941.1(E), the Executive Director may alter the reimbursement for any service with the condition that expenditures remain within the constitutional and statutory limits. [Eff 07/30/2007]

THIS PAGE NOT FOR PUBLICATION

Title of Rule: Pharmaceuticals Rule Reorganization and Update

Rule Number: MSB 08-05-22-A

Division / Contact / Phone: Medical and CHP+ Program Administration Office / Kerri Coffey / 303-866-4131

SECRETARY OF STATE
RULES ACTION SUMMARY AND FILING INSTRUCTIONS

SUMMARY OF ACTION ON RULE(S)

1. Department / Agency Name: Health Care Policy and Financing / Medical Services Board
2. Title of Rule: MSB 08-05-22-A, Pharmaceuticals Rule Reorganization and Update
3. This action is an adoption of: an amendment
4. Rule sections affected in this action (if existing rule, also give Code of Regulations number and page numbers affected):

   Sections(s) Insert Section(s) affected, Colorado Department of Health Care Policy and Financing, Staff Manual Volume 8, Medical Assistance (10 CCR 2505-10).
5. Does this action involve any temporary or emergency rule(s)? No
   If yes, state effective date:
   Is rule to be made permanent? (If yes, please attach notice of hearing). Yes

PUBLICATION INSTRUCTIONS*

This is a complete re-write of the rule at §8.800 PHARMACEUTICALS. Please replace all current text from §8.800 through §8.895.5 REIMBURSEMENTS with the new attached text from §8.800 through 8.800.18.E.

This rule change is effective 6/30/2009.

*to be completed by MSB Board Coordinator

THIS PAGE NOT FOR PUBLICATION

Title of Rule:	Pharmaceuticals Rule Reorganization and Update
Rule Number:	MSB 08-05-22-A
Division / Contact / Phone:	Medical and CHP+ Program Administration Office / Kerri Coffey / 303-866-4131

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).

   The purpose of this Pharmaceuticals rule revision is to reorganize the rules into the Department's current standardized format for rules and to clarify existing rules contained in section 8.800. The reorganization is to make the rules more clearly written and better organized so that the rules are easier to understand and confusion can be avoided. Also, the reorganization is to put similar concepts, such as definitions, together. Although wording has changed, the revised wording results in no changes to the implementation of existing policy.

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. Section 1396r-8

4. State Authority for the Rule:

   25.5-1-301 through 25.5-1-303, C.R.S. (2008);
   25.5-5-501, et seq.

Initial Review	**04/10/2009**	Final Adoption	**05/08/2009**
Proposed Effective Date	**07/01/2009**	Emergency Adoption	

DOCUMENT #04

THIS PAGE NOT FOR PUBLICATION

Title of Rule:	Pharmaceuticals Rule Reorganization and Update
Rule Number:	MSB 08-05-22-A
Division / Contact / Phone:	Medical and CHP+ Program Administration Office / Kerri Coffey / 303-866-4131

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.

   No changes have been made to existing policy; therefore, there is no increase or decrease in benefits and no new or additional costs are anticipated.

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

   No changes have been made to existing policy; therefore, there is no increase or decrease in benefits and no new or additional costs are anticipated.

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.

   No changes have been made to existing policy; therefore, there is no increase or decrease in benefits and no new or additional costs are anticipated.

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

   No changes have been made to existing policy; therefore, there is no increase or decrease in benefits and no new or additional costs are anticipated.

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

   No changes have been made to existing policy; therefore, there is no increase or decrease in benefits and no new or additional costs are anticipated.

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.

   No changes have been made to existing policy; therefore, there is no increase or decrease in benefits and no new or additional costs are anticipated.

8.800 PHARMACEUTICALS

8.800.1 DEFINITIONS

Conflict of Interest means having competing professional or personal obligations or personal or financial interests that would make it difficult to fulfill duties in an objective manner.

Department means the Colorado Department of Health Care Policy and Financing.

Dispensing Physician means a licensed physician who prepares, dispenses and instructs clients to self administer medication.

Drug Class means a group of drugs that treat a particular disease or symptom and are in the same therapeutic class.

Emergency Situation means any condition that is life threatening or requires immediate medical intervention as determined in good faith by the pharmacist.

E-prescription means the transmission of a prescription through an electronic application.

Fiscal Agent means a private contractor that supports and operates Colorado's Medicaid Management Information System and performs operational activities that support the administration of the Medical Assistance Program.

Federal Upper Limit (FUL) means the upper limit for multiple source drugs as set by the Centers for Medicare and Medicaid Services pursuant to 42 C.F.R. 447.300-447.334 (2008), which is incorporated herein by reference. No amendments or later editions are incorporated. Copies are available for inspection from the following person at the following address: Custodian of Records, Colorado Department of Health Care Policy and Financing, 1570 Grant Street, Denver, Colorado 80203-1818. Any material that has been incorporated by reference in this rule may be examined at any state publications depository library.

Good Cause means failing to disclose a Conflict of Interest; participating in wrongdoing or misconduct in the case of serving as a member of a committee or other advisory body for the Department; failing to perform required duties; or missing two scheduled meetings per calendar year.

Government Pharmacy means a pharmacy whose primary function is to provide drugs and services to clients of a facility whose operating funds are appropriated directly from the State of Colorado or the federal government excluding pharmacies funded through Indian Health Services.

Institutional Pharmacy means a pharmacy that participates in the Federal Public Health Service's 340B drug pricing program as described in 42 U.S.C. Section 256b (2008), or 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. 42 U.S.C. Section 256b (2008) is incorporated herein by reference. No amendments or later editions are incorporated. Copies are available for inspection from the following person at the following address: Custodian of Records, Colorado Department of Health Care Policy and Financing, 1570 Grant Street, Denver, Colorado 80203-1818. Any material that has been incorporated by reference in this rule may be examined at any state publications depository library.

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

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

Medical Assistance Program shall have the meaning defined in 25.5-1-103(5), C.R.S. (2008).

Medical Assistance Program Allowable Charge means the allowed ingredient cost plus a dispensing fee or the provider's Usual and Customary Charge, whichever is less, minus the client's copayment as determined according to 10 C.C.R. 2505-10, Section 8.754.

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

Medicare Part D means the drug benefit provided to Part D Eligible Individuals pursuant to the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

Medicare Part D Drugs means drugs defined at 42 U.S.C. Sections 1395w-102 and 141 and 42 C.F.R. Section 423, et seq. (2008), which are incorporated herein by reference. No amendments or later editions are incorporated. Copies are available for inspection from the following person at the following address: Custodian of Records, Colorado Department of Health Care Policy and Financing, 1570 Grant Street, Denver, Colorado 80203-1818. Any material that has been incorporated by reference in this rule may be examined at any state publications depository library.

Non-preferred Drug means a drug that requires a prior authorization as described in 10 C.C.R. 2505-10, Section 8.800.7, before being payable by the Medical Assistance Program.

Old Age Pension Health Care Program and Old Age Pension Health Care Supplemental Program (OAP State Only) means the program established to provide necessary medical care for clients that qualify for Old Age Pension but do not qualify for the Medical Assistance Program under Title XIX of the Social Security Act and Colorado statutes.

Over-the-Counter (OTC) means a drug that can be purchased without a physician's prescription.

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

Pharmacy and Therapeutics Committee (P&T Committee) means an advisory board that shall perform reviews and make recommendations which facilitate the development and maintenance of the Preferred Drug List as described in 10 C.C.R. 2505-10, Section 8.800.17.

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.

Preferred Drug means a drug that is payable by the Medical Assistance Program without first obtaining a prior authorization unless otherwise required to protect the health and safety of specific clients.

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 Drugs and Non-preferred Drugs within a drug class.

Provider Bulletin means a document published and distributed by program and policy staff to communicate information to providers related to the Department.

Retail Pharmacy means any pharmacy that is not a Government Pharmacy, an Institutional Pharmacy or a Mail Order Pharmacy.

Rural Pharmacy means any pharmacy that is the only pharmacy within a twenty-mile radius.

State Maximum Allowable Cost (State MAC) means the maximum ingredient cost allowed by the Department for certain multiple-source drugs.

Usual and Customary Charge means the reimbursement amount the provider charges the general public to pay for a drug.

8.800.2 CONDITIONS OF PARTICIPATION

8.800.2.A. A pharmacy must be licensed or certified by the appropriate regulatory body in the state in which it is located. Pharmacies located outside of Colorado must also be registered in Colorado if required by the Colorado Board of Pharmacy.

8.800.2.B. Any pharmacy or Dispensing Physician, whether in-state or out-of-state, that submits claims for reimbursement must first submit an application for participation to the Department. The provider shall be notified whether or not the application is accepted and, if accepted, the effective date. An accepted application must be on file with the Department before reimbursement shall be made. An application may be denied, terminated or not renewed for any of the grounds set forth in 10 C.C.R. 2505-10, Sections 8.050 or 8.l30.

8.800.2.C. An out-of-state pharmacy may enroll as a provider and receive payment for dispensed drugs under any of the following circumstances:

1. The client has been injured or suffered a disease or illness while temporarily absent from Colorado. In that case, the Department shall reimburse an out-of-state pharmacy for drugs dispensed on an emergency basis only.

2. The out-of-state pharmacy is located in a town that is near the Colorado border and is listed in the Medical Assistance Program Manual as an approved town that borders Colorado. Such pharmacy shall be reimbursed for drugs in the same manner as in-state pharmacies.

3. The out-of-state pharmacy provides drugs to foster care children or other clients who permanently reside in other states and are wards of Colorado. Such pharmacy shall be reimbursed for drugs in the same manner as in-state pharmacies.

4. The out-of-state pharmacy provides a drug that is not available through any pharmacies located within Colorado. In that case, the Department shall reimburse the out-of-state pharmacy for those services only.

5. The out-of-state pharmacy is a Mail Order Pharmacy that mails Maintenance Medications to clients meeting the requirements of 10 C.C.R. 2505-10 Section 8.800.3.

8.800.3 MAIL ORDER

8.800.3.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.

8.800.4 DRUG BENEFITS

8.800.4.A. Only those drugs designated by companies participating in the federally approved Medical Assistance Program drug rebate program and not otherwise excluded according to these rules are regular drug benefits. Notwithstanding the foregoing, drugs not covered by rebate agreements may be reimbursed if the Department has made a determination that the availability

of the drug is essential, such drug has been given an “A” rating by the U. S. Food and Drug Administration (FDA), and a prior authorization has been approved. Reimbursement of any drugs that are regular drug benefits may be restricted as set forth in these rules.

8.800.4.B. The following drug categories may be excluded from being a drug benefit or may be subject to restrictions:

1. Agents when used for anorexia, weight loss or weight gain;

2. Agents when used to promote fertility;

3. Agents when used for cosmetic purposes or hair growth;

4. Agents when used for symptomatic relief of cough and colds;

5. Agents when used to promote smoking cessation;

6. Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations;

7. Non-prescription Drugs;

8. Covered outpatient drugs that the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee;

9. Barbiturates;

10. Benzodiazepines; and

11. Agents used for the treatment of sexual or erectile dysfunction unless such agents are used to treat a condition, other than a sexual or erectile dysfunction, for which the agents have been approved by the FDA.

8.800.4.C. The following are not pharmacy benefits of the Medical Assistance Program:

1. Spirituous liquors of any kind;

2. Dietary needs or food supplements;

3. Personal care items such as mouth wash, deodorants, talcum powder, bath powder, soap of any kind, dentifrices, etc.;

4. Medical supplies;

5. Drugs classified by the FDA as "investigational" or "experimental”;

6. Less-than-effective drugs identified by the Drug Efficacy Study Implementation (DESI) program; and

7. Medicare Part D Drugs for Part D Eligible Individuals.

8.800.4.D. Aspirin, OTC insulin and medications that are available OTC and that have been designated as Preferred Drugs on the PDL, in compliance with the provisions of Section 8.800.16, are the only OTC drugs that are regular benefits without restrictions.

8.800.4.E. Restrictions may be placed on drugs in accordance with 42 U.S.C. Section 1396r-8(d) (2007), which is incorporated herein by reference. No amendments or later editions are

incorporated. Copies are available for inspection from the following person at the following address: Custodian of Records, Colorado Department of Health Care Policy and Financing, 1570 Grant Street, Denver, Colorado 80203-1818. Any material that has been incorporated by reference in this rule may be examined at any state publications repository library. Without limiting the foregoing, restrictions may be placed on drugs for which it has been deemed necessary to address instances of fraud or abuse, potential for, and history of, drug diversion and other illegal utilization, overutilization, other inappropriate utilization or the availability of more cost-effective comparable alternatives.

8.800.4.F. Medicare Part D Drugs shall not be covered by the Medical Assistance Program for Part D Eligible Individuals.

8.800.4.G. The excluded drugs listed in Section 8.800.4.B shall be covered for Part D Eligible Individuals in the same manner as they are covered for all other eligible Medical Assistance Program clients.

8.800.4.H. Generic drugs shall be dispensed to clients in fee-for-service programs unless:

1. Only a brand name drug is manufactured.

2. A generic drug is not therapeutically equivalent to the brand name drug.

3. The final cost of the brand name drug is less expensive to the Department.

4. The drug is in one of the following exempted classes for the treatment of:

   a. Biologically based mental illness as defined in C.R.S. 10-16-104 (5.5) (2008). Without limiting the foregoing, restrictions may be placed on drugs for which it has been deemed necessary to address instances of fraud or abuse, potential for, and history of, drug diversion and other illegal utilization, overutilization, other inappropriate utilization or the availability of more cost-effective comparable alternatives.;

   b. Treatment of cancer;

   c. Treatment of epilepsy; or

   d. Treatment of Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome.

5. The Department shall grant an exception to this requirement if:

   a. The client has been stabilized on a medication and the treating physician, or a pharmacist with the concurrence of the treating physician, is of the opinion that a transition to the generic equivalent of the brand name drug would be unacceptably disruptive; or

   b. The client is started on a generic drug but is unable to continue treatment on the generic drug.

   Such exceptions shall be granted in accordance with procedures established by the Department.

8.800.5 DRUGS ADMINISTERED OR PROVIDED IN PHYSICIAN OFFICES OR CLINICS

8.800.5.A. Any drugs administered in a physician's office or clinic are considered part of the physician's services and not a pharmacy benefit. Such drugs shall be billed on the physician

claim form. Pharmacies may not bill for any products that shall be administered in a physician's office or clinic.

8.800.5.B. Dispensing Physicians whose offices or sites of practice are located more than 25 miles from the nearest participating pharmacy may be reimbursed for drugs that are dispensed from their offices and that shall be self-administered by the client.

8.800.6 COMPOUNDED PRESCRIPTIONS

8.800.6.A Compounded prescriptions shall be billed by submitting all ingredients in the prescription as one multiple-line claim. The provider will be reimbursed for each ingredient of the prescription according to Section 8.800.13.A-F, and will also be reimbursed for the dispensing fee according to Section 8.800.13.H. A compounding fee, over and above the stated dispensing fee, will not be paid.

8.800.7 PRIOR AUTHORIZATION REQUIREMENTS

8.800.7.A. Prior authorization shall be obtained before drugs that are subject to prior authorization restrictions may be provided as a benefit. Prior authorization requests may be made by the client's physician, any other health care provider who has authority under Colorado law to prescribe the medication being requested or any long-term-care pharmacy or infusion pharmacy that fills prescriptions on behalf of the client and is acting as the agent of the prescriber. The prior authorization request shall be made to the Fiscal Agent. The prescriber shall provide any information requested by the Fiscal Agent including, but not limited to, the following:

1. Client name, Medical Assistance Program state identification number, and birth date;

2. Name of the drug(s) requested;

3. Strength and quantity of drug(s) requested; and

4. Prescriber's name and medical license number, Drug Enforcement Administration number, or National Provider Identifier.

8.800.7.B. When the prior authorization request is received, it shall be reviewed to determine if the request is complete. If it is complete, the requesting provider shall be notified of the approval or denial of the prior authorization request via telephone and/or facsimile at the time the request is made, if possible, but in no case later than 24 hours after the request is made. Any verbal decision shall be confirmed in writing. If the prior authorization request is incomplete or additional information is needed, an inquiry to the party requesting the prior authorization shall be initiated within one working day from the day the request was received. If no response is received from that party within 24 hours of the Department's inquiry, the prior authorization shall be denied.

8.800.7.C. In an emergency situation, the pharmacy may dispense up to a 72-hour supply of a covered drug that requires a prior authorization if it is not reasonably possible to request a prior authorization for the drug before it must be dispensed to the client for proper treatment. The pharmacist may call the Prior Authorization Help Desk to receive override approval.

8.800.7.D. The Department shall solicit and maintain a list of any interested parties who wish to comment on any proposed additions to the drugs that are subject to prior authorization. The list of interested parties shall be notified of any proposal and shall be given reasonable time, not to exceed 30 days, to comment or recommend changes before any drugs become subject to prior authorization. Notwithstanding the foregoing, if a new drug is approved by the FDA and that drug is in a class of drugs already subject to prior authorization, the new drug shall also be subject to prior authorization without any comment period.

8.800.7.E. Any changes to the drugs that are subject to prior authorization or any documentation required to obtain a prior authorization shall be published in the Provider Bulletin. Notification in the Provider Bulletin shall satisfy any notification requirements of any such changes.

8.800.8 LIMIT REQUIREMENTS

8.800.8.A. Limits shall include a limit on the number of units of a drug that a client may receive in a 30-day or 100-day period, as applicable. Limits placed on the coverage of any drugs under the Medical Assistance Program shall result in pharmaceutical services still being sufficient in the amount, duration and scope to meet all applicable federal laws and regulations.

8.800.8.B. The Department shall solicit and maintain a list of any interested parties who wish to comment on any proposed limits on drugs. The list of interested parties shall be notified of any proposal and shall be given reasonable time, not to exceed 30 days, to comment or recommend changes before any such drugs are limited. Notwithstanding the foregoing, if a new drug is approved by the FDA and that drug is in a class of drugs already subject to limits, the new drug shall also be subject to limits without any comment period.

8.800.8.C. Any limits on drugs or changes to the drugs that are subject to limits shall be published in the Provider Bulletin. Notification in the Provider Bulletin shall satisfy any notification requirements of any such limits or changes to the limits.

8.800.9 DRUG UTILIZATION REVIEW

8.800.9.A. Prospective Drug Utilization Review

1. A pharmacist shall review the available client record information with each drug order presented for dispensing for purposes of promoting therapeutic appropriateness by considering the following:

    a. Over-utilization or under-utilization;

    b. Therapeutic duplication;

    c. Drug-disease contraindications;

    d. Drug-drug interactions;

    e. Incorrect drug dosage or duration of drug treatment;

    f. Drug-allergy interactions; and

    g. Clinical abuse/misuse.

2. When in the pharmacist's professional judgment a potential problem is identified, the pharmacist shall take appropriate steps to avoid or resolve the problem, which may, if necessary, include consultation with the prescriber.

8.800.9.B. Client Counseling

1. A pharmacist or pharmacy intern shall offer drug therapy counseling to each Medical Assistance Program client or the caregiver of such client with a new prescription or with a refill prescription if the pharmacist or pharmacy intern believes that it is in the best interest of the client. The offer to counsel shall be face-to-face communication whenever practicable or by telephone.

2. If the offer to counsel is accepted, a pharmacist or pharmacy intern shall review the client’s record and then discuss with the client or the client’s caregiver those matters that,

in the exercise of his or her professional judgment, the pharmacist or pharmacy intern considers significant including the following:

a. The name and description of the drug;

b. The dosage form, dose, route of administration, and duration of drug therapy;

c. Intended use of the drug and expected action;

d. Special directions and precautions for preparation, administration, and use by the client;

e. Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

f. Techniques for self-monitoring drug therapy;

g. Proper storage;

h. Prescription refill information; and

i. Action to be taken in the event of a missed dose.

3. Alternative forms of client information shall not be used in lieu of the personal discussion requirement for client counseling but may be used to supplement this discussion when appropriate. Examples of such alternative forms of client information include written information leaflets, auxiliary or pictogram labels, and video programs.

4. Client counseling by a pharmacist or pharmacy intern as described in this section shall not be required for clients of a hospital or institution where other licensed health care professionals administer the prescribed drugs pursuant to a chart order.

5. A pharmacist or pharmacy intern shall not be required to counsel a client or caregiver when the client or caregiver refuses such consultation. The pharmacist or pharmacy intern shall keep records indicating when counseling was not or could not be provided.

8.800.9.C. Retrospective Drug Utilization Review

1. The Department shall periodically review claims data in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists and clients receiving drug benefits or associated with specific drugs or categories of drugs.

2. Such reviews shall be based on predetermined criteria that monitor for therapeutic problems including but not limited to therapeutic appropriateness, over-utilization, under-utilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, and clinical abuse/misuse.

8.800.9.D. Drug Utilization Review (DUR) Board

1. The DUR Board shall serve in an advisory capacity to the Department. The DUR Board's activities shall include but are not limited to the following:

a. Approving the application of standards;

b. Conducting retrospective DUR;

c. Conducting ongoing interventions with pharmacists and physicians concerning therapy problems identified in the course of the DUR program;

d. Making recommendations regarding certain Department policy issues as determined by the Department; however, the Department shall consider all such recommendations but shall not be bound by them; and

e. Engaging in any other activities as designated by the Department.

2. The DUR Board shall meet no less frequently than quarterly.

3. The DUR Board shall consist of nine members appointed by the Executive Director of the Department based upon recommendations of relevant professional associations. Membership on the Board shall consist of four physicians and four pharmacists, all of whom are licensed and actively practicing in Colorado, and one non-voting representative from the pharmaceutical industry. The physicians and pharmacists shall serve two-year terms and may be reappointed to additional terms at the discretion of the Executive Director. The terms shall be staggered so that in each year, there are two physician members and two pharmacist positions that are reappointed. The pharmaceutical industry representative shall serve a one-year term and shall not be reappointed.

4. The membership of the DUR Board shall include health care professionals who have recognized knowledge and expertise in one or more of the following:

a. The clinically appropriate prescribing of covered outpatient drugs;

b. The clinically appropriate dispensing and monitoring of outpatient drugs;

c. Drug utilization review, evaluation and intervention; or

d. Medical quality assurance.

5. The DUR Board shall have those responsibilities as set forth in 42 U.S.C. Section 1396r-8(g)(3)(C)(2007) and 42 C.F.R. Section 456-716(d) (2008), both of which are incorporated herein by reference. No amendments or later editions are incorporated. Copies are available for inspection from the following person at the following address: Custodian of Records, Colorado Department of Health Care Policy and Financing, 1570 Grant Street, Denver, Colorado 80203-1818. Any material that has been incorporated by reference in this rule may be examined at any state publications repository library.

6. The DUR Board is also responsible for preparing and submitting a report to the Department on an annual basis which shall include the following information:

a. A description of the activities of the DUR Board, including the nature and scope of the prospective and retrospective drug utilization review programs;

b. A summary of the interventions used;

c. An assessment of the impact of these educational interventions on quality of care; and

d. An estimate of the cost savings generated as the result of the program.

7. The DUR Board under the direction of the Department may delegate to a retrospective DUR contractor the responsibility of preparation of continuing education programs, the conduct of interventions and the preparation of any reports.

8.800.10 BILLING PROCEDURES

8.800.10.A. Charges for prescribed drugs shall be submitted on an appropriate pharmacy claim form or electronically in a Department approved format. All entries shall be legible.

8.800.10.B. Each claim must identify the client, prescribing physician, date of service, National Drug Code number of the drug actually dispensed, prescription number, quantity dispensed, days' supply, the Usual and Customary Charge and any other information required by the Department.

8.800.11 PRESCRIPTION RECORD REQUIREMENTS

8.800.11.A. The original prescription shall be a hard copy written, faxed or electronically mailed or otherwise transmitted by the prescriber or reduced to writing by pharmacy staff when received by telephone. All information required by the Colorado State Board of Pharmacy shall appear on each prescription including any information required if a substitution for a drug is made. All refill information shall be recorded in accordance with the Colorado State Board of Pharmacy requirements.

8.800.11.B. All records for new prescriptions and refills for which payment from the Medical Assistance Program is requested shall be maintained in accordance with Colorado State Board of Pharmacy requirements except that such records must be retained for the length of time set forth in 10 C.C.R. 2505-10, Section 8.040.2.

8.800.11.C. The pharmacist shall be responsible for assuring that reasonable efforts have been made to obtain, record, and maintain the following client information from the client or his/her apparent agent for each new prescription:

1. Name, address, telephone number, date of birth or age, and gender;

2. Individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive, chronological list of medications and prescribed relevant devices; and

3. Additional comments relevant to the client's pharmaceutical care as described in the Prospective Drug Review and Client Counseling sections set forth in 10 C.C.R. 2505-10, Section 8.800.9.

8.800.11.D. TAMPER-RESISTANT PRESCRIPTION DRUG PADS OR PAPER

1. The use of tamper-resistant prescription drug pads or paper is required for all written or electronically printed prescriptions for all Medical Assistance Program clients when:

   a. Prescriptions are issued for outpatient drugs, including controlled and uncontrolled substances, or OTC drugs that are reimbursable through the Medical Assistance Program and dispensed by a pharmacy; and

   b. The Medical Assistance Program is the primary or secondary payer of the prescription being filled.

2. To be considered tamper-resistant, the pad/paper used for a written or electronically printed prescription shall integrate three distinct characteristics. The three characteristics and the specific features required are as follows:

   a. Characteristic #1: One or more industry-recognized features designed to prevent unauthorized copying of completed or blank prescription form. A prescription shall contain at least one of the following features:

      i) Void/Illegal/Copy Pantograph with or with the Reverse Rx feature. The word “Void”, “Illegal”, or “Copy” appears when the prescription is photocopied. If the paper has the Reverse Rx feature, the Rx symbol

must disappear when photocopied at light setting. The Reverse Rx feature is not allowed as a feature by itself.

ii) Micro-fine printed security message generated by a computer, electronic medical records system or other electronic means. The message may serve as a signature line or border. This must be printed in 0.5 font or smaller and readable when viewed at 5x magnification or greater and illegible when copied.

iii) Coin-reactive ink or security mark. The pad or paper identifies an area on the pad/paper where the ink changes color or reveals wording or a picture when that area is rubbed by a coin. This must be accompanied by a message describing what is necessary to demonstrate authenticity.

iv) Security print watermark. Specific wording is printed on the front or back of the prescription paper and can only be seen when viewed at an angle.

v) Paper with a watermark. This is paper that contains a watermark that can be seen when backlit.

b. Characteristic #2: One or more industry recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber. A prescription shall contain at least one of the following features:

i) An erasure-revealing background. This is a background that consists of a non-white solid color or consistent pattern that has been printed onto the paper. If an erasure or modification is attempted, the background will show marks or the color of the underlying paper where the alterations were made.

ii) Toner fusing technology for laser-printed prescriptions. This is a treatment that is added to the surface of the paper to create a strong bond between the laser-printed text and the paper. The computer-printed information cannot be lifted from the surface of the paper without damaging the paper.

iii) Chemical-reactive paper. This is paper that contains features that show discoloration or reveals a hidden message if solvents are used to attempt to wash the ink from its surface.

iv) Plain bond paper combined with inkjet-printing. The inkjet printing is absorbed into the high grade paper stock. Erasures and modifications cannot be made without damaging the paper.

v) Pre-printed quantity check-off boxes indicated in ranges of no more than 25 per range combined with a written quantity. The range box corresponding to the quantity prescribed must be checked by the prescriber for the prescription to be valid.

vi) Pre-printed refill indicator where the number of refills allowed is marked or no refills or “NR” is marked when no refills are authorized. Refill information must be completed by the prescriber for the prescription to be valid.

vii) Characters surrounding the authorized dispensing quantity and the number of refills. Special characters such as a series of asterisks must be repeated on both sides of the numbers indicating the quantity and the number of refills authorized (e.g., Quantity ***50*** Refill ***3***). This is

acceptable only for prescriptions that are generated by a computer, electronic medical records system or other electronic means.

c. Characteristic #3: One or more industry recognized features designed to prevent the use of counterfeit forms. A prescription must contain at least one of the following features:

i) Security features listed visibly in a box, band or border on the prescription. This must be a complete listing of all of the security features incorporated into the prescription pad/paper in order to minimize tampering.

ii) Security threads. Metal, fluorescent or plastic security threads are embedded into the prescription pad/paper.

iii) Thermochromic ink. All or some of the pad or paper is pre-printed with ink that changes color when exposed to heat and then changes back to its original color when cooled. This must be accompanied by a message describing what is necessary to demonstrate authenticity.

3. The use of tamper-resistant prescription pads or paper is not required when:

a. Prescriptions are transmitted by telephone, fax or E-prescription directly to the pharmacy by the prescriber or prescriber's staff that is authorized to act on the prescriber's behalf; or

b. A prescriber administers or provides the drug directly to the client; or

c. A prescriber in an institutional setting writes the order into the medical record and then the order is given by medical staff directly to the pharmacy; or

d. A Medical Assistance Program managed care entity pays for or dispenses the prescription;

4. A prescription is written for any medical item, service or equipment that is not considered an outpatient drug; or

5. A drug that is provided as part of, or as incident to and in the same setting as, any of the following (and for which payment may be made as part of payment for the following and not as direct reimbursement for the drug):

a. Inpatient hospital services;

b. Hospice services;

c. Dental services (except when a State Plan authorizes direct reimbursement to the dispensing dentist);

d. Physician services;

e. Outpatient hospital services;

f. Nursing facilities and intermediate care facilities for the mentally retarded;

g. Other laboratory and x-ray services; or

h. Renal dialysis.

6. The pharmacy may dispense up to a 72-hour supply of a covered outpatient prescription drug in an emergency situation, provided that the pharmacy obtains a compliant prescription in writing, or by telephone, facsimile, or E-prescription, within 72 hours of filling the prescription.

7. When a Medical Assistance Program client is determined retroactively eligible after a pharmacy has filled the recipient's prescription, the prescription shall be deemed to comply with the tamper-resistant pad/paper requirements. This presumption applies only to prescriptions that were filled before the client was determined eligible. Prescriptions that are filled or refilled after the client is determined eligible require a new, tamper-resistant prescription or the pharmacy may obtain verbal confirmation of the prescription from the prescriber or may obtain the prescription from the prescriber by facsimile or E-prescription.

8.800.11.E. Prescription tracking and claim reversals

1. The pharmacy shall keep:

   a. A chronological log that contains the client's name, his or her signature or agent's signature and date of the receipt of the prescription; or

   b. An electronic prescription tracking system that records the status of prescriptions through the fill process including the date and time that the prescription was transferred to a person whom pharmacy personnel verified was the client or agent of the client.

2. Pharmacies using a chronological log shall review all Medical Assistance Program prescriptions in shall-call status (filled but not released to the client or the client's agent) at least weekly and enter a reversal of prescriptions not picked up within 14 days of billing. In no case shall prescriptions be kept in shall-call status for more than 21 days. The pharmacy shall maintain a record of each reversal for audit purposes.

3. Pharmacies using an electronic prescription tracking system shall review all Medical Assistance Program prescriptions in shall-call status on a daily basis and enter a reversal of prescriptions not picked up within 10 days of billing. In no case shall prescriptions be kept in shall-call status for more than 14 days. The pharmacy shall maintain a record of each reversal for audit purposes.

4. Upon receipt of a written request from the Department or the Medicaid Fraud Unit for a record of Medical Assistance Program claims and reversals, the pharmacy has up to 72 hours or three working days to provide the requested information or to enter into an agreement with the Department or Unit stating the specific time within which the data shall be produced.

8.800.11.F. Any information, documents or records required to be retained under 10 C.C.R. 2505-10, Section 8.800.11 shall be made available for inspection to authorized personnel of the Department, U.S. Department of Health and Human Services or the Medicaid Fraud Control Unit.

8.800.12 BASIS FOR REIMBURSEMENT

8.800.12.A. Reimbursement shall be made for prescribed drugs provided to clients when all of the following conditions are met:

1. The item dispensed is a covered benefit under the Medical Assistance Program and meets any and all restriction requirements as set forth in 10 C.C.R. 2505-10, Section 8.800 or any policies thereunder;

2. The person prescribing the item is licensed to do so under applicable law;

3. The item is dispensed pursuant to a valid prescription order;

4. The prescription is dispensed in accordance with applicable federal and state laws, rules, and regulations, including those regulations governing the Medical Assistance Program; and

5. The prescription is written on a tamper-resistant prescription drug pad or paper or is excluded from the tamper-resistant prescription drug pad or paper requirements set forth in 10 C.C.R. 2505-10, Section 8.800.11.D.

8.800.13 REIMBURSEMENT CALCULATION

8.800.13.A. Covered drugs for all clients except for OAP State Only clients shall be reimbursed at the provider's Usual and Customary Charge minus the client's copayment, as determined according to 10 C.C.R. 2505-10, Section 8.754, or the allowed ingredient cost plus a dispensing fee minus the client's copayment, whichever is less. Covered drugs for the OAP State Only Programs shall be reimbursed according to 10 C.C.R. 2505-10, Section 8.941.

8.800.13.B. The allowed ingredient cost for Retail Pharmacies and Mail Order Pharmacies is the price of the drug calculated according to the applicable pricing methodologies set forth in 10 C.C.R. 2505-10, Section 8.800.13.D, whichever is less.

8.800.13.C. The allowed ingredient cost for Institutional and Government Pharmacies is the actual cost of acquisition for the drug dispensed or the price of the drug calculated according to the applicable pricing methodologies set forth in 10 C.C.R. 2505-10, Section 8.800.13.D, whichever is less.

8.800.13.D. The allowed ingredient cost is determined utilizing different methodologies as applicable. The pricing methodologies are:

1. Based on Average Wholesale Price (AWP):

   a. AWP less 13.5% for brand name drugs; and

   b. AWP less 35% for generic drugs;

2. Direct price plus 18%;

3. State MAC; and

   a. The State MAC shall be established as the pharmacy acquisition cost of generic drugs available in the marketplace plus 18%; and

   b. The establishment of a State MAC is subject to, but not limited to, the following considerations:

      i) Multiple manufacturers;

      ii) Broad wholesale price span;

      iii) Availability of drugs to retailers at the selected cost;

      iv) High volume of Medical Assistance Program client utilization; and

      v) Bioequivalence or interchangeability.

4. FUL

a. When FUL rates are announced, the Department shall adopt them; and

b. A drug that is subject to FUL may be reimbursed at a rate greater than FUL if the prescriber certifies that the brand name drug is medically necessary for the client. The prescriber must make such certification through the prior authorization process or other procedures established by the Department.

8.800.13.E. A drug-pricing file containing all of the pricing methodologies shall be maintained and updated at least monthly by the Department.

8.800.13.F. Any pharmacy, except a Mail Order Pharmacy, that is the only pharmacy within a twenty-mile radius may submit a letter to the Department requesting to become a Rural Pharmacy. If approved as a Rural Pharmacy, the modified estimated acquisition cost shall be AWP minus 12% for brand name and generic drugs instead of the amount set forth in 10 C.C.R. 2505-10, Section 8.800.13.D.1.

8.800.13.G. Information on current pricing may be obtained by contacting the Department's Pharmacy Section.

8.800.13.H. Dispensing Fee

1. The dispensing fee is a pre-determined amount paid to a pharmacy for dispensing a prescription. It is established and periodically adjusted based upon the results of a cost survey which is designed to measure actual costs of filling prescriptions. The results of any such survey shall be reported to the Medical Services Board at the next regular meeting following delivery of the report to the Department.

2. Retail Pharmacies shall receive a dispensing fee of $4.00.

3. Institutional Pharmacies shall receive a dispensing fee of $1.89.

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

5. Government Pharmacies shall receive no dispensing fee.

6. 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 that case, the Dispensing Physician shall receive a dispensing fee of $1.89.

8.800.14 PRESCRIPTION QUANTITIES

8.800.14.A For chronic conditions requiring maintenance drugs, the maximum dispensing quantities for new and refill prescriptions shall be a 100-day supply. For all other drugs, the maximum dispensing quantities for new and refill prescriptions shall be a 30-day supply. The Department may set or change minimum or maximum dispensing quantities of certain drugs.

8.800.15 REIMBURSEMENT FROM PHARMACIES REDISPENSING UNUSED MEDICATION

8.800.15.A. A pharmacy participating in the Medical Assistance Program may accept unused medication from a hospital, hospital unit, hospice, nursing care facility, or assisted living residence that is required to be licensed pursuant to Section 25-3-101, C.R.S. (2008), or a licensed health care provider for the purpose of dispensing the medication to another person.

8.800.15.B. A pharmacy shall reimburse the Department for the Medical Assistance Program Allowable Charge that the Department has paid to the pharmacy if medications are returned to a pharmacy and the medications are available to be dispensed to another person.

8.800.16 PREFERRED DRUG LIST

8.800.16.A. ESTABLISHING THE PREFERRED DRUG LIST

1. To develop and maintain the PDL, the Department shall take the following steps:

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

   b. Refer selected drugs and Drug Classes to the 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 8.800.17.C.

   c. Make recommendations to the Medical Director based on evaluations of relevant criteria, including but not limited to:

      i) Drug safety;

      ii) Drug efficacy;

      iii) The recommendations of the P&T Committee;

      iv) Public comments received by the Department before a drug or Drug Class is reviewed at the relevant P&T Committee meeting;

      v) Cost-effectiveness;

      vi) Scientific evidence, standards of practice and other relevant drug information for such evaluation; and

      vii) Compliance with the Generic Mandate, 25.5-5-501 C.R.S. (2008) and Federal Upper Limits, 42 C.F.R. Sections 447.331-447.334 (2008), is incorporated herein by reference. No amendments or later editions are incorporated. Copies are available for inspection from the following person at the following address: Custodian of Records, Colorado Department of Health Care Policy and Financing, 1570 Grant Street, Denver, Colorado 80203-1818. Any material that has been incorporated by reference in this rule may be examined at any state publications depository library.

2. After the P&T Committee meets, the Medical 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.

3. After the Medical 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.

4. After the DUR Board meets, the Medical 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.

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

6. Drug Classes included on the PDL shall be reviewed annually.

8.800.16.B. NEW DRUGS

1. 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:

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

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

   c. The new drug must be designated a Preferred Drug in order to comply with the Generic Mandate, 25.5-5-501 C.R.S. (2008) and/or Federal Upper Limits, 42 C.F.R. Sections 447.331-447.334 (2008), which is incorporated herein by reference. No amendments or later editions are incorporated. Copies are available for inspection from the following person at the following address: Custodian of Records, Colorado Department of Health Care Policy and Financing, 1570 Grant Street, Denver, Colorado 80203-1818. Any material that has been incorporated by reference in this rule may be examined at any state publications depository library.

2. 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 8.800.16.A.

8.800.16.C. EXCLUSION OF DRUGS, DRUG CLASSES OR INDIVIDUALS FROM THE PDL

1. 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.

2. After reviewing the recommendations of the P&T Committee and the Department, the Medical Director may, notwithstanding any other provision of this section and to the extent allowed by federal and state law:

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

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

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

3. Individual Medical Assistance Program clients shall be exempted, on an annual basis, from prior authorization requirements for all Non-preferred Drugs if:

   a. A client meets clinical criteria recommended by the Department and P&T Committee and approved by the Medical Director; and

   b. A client’s physician submits a request for exemption and meets the criteria for approval.

8.800.16.D. AUTHORITY OF THE EXECUTIVE DIRECTOR

1. The decisions of the Medical Director, made under the authority of this section, shall be implemented by the Department at the sole discretion of the Executive Director.

2. If the Medical Director position is unfilled, the duties and obligations of that position, as described in this section, shall be performed by the Executive Director.

8.800.16.E. SUPPLEMENTAL REBATES 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.

8.800.16.F. ANNUAL REPORT The Department shall prepare and publicly post an annual report that includes an estimate of cost savings generated by the PDL program.

8.800.16.G. DRUG CLASS MORATORIUM The following Drug Classes cannot be considered for inclusion on the PDL until after December 31, 2009:

1. Atypical and typical antipsychotic drugs;

2. Drugs used for the treatment of HIV/AIDS;

3. Drugs used for the treatment of hemophilia; and

4. Drugs used for the treatment of cancer.

8.800.17 PHARMACY AND THERAPEUTICS COMMITTEE

8.800.17.A. MEMBERSHIP

1. The P&T Committee shall consist of at least nine members, but not more than thirteen members, appointed by the Executive Director.

   a. The P&T Committee membership shall include:

      i) Four pharmacists;

      ii) Two client representatives;

      iii) One physician who specializes in the practice of psychiatry;

      iv) One physician who specializes in the practice of pediatrics;

      v) One physician who specializes in the treatment of clients with disabilities; and

      vi) Four physicians from any other medical specialty.

   b. Physicians and pharmacists must be licensed and actively practicing in the State of Colorado while a member of the P&T Committee.

   c. The Department shall solicit recommendations for P&T Committee members from professional associations, client advocacy groups and other Medical Assistance Program stakeholders.

   d. The P&T Committee may meet and conduct business when at least any nine members are appointed to the P&T Committee. A majority of the appointed P&T Committee members constitutes a quorum for the transaction of business at any P&T Committee meeting.

   e. All P&T Committee members may vote on P&T Committee business when a vote is required. The affirmative vote of the majority of the appointed P&T Committee members is required to take action.

f. P&T Committee members shall serve two-year terms and may be reappointed to additional terms at the discretion of the Executive Director.

g. The terms shall be staggered so that in each year at least two pharmacists, one consumer representative and any three physicians are reappointed.

h. The Executive Director may appoint initial P&T Committee members to serve less than two years to provide for staggered terms.

i. The Executive Director may terminate the appointment of any P&T Committee member for Good Cause.

j. The Executive Director shall fill a vacancy occurring in the membership of the P&T Committee for the remainder of the unexpired term. Such replacement shall meet all applicable requirements as set forth in this section.

2. Physicians and pharmacists on the P&T Committee shall have knowledge and expertise in one or more of the following:

a. The clinically appropriate prescribing of covered outpatient drugs;

b. The clinically appropriate dispensing of outpatient drugs;

c. Drug use review, evaluation and intervention;

d. Medical quality assurance; or

e. The treatment of Medical Assistance Program clients.

8.800.17.B. CONFLICT OF INTEREST

1. P&T Committee members must complete and sign a conflict of interest disclosure form, prior to their appointment to the P&T Committee, that discloses any financial or other affiliation with organizations that may have a direct or indirect interest in business before the P&T Committee.

2. At any meeting, a P&T Committee member must recuse himself or herself from discussion and decision making for an entire Drug Class if he or she has a Conflict of Interest with any drug in that Drug Class.

8.800.17.C. DUTIES

1. Among other duties, the P&T Committee shall:

a. Review drugs or Drug Classes selected by the Department.

b. Utilize scientific evidence, standards of practice and drug information.

c. Consider drug safety and efficacy and other review criteria requested by the Department.

d. Request information, recommendations or testimony from any health care professional or other person with relevant knowledge concerning a drug or Drug Class subject to P&T Committee review, at their discretion.

e. Make clinical recommendations on drugs or Drug Classes. Such recommendations shall be considered by the Executive Director, when making final determinations on PDL implementation and maintenance.

f. Perform any other act requested by the Department necessary for the development and maintenance of the PDL as described in 10 C.C.R. 2505-10, Section 8.800.16.A.

g. Adopt a Department approved plan of operation that sets forth the policies and procedures that shall be followed by the P&T Committee.

h. Meet at least quarterly and other times at the discretion of the Department or the P&T Committee.

8.800.17.D. NOTICE/OPEN MEETINGS

1. P&T Committee meetings and the proposed agenda shall be posted publicly at least thirty days before the meeting.

2. The P&T Committee meetings shall be open to the public. If a P&T Committee meeting is required to be held in executive session pursuant to state or federal law, the executive session shall be convened after conclusion of the open meeting.

8.800.18 PRESCRIPTION DRUG CONSUMER INFORMATION AND TECHNICAL ASSISTANCE PROGRAM

8.800.18.A The Prescription Drug Consumer Information and Technical Assistance Program provides Medical Assistance Program clients the opportunity to meet with a pharmacist to review the client's medications, receive information on the prudent use of prescription drugs and, with the approval of the appropriate prescribing health care provider, how to avoid dangerous drug interactions, improve client outcomes, and save the state money for the drugs prescribed.

8.800.18.B. REQUIREMENTS FOR PARTICIPATION IN THE PROGRAM

1. The Department shall refer clients to pharmacists based on location.

2. Pharmacists shall:

a. Have and maintain an unrestricted license in good standing to practice pharmacy in Colorado; and

b. Maintain liability insurance; and

c. Complete an application; and

d. Enter into a contract with the Department; and

e. Meet one of the following qualifications:

i) Provide proof of completion of a pharmacy practice residency accredited by the American Society of Health Systems Pharmacists or the American Pharmaceutical Association; or

ii) Earned a bachelor of pharmacy degree and completed a certificate program accredited by the Accreditation Council for Pharmacy Education (ACPE) in each area of practice, and 40 hours of on-site supervised clinical practice and training in each area in which the pharmacist is choosing to practice; or

iii) Earned a Doctor of Pharmacy degree and completed at least 40 hours of ACPE-approved continuing education regarding clinical practice and 40

hours of on-site supervised clinical practice and training in the area in which the pharmacist is choosing to practice; or

iv) Possess current board specialty certification from the Board of Pharmaceutical Specialties, current certification from the National Institute for Standards in Pharmacist Credentialing, or current certification from the Commission for Certification in Geriatric Pharmacy. Such credentials must be in the area of pharmacy practice undertaken in the drug therapy management

i)

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3. Clients may participate in the program if they are a fee-for-service client who receives prescription drug benefits, is at high risk of complications from drug interactions and who otherwise lacks access to informational consultation with a pharmacist.

8.800.18.C. SERVICES

1. Pharmacists participating in the program shall:

a. Schedule a face-to-face meeting with the client within ten days of the referral. If the client is unable or refuses to participate in a face-to-face meeting, the pharmacist may conduct the consultation by telephone.

b. Collect and review client drug histories.

c. Hold face-to-face or telephonic consultations with clients.

d. Notify clients that they will provide clinical recommendations to the client, the prescribing health care provider and the Department.

e. Provide the client with information regarding:

i) The prudent use of prescription drugs.

ii) How to avoid dangerous drug interactions.

iii) The appropriate use of medication to optimize therapeutic outcomes.

iv) How to reduce the risk of adverse events, including adverse drug interactions.

2. The Department shall notify clients participating in the program in writing that a pharmacist has been assigned to review the client's records and that the pharmacist will contact the client within ten days from the date of notification.

8.800.18.D. REPORTING Within ten days following the consultation, the pharmacist shall provide a letter to the client, all appropriate health-care providers and the Department outlining the face-to-face meeting. The letter shall include the pharmacist's recommendations for possible alternatives available for the client.

8.800.18.E. REIMBURSEMENT The Department shall pay each pharmacist participating in the program a predetermined amount.

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 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).

.12 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 mat provide regular services to Colorado recipients or those pharmacies who provide drags for foster care children or other recipients that permanently reside in other states and are wards of the State of Colorado.

8.830 DRUG BENEFITS

A. Only those drugs supplied by companies participating in the federally approved Medicaid drug rebate program are regular drug benefits.

B. The following drug categories may be excluded from being a drug benefit or may be subject to prior authorization:

1. Agents when used for anorexia or weight gain

2. Agents when used to promote fertility

3. Agents when used for cosmetic purposes or hair growth

4. Agents when used for symptomatic relief of cough and colds

5. Agents when used to promote smoking cessation

6. Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations

7. Non-prescription drugs

8. Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee

9. Less than effective drugs (LTE) identified by the Drug Efficacy Study Implementation (DESI) program

10. Barbiturates

11. Benzodiazepines

C. Aspirin and insulin are the only OTC Drugs that are regular benefits without restriction. All other OTC Drugs must be prior authorized before a client may receive them as a drug benefit.

D. Restrictions may be placed on drugs in accordance with 42 U.S.C. Section 1395r 8(d) which is incorporated herein by reference. U.S.C. refers to the United States Code. The Custodian of Records, Department of Health Care Policy and Financing may be contacted at 1570 Grant Street, Denver, Colorado 80203, for a copy of 42 U.S.C. 1396r 8, or the materials may be examined at any state publications depository library. Without limiting the foregoing, restrictions may be placed on drugs for which it has been deemed necessary to address instances of fraud or abuse, potential for, and history of, drug diversion and other illegal utilization, overutilization, other inappropriate utilization or the availability of more cost-effective comparable alternatives.

E. Drugs not covered by rebate agreements may be reimbursed only if the Department has made a determination that the availability of the drug is essential, such drug has been given 1-A rating by FDA, and prior authorized.

F. Medicare Part D Drugs shall not be covered as Medicaid drugs for Part D Eligible Individuals.

G. The excluded drugs listed in Section 8.830.B above shall be covered for Part D Eligible Individuals in the same manner as they are covered for all other eligible Medicaid clients.

Drugs or drug categories which are subject to prior authorization, maximum reimbursement constraints such as State Maximum Allowable Cost (M.A.C.) or the Federal Upper Limit (FUL) are identified in provider bulletins. Advice from the Drug Use Review Board is used to determine which drugs will be subject to, prior authorization or exclusion, or State M.A.C.

8.831 DRUGS ADMINISTERED OR PROVIDED IN PHYSICIAN OFFICES

Injectable drugs administered in a physician's office are considered part of the physician's services and shall be billed on the physician claim form. An exception to this are allergen extracts provided by the physician. They shall be submitted as a service on the physician's claim form.

8.832 Compounded Prescriptions [Eff. 10/30/07]

Compounded prescriptions shall be billed by submitting all ingredients in the prescription as one multiple-line claim. The provider will be reimbursed for each ingredient of the prescription according to 8.850.02, and will also be reimbursed for the dispensing fee according to 8.850.1. A compounding fee, over and above the stated dispensing fee, will not be paid.

8.834 PRIOR AUTHORIZATION REQUIREMENTS

Prior authorization shall be obtained before drugs which are subject to restrictions may be provided as a benefit except for injectable drugs administered in physicians' offices described in 8.831 or for emergency drugs. The prior authorization request shall be made to the Fiscal Agent and include the following:

A. Recipient name, state identification number, and birth date;

B. Patient diagnosis, prognosis, and other pertinent information;

C. Other drugs currently prescribed for the patient;

D. Name of the drug(s) requested - (can be single or multiple request);

E. Requesting physician's name and address.

When the request is received, it will be reviewed and a determination made whether or not to add the drug as a limited benefit for the recipient.

If the prior authorization request is incomplete or additional information is needed, an inquiry to the physician will be initiated within one working day from the day the request was received. If no response is received from the physician's office within 24 hours, the prior authorization will be denied. The physician's office will be notified of the approval or denial of the prior authorization via telephone, at the time the request is made. The verbal decision will be confirmed in writing. The provider may dispense at least a 72-hour supply of a covered outpatient prescription drug in an emergency situation.

Emergency prior authorization may be given retroactively if the drug had to be dispensed immediately for the patient's well-being. The physician must call in a prior authorization the next business day and must include a description and justification of the emergency and follow the same procedure as discussed above.

The Department shall solicit and maintain a list of any interested parties that wish to comment on proposed changes to prior authorized classes of prescribed drugs. The list of interested parties

shall be notified of any proposal and shall be given a reasonable time, not to exceed 30 days, to comment or recommend changes before a class is prior authorized.

8.836 CLARIFICATION OF CERTAIN BENEFIT LIMITATIONS

The following are not benefits of the Medicaid Program:

A. Spirituous liquors of any kind;

B. Dietary needs or food supplements unless prior authorized within Department guidelines;

C. Personal care items i.e., mouth wash, deodorants, talcum powder, bath powder, soap (of any kind), dentifrices, etc.;

D. Medical supplies unless due to their therapeutic or diagnostic characteristics are essential for care in the home which the physician has ordered for the treatment and diagnosis of the recipient's illness or injury. Prior authorization may be required to obtain Medicaid reimbursement;

E. I.V. equipment (i.e., venopaks) dispensed without the I.V. solutions to an out patient (Nursing homes must furnish I.V. equipment for their patients);

F. Drugs classified by the Food and Drug Administration as "investigational" or "experimental";

G. Drugs for which there is no federal financial participation;

H. Medicare Part D Drugs for Part D Eligible Individuals.

8.837 PRESCRIPTION REQUIREMENTS

8.837.1 REIMBURSEMENT

8.837.1.A. Reimbursement shall be made for prescribed drugs provided to eligible recipients when the following conditions are met:

1. The item dispensed is a covered prescription drug by a participating company, a compounded prescription as described in 10 C.C.R. 2505-10, Section 8.832, or has been prior authorized;

2. The person prescribing the item is authorized to do so by appropriate Colorado statutes;

3. The prescription is dispensed in accordance with applicable federal and state laws, rules, and regulations;

4. The prescription is dispensed in accordance with the law, rules, and regulations governing the Colorado Medical Assistance Program; and

5. The prescription is written on a tamper-resistant prescription drug pad or is excluded from the tamper-resistant prescription drug pad requirements set forth in 10 C.C.R. 2505-10, Section 8.837.2.

8.837.2 TAMPER-RESISTANT PRESCRIPTION DRUG PADS

8.837.2.A. Tamper-resistant prescription drug pads are written prescription pads used for Medicaid outpatient drugs, including over-the-counter drugs, that prevent unauthorized copying of a completed or blank form, erasure of information written on the prescription by the prescriber, or the use of counterfeit prescription forms.

8.837.2.B. To be considered tamper-resistant, a prescription pad must contain one of the following characteristics by April 1, 2008. By October 1, 2008, the pad must contain all three features.

1. One or more industry recognized features designed to prevent unauthorized copying of completed or blank prescription form.

2. One or more industry recognized features designed to prevent the erasure or modification of information written on the pad by the prescriber.

3. One or more industry recognized features designed to prevent the use of counterfeit forms.

8.837.2.C. The use of tamper-resistant prescription pads is not required when:

1. Prescriptions are transmitted from the prescriber to the pharmacy electronically; or

2. Prescriptions are sent by facsimile to the pharmacy; or

3. Prescriptions are called in by the prescriber; or

4. A Medicaid managed care entity pays for the prescription.

8.837.2.D. The use of tamper-resistant prescription drug pads does not apply to drugs that are provided as part of the following:

1. Inpatient hospital services.

2. Hospice services.

3. Dental services (except when a State Plan authorizes direct reimbursement to the dispensing dentist).

4. Physician services.

5. Outpatient hospital services.

6. Nursing facilities and intermediate care facilities for the mentally retarded.

7. Other laboratory and x-ray services.

8. Renal dialysis.

8.837.2.E. The pharmacy may dispense at least a 72-hour supply of a covered outpatient prescription drug in an emergency situation, provided that the pharmacy obtains a compliant prescription in writing, or by telephone, facsimile, or e-prescription, within 72 hours of filling the prescription.

8.837.2.F. When a Medicaid recipient is determined retroactively eligible after a pharmacy has filled the recipient's prescription, the prescription shall be deemed to comply with the tamper-resistant pad requirements. This presumption applies only to prescriptions that were filled before the recipient was determined eligible. Prescriptions that are filled or refilled after the recipient is determined eligible require a new, tamper-resistant prescription or the pharmacy may obtain verbal confirmation of the prescription from the prescriber or may obtain the prescription from the prescriber by facsimile or e-prescription.

8.837.3 RECORD RETENTION

8.837.3.A. Participating pharmacy providers must maintain the original copy of all prescriptions for which payment from the Medical Assistance Program is requested. The original prescription shall be a hard copy either written by the prescriber or reduced to writing when received by the pharmacist

by telephone or other electronic means. Information required by the Colorado State Board of Pharmacy shall be recorded on each prescription but must include, name of patient, name of drug, quantity ordered, directions, name of prescribing practitioner, date written and date filled, and initials of pharmacist filling the prescription or responsible for its contents.

8.837.3.B. In addition, if a substitution for a prescribed brand name drug is made or the prescription is written generically, the name and manufacturer of the drug dispensed shall be recorded on the face of the prescription. A copy of a label which is created to accompany the drug will not suffice as the prescription.

8.837.2.C. Any refill prescription records shall be maintained in accordance with Colorado State Board of Pharmacy requirements and contain the same information as required above.

8.837.3.D. Such files and records shall be maintained in an orderly manner and shall promptly be available for inspection by authorized personnel of the Colorado State Department of Health Care Policy and Financing, the U. S. Department of Health and Human Services, and the Colorado Medicaid Fraud Control Unit.

8.838 DRUG USE REVIEW

8.838.1 PATIENT RECORDS

The pharmacist shall be responsible for assuring that reasonable efforts have been made to obtain, record, and maintain the following patient information generated at the individual pharmacy and from the patient or his/her apparent agent for each new prescription:

A. Name, address, telephone number, date of birth or age, and gender;

B. Individual history where significant, including known allergies and drug reactions, and a comprehensive, chronological list of medications and prescribed relevant devices; and

C. Additional comments relevant to the patient's pharmaceutical care as defined in Section 8.838.2, Prospective Drug Review, and Section 8.838.3, Patient Counseling of this staff manual.

.11 CONFIDENTIALITY OF PATIENT RECORD INFORMATION

All patient information collected by an individual pharmacy for the purpose of performing drug use review and patient counseling shall be considered confidential. Pharmacies shall establish safeguards which prohibit access to this information by unauthorized individuals.

8.838.2 PROSPECTIVE DRUG REVIEW

A. A pharmacist shall review the available patient record information with each prescription drug order presented for dispensing for purposes of promoting therapeutic appropriateness by considering the following:

1. over-utilization or under-utilization;

2. therapeutic duplication;

3. drug-disease contraindications;

4. drug-drug interactions;

5. incorrect drug dosage or duration of drug treatment;

6. drug-allergy interactions;

7. clinical abuse/misuse.

B. When in the pharmacist's professional judgement a potential problem is identified in the above review, the pharmacist shall take appropriate steps to avoid or resolve the problem which may, if necessary, include consultation with the prescriber.

8.838.3 PATIENT COUNSELING

A. A pharmacist or pharmacist designee shall offer counseling regarding the drug therapy to each Medicaid patient with a new prescription. The offer to counsel shall be face-to-face communication whenever practicable or by telephone.

B. If the offer to counsel is accepted, and following a review of the patient's record, a pharmacist or pharmacy intern shall personally discuss matters which enhance or optimize drug therapy with each patient or caregiver of such patient Such discussion shall be in person, whenever practicable, or by telephone and shall include those matters listed below that in the exercise of his or her professional judgment, the pharmacist considers significant as well as other matters the pharmacist considers significant:

1. the name and description of the drug;

2. the dosage form, dose, route of administration, and duration of drug therapy,

3. intended use of the drug and expected action;

4. special directions and precautions for preparation, administration, and use by the patient;

5. common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

6. techniques for self monitoring drug therapy;

7. proper storage;

8. prescription refill information;

9. action to be taken in the event of a missed dose; and

Alternative forms of patient information shall not be used in lieu of the personal discussion requirement for patient counseling but may be used to supplement this discussion when appropriate. Examples to include written information leaflets, pictogram labels, video programs, etc.

C. Patient counseling by a pharmacist or pharmacy intern, as described above shall not be required for patients of a hospital or institution where other licensed health care professionals administer the prescribed drugs pursuant to a chart order.

D. A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation. The pharmacist shall keep records indicating when counseling was not or could not be provided.

8.838.4 DRUG USE REVIEW BOARD (DUR BOARD)

The DUR Board shall serve in an advisory capacity to the Department and is responsible for making recommendations in three areas: application of standards (as described in Section 8.838 of this manual), retrospective DUR, and ongoing interventions with pharmacists and physicians concerning therapy problems identified in the course of the DUR program.

.41 The DUR Board shall consist of nine members appointed by the executive director based upon recommendations of relevant professional associations. Membership on the Board shall consist of four physicians, four pharmacists who are licensed and actively practicing in the State of Colorado and one non-voting representative from the pharmaceutical industry.

The membership of the DUR Board shall include health care professionals who have recognized knowledge and expertise in one or more of the following:

A. the clinically appropriate prescribing of covered outpatient drugs;

B. the clinically appropriate dispensing of outpatient drugs;

C. drug use review, evaluation and intervention;

D. medical quality assurance.

.42 DRUG USE REVIEW BOARD ACTIVITIES

A. Application of Predetermined Standards

The DUR Board shall perform the following activities:

1. Review and make recommendations of predetermined standards submitted to it by the department or the department's contractor.

2. Evaluate the use of the predetermined standards, including assessing the operational effect of the predetermined standards in use and make recommendations to the department or department's contractor concerning modification or elimination of existing predetermined standards or the addition of new ones.

3. Recommend guidelines governing written predetermined standards that pharmacies not using approved software must use in conducting prospective DUR.

B. Retrospective DUR

The DUR Board shall perform the following activities:

1. Review and make recommendations on predetermined standards submitted to it by the department or department's contractor.

2. Make recommendations to the department or the department's contractor concerning the modification or elimination of existing predetermined standards or the addition of new ones.

C. Education Intervention Program

1. The DUR Board must establish an educational program under the direction of the Department or the Department may contract with accredited health care educational institutions (e.g. pharmacy or medical schools, retrospective DUR contractor, pharmacy associations, medical societies, for the purpose of educating practitioners with regard to common therapy problems to improve prescribing and dispensing practices.

2. This program may include the following intervention activities:

a. Information dissemination;

b. Written, oral or electronic reminders;

c. Face to face discussions; and

d. Intensified review or monitoring.

3. The DUR Board, based upon the Department's reports on the application of standards shall:

a. Identify general education topics and develop educational materials;

b. Share information on general education topics with other entities involved in continuing education of pharmacists and physicians;

c. Determine circumstances for use of each type of provider specific intervention method (e.g. written, oral, electronic reminders, face to face discussion, etc.); and,

d. Reevaluate no less often then semiannually the appropriateness of existing intervention methods and make changes when appropriate.

4. The DUR Board under the direction of the Department may delegate to the retrospective DUR contractor the responsibility of preparation of continuing education programs and the conduct of interventions.

D. Drug Use Review Board Annual Report

The Board is responsible for preparing and submitting a report to the State an annual basis. This report shall contain the following information:

1. A description of the activities of the Board, including the nature and scope of the prospective and retrospective drug use review programs;

2. A summary of the interventions used;

3. An assessment of the impact of these educational interventions on quality of care

4. An estimate of the cost savings generated as the result of the program.

8.840 BILLING PROCEDURES

Charges for prescribed drugs which are a benefit of the Medical Assistance Program shall be submitted on an appropriate pharmacy claim form. All entries shall be legible. The signature of an owner/employee pharmacist must appear on each claim form. A rubber stamp or other facsimile signature is not permitted.

Each claim must identify the recipient, prescribing physician, date of service, National Drug Code number of the drug actually dispensed as it is listed in the formulary, its supplements or a prior authorization request, prescription number, quantity dispensed and the reimbursement charge as defined in 8.800.09. The Medicaid program is to be considered the same as a private pay patient who immediately pays for the prescription.

An exception to the requirement for submitting claims for reimbursement on a pharmacy claim form may be made when claims are submitted electronically in a State approved format.

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.

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 (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 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.

8.870 PRESCRIPTION QUANTITIES

.01 NEW PRESCRIPTIONS

A new prescription is an order for a drug which is being initially prescribed to treat a current illness or condition. The drug has not been used during the most recent course of therapy. In this case, the quantity prescribed will be at the discretion of the physician. Merely assigning a new prescription number or creating a new prescription each time the drug is dispensed to provide continuous treatment for a condition or illness does not meet the definition of a new prescription, but will be considered and governed by the rules pertaining to refill prescriptions.

.02 REFILL PRESCRIPTIONS

For chronic conditions requiring maintenance drugs, refill prescriptions shall be for quantities sufficient for a minimum 30-day supply. Maximum quantity which can be dispensed is one which will supply drugs sufficient for 100 days.

.03 PAYMENT OF DISPENSING FEE

When prescriptions for the same drug used to treat chronic conditions are dispensed more than twice, only one dispensing fee a month thereafter will be paid to the pharmacy unless the prescription is ordered for an allowable package size as described above which is less than a 30-day supply. Only ingredient cost will be reimbursed for those prescriptions which are not a package size and less than a 30-day supply.

.04 PRESCRIPTION QUANTITIES EXCEPTIONS

The 30-day policy does not apply to drugs prescribed for short-term illnesses.

.05 MINIMUM QUANTITIES

The State may set minimum quantities of certain drugs which shall be dispensed based upon the advice of the Drug Use Review Board.

.06 PRESCRIPTION TRACKING AND CLAM REVERSALS

The pharmacy provider shall keep 1) a chronological log that contains the client's name, his or her signature or agent's signature and date of the receipt of the prescription, or 2) an electronic prescription tracking system that records the status of prescriptions through the fill process including the date and time that the prescription was transferred to a person verified by pharmacy personnel to be the client or agent of the client.

Pharmacies using a chronological log shall review all Medicaid prescriptions in will-call status (filled not released to patient or patient's agent) at least weekly. All prescriptions billed to Medicaid for fourteen (14) days or more shall be reversed on the day of review. In no case shall prescriptions be kept in will-call status for more than twenty-one (21) days. The pharmacy shall maintain a record of each reversal for audit purposes.

Pharmacies using an electronic prescription tracking system shall review prescriptions in will-call status on a daily basis and enter a reversal of prescriptions not picked up within ten (10) days of billing. In no case shall prescriptions be kept in will-call status for more than fourteen (14) days. The pharmacy shall maintain a record of each reversal for audit purposes.

Upon receipt of a written request from the Department of Health Care Policy and Financing or the Medicaid Fraud Unit for a record of Medicaid claims and reversals, the pharmacy may have up to 72 hours or three working days to provide the requested information or to enter into an agreement with the Departments) stating the specific time within which the data will be produced.

8.880 REIMBURSEMENT FROM PHARMACISTS REDISPENSING UNUSED MEDICATION

A. A pharmacist participating in the medical assistance program may accept unused medication from a hospital, hospital unit, hospice, nursing care facility, or assisted living residence that is required to be licensed pursuant to section 25-3-101, C.R.S., or a licensed health care provider for the purpose of dispensing the medication to another person.

B. A pharmacist shall reimburse the Department for the Medicaid allowable reimbursement charge that the Department has paid to the pharmacist if medications are returned to a pharmacist and the medications are available to be dispensed to another person.

8.885 PREFERRED DRUG LIST [Eff. 11/30/07]

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 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.

8.885.2.B. After the P&T Committee meets, the Medical 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 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 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 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.

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 shall 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; 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 AUTHORITY OF THE EXECUTIVE DIRECTOR

8.885.5.A. The decisions of the Medical Director, made under the authority of this section, shall be implemented by the Department at the sole discretion of the Executive Director.

8.885.5.B. If the Medical Director position is unfilled, the duties and obligations of that position, as described in this section, shall be performed by the Executive Director.

8.885.6 OVER-THE-COUNTER DRUGS

8.885.6.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.

8.885.7 SUPPLEMENTAL REBATES

8.885.7.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.

8.885.8 ANNUAL REPORT

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

8.885.9 DRUG CLASS MORATORIUM

8.885.9.A. The following Drug Classes cannot be considered for inclusion on the PDL until after December 31, 2008:

1. Atypical and typical antipsychotic drugs;

2. Drugs used for the treatment of HIV/AIDS;

3. Anticonvulsant drugs;

4. Immunosuppressants;

5. Drugs used for the treatment of hemophilia; and

6. Drugs used for the treatment of cancer.

8.890 PHARMACY AND THERAPEUTICS COMMITTEE [Perm. Rule eff. 10/30/2007]

8.890.1 DEFINITIONS

Conflict of Interest means a P&T Committee member has competing professional or personal obligations or personal or financial interests that would make it difficult to fulfill P&T Committee duties in an objective manner.

Good Cause means failing to disclose a Conflict of Interest, participating in wrongdoing or misconduct while a member of the P&T Committee, failing to perform required duties as described in this section, or missing two scheduled P&T Committee meetings per calendar year.

Pharmacy and Therapeutics Committee (P&T Committee) means an advisory board that shall perform reviews and make recommendations which facilitate the development and maintenance of the Preferred Drug List as described in 10 C.C.R. 2505-10, Section 8.885.

8.890.2 MEMBERSHIP

8.890.2.A. The P&T Committee shall consist of at least nine members, but not more than thirteen members, appointed by the Executive Director.

1. The P&T Committee membership shall include:

   a. Four pharmacists;

   b. Two client representatives;

   c. One physician who specializes in the practice of psychiatry;

   d. One physician who specializes in the practice of pediatrics;

   e. One physician who specializes in the treatment of clients with disabilities; and

   f. Four physicians from any other medical specialty.

2. Physicians and pharmacists must be licensed and actively practicing in the State of Colorado while a member of the P&T Committee.

3. The Department shall solicit recommendations for P&T Committee members from professional associations, client advocacy groups and other Medical Assistance Program stakeholders.

4. The P&T Committee may meet and conduct business when at least any nine members are appointed to the P&T Committee. A majority of the appointed P&T Committee members constitutes a quorum for the transaction of business at any P&T Committee meeting.

5. All P&T Committee members may vote on P&T Committee business when a vote is required. The affirmative vote of the majority of the appointed P&T Committee members is required to take action.

6. P&T Committee members shall serve two-year terms and may be reappointed to additional terms at the discretion of the Executive Director.

7. The terms shall be staggered so that in each year at least two pharmacists, one consumer representative and any three physicians are reappointed.

8. The Executive Director may appoint initial P&T Committee members to serve less than two years to provide for staggered terms.

9. The Executive Director may terminate the appointment of any P&T Committee member for Good Cause.

10. The Executive Director shall fill a vacancy occurring in the membership of the P&T Committee for the remainder of the unexpired term. Such replacement shall meet all applicable requirements as set forth in this section.

8.890.2.B. Physicians and pharmacists on the P&T Committee shall have knowledge and expertise in one or more of the following:

1. The clinically appropriate prescribing of covered outpatient drugs;

2. The clinically appropriate dispensing of outpatient drugs;

3. Drug use review, evaluation and intervention;

4. Medical quality assurance; or

5. The treatment of Medical Assistance Program clients.

8.890.3 CONFLICT OF INTEREST

8.890.3.A. P&T Committee members must complete and sign a conflict of interest disclosure form, prior to their appointment to the committee, that discloses any financial or other affiliation with organizations that may have a direct or indirect interest in business before the P&T Committee.

8.890.3.B. At any meeting, a P&T Committee member must recuse himself or herself from discussion and decision making for an entire drug class if he or she has a Conflict of Interest with any drug in that class.

8.890.4 DUTIES

8.890.4.A. The P&T Committee, shall, among other things:

1. Review drugs or drug classes selected by the Department.

2. Utilize scientific evidence, standards of practice and drug information.

3. Consider drug safety and efficacy and other review criteria requested by the Department.

4. Request information, recommendations or testimony from any health care professional or other person with relevant knowledge concerning a drug or drug class subject to P&T Committee review, at their discretion.

5. Make clinical recommendations on drugs or drug classes. Such recommendations shall be considered by the Executive Director, when making final determinations on Preferred Drug List implementation and maintenance.

6. Perform any other act requested by the Department necessary for the development and maintenance of the Preferred Drug List as described in 10 C.C.R. 2505-10, Section 8.885.

7. Adopt a Department approved plan of operation that sets forth the policies and procedures that shall be followed by the Committee.

8. Meet at least quarterly and other times at the discretion of the Department or the P&T Committee.

8.890.5 NOTICE/OPEN MEETINGS

8.890.5.A. P&T Committee meetings and the proposed agenda shall be posted publicly at least thirty days before the meeting.

8.890.5.B. The P&T Committee meetings shall be open to the public. If a P&T Committee meeting is required to be held in executive session pursuant to state or federal law, the executive session shall be convened after conclusion of the open meeting.

8.895 PRESCRIPTION DRUG CONSUMER INFORMATION AND TECHNICAL ASSISTANCE PROGRAM

8.895.1 DEFINITION

The Prescription Drug Consumer Information and Technical Assistance Program means the program that provides Colorado Medicaid clients the opportunity to meet with a pharmacist to review the client's medications, receive information on the prudent use of prescription drugs and, with the approval of the appropriate prescribing health care provider, how to avoid dangerous drug interactions, improve patient outcomes, and save the state money for the drugs prescribed.

8.895.2 REQUIREMENTS FOR PARTICIPATION

8.895.2.A. The Department shall refer clients to pharmacists based on location.

8.895.2.B. Pharmacists

1. To participate in the program, a pharmacist must:

a. Have and maintain an unrestricted license in good standing to practice pharmacy in Colorado; and

b. Maintain liability insurance; and

c. Complete an application; and

d. Enter into a contract with the Department; and

e. Meet one of the following qualifications:

i) Proof of completion of a pharmacy practice residency accredited by the American Society of Health Systems Pharmacists or the American Pharmaceutical Association; or

ii) A bachelor of pharmacy degree and completion of a certificate program accredited by the Accreditation Council for Pharmacy Education in each area of practice, and 40 hours of on site supervised clinical practice and training in each area in which the pharmacist is choosing to practice; or

iii) A Doctor of Pharmacy degree and completion of at least 40 hours of ACPE approved continuing education regarding clinical practice and 40 hours of on site supervised clinical practice and training in the area in which the pharmacist is choosing to practice; or

iv) Current Board specialty certification from the Board of Pharmaceutical Specialties, current certification from the National Institute for Standards in Pharmacist Credentialing, or current certification from the Commission for Certification in Geriatric Pharmacy. Such credentials must be in the area of pharmacy practice undertaken in the drug therapy management.

8.895.2.C. Clients

1. Any fee-for-service client who receives prescription drug benefits, is at high risk of complications from drug interactions and who otherwise lacks access to informational consultation with a pharmacist, may participate in the prescription Drug Consumer Information and Technical Assistance Program.

2. The Department shall notify clients participating in the program in writing that a pharmacist has been assigned to review the client's records and that the pharmacist will contact the client within ten days from the date of notification.

8.895.3 SERVICES

8.895.3.A. Pharmacists shall:

1. Schedule a face-to-face meeting with the client within ten days of the referral.

2. Collect and review client drug histories.

3. Hold face-to-face consultations with clients.

4. Notify clients that they will provide clinical recommendations to the client, the prescribing health care provider and the Department.

5. Provide the client with information regarding:

a. The prudent use of prescription drugs.

b. How to avoid dangerous drug interactions.

c. The appropriate use of medication to optimize therapeutic outcomes.

d. How to reduce the risk of adverse events, including adverse drug interactions.

8.895.4 REPORTING

Within ten days following the consultation, the pharmacist shall provide a letter to the client, all appropriate health-care providers and the Department outlining the face-to-face meeting. The letter shall include the pharmacist's recommendations for possible alternatives available for the client.

8.895.5 REIMBURSEMENT

The Department shall pay each pharmacist a predetermined amount.