Title of Rule: Revision to the Medical Assistance Pharmacy Rule Concerning Medicaid Option For Prescribed Drugs By Mail , Section 8.800
Rule Number: MSB 16-05-31-A
Division / Contact / Phone: Client and Clinical Care Office / January Montano / (303) 866-6977

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 current Mail Order rule requires that, in order to qualify for mail delivery of maintenance medications, members must have a physical hardship or third-party insurance coverage allowing mail delivery. SB 16-027 eliminated the physical hardship and third-party insurance requirements so that any Medicaid member may receive their maintenance mediations through mail delivery. The purpose of the proposed rule change is to remove the member requirements for mail delivery and bring the Department into compliance with SB 16-027.

   The current Conditions of Participation rules require out-of-state pharmacies to meet one of the listed criteria, such as being a mail order pharmacy, in order to enroll as a Medicaid provider. In practice, the requirement serves only to create an administrative burden for enrolling out-of-state pharmacies and for Department staff reviewing provider applications. The proposed rule change would remove the criteria and result in out-of-state pharmacies being treated the same as in-state pharmacies.

2. An emergency rule-making is imperatively necessary

   ☐ to comply with state or federal law or federal regulation and/or
   ☐ for the preservation of public health, safety and welfare.

   Explain:

3. Federal authority for the Rule, if any:

4. State Authority for the Rule:

   25.5-1-301 through 25.5-1-303, C.R.S. (2015);
   25.5-2.5-102 through 25.5-2.5-103, C.R.S. (2015);
   25.5-1-104, C.R.S. (2015);
   Senate Bill 16-027

Initial Review	**08/12/2016**	Final Adoption	**09/09/2016**
Proposed Effective Date	**10/30/2016**	Emergency Adoption	

DOCUMENT #06

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REGULATORY ANALYSIS

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

   Medicaid members who take maintenance medications and did not previously qualify for mail delivery are the class of persons affected by the proposed rule.

   Pharmacies are the affected provider group.

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

   Medicaid members will have greater access to maintenance medications which in turn may increase adherence to medication regimens. Also, members who usually fill their maintenance medications monthly may pay fewer copays since prescriptions provided through mail delivery are normally dispensed for a 90-day supply.

   Pharmacies may see an increase in requests for mail delivery of maintenance medications, and depending on whether a pharmacy provides that service they may see a change in the number of prescriptions filled for maintenance drugs.

   The enrollment process for out-of-state pharmacies will be simplified by treating them the same as in-state pharmacies.

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 estimates that the proposed rule will generate state savings of $9,493 in General and Cash Funds within FY 2016-17 and $581,311 by FY 2017-18. Total fund cost-savings is estimated to reach $2 million in FY 2018-19.

   The Department's estimated net savings was calculated from reduced dispensing fees and annual cost-shifting. The Department will reimburse pharmacies one dispensing fee for a 90-day supply of prescriptions through the mail, rather than three dispensing fees for three fills of a 30-day supply. Cost-shifting was included in estimated savings, as costs for a portion of the medication will shift forward into the year when the 90-day supply is purchased and avoided in the next year while it is being consumed.

External agencies will not be effected by this rule change.

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

   The costs of inaction are non-compliance with state law, denying greater access to pharmacy services for members and maintaining an unnecessary administrative burden on out-of-state pharmacies and the Department.

   The benefits of the proposed rule are compliance with state law, increased access for members and cost-savings to the Department.

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

   There are no other less costly or less intrusive methods. The proposed rules brings the Department into compliance with SB 16-027 and removes unnecessary criteria in the Conditions of Participation rules for out-of-state pharmacies.

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 alternative methods were considered by the Department as the mail delivery change is pursuant to the passing of SB 16-027 on June 1, 2016. The Department must promulgate the proposed rule in order to come into compliance with state statute.

8.800 PHARMACEUTICALS

8.800.1 DEFINITIONS

340B Pharmacy means any pharmacy that participates in the Federal Public Health Service's 340B Drug Pricing Program as described in 42 U.S.C. Section 256b (2011). 42 U.S.C. Section 256b (2011) is hereby incorporated by reference into this rule. This rule does not include any later amendments or editions of the code. A copy of the code is available for public inspection at the Colorado Department of Health Care Policy and Financing, 1570 Grant Street, Denver, CO 80203 where a copy of the code provision is available for a reasonable charge. A copy is also available, for a reasonable charge from Superintendent of Documents, U.S. Government Printing Office, P.O. Box 371954, Pittsburgh, PA 15250-79524.

Average Acquisition Cost (AAC) means the average acquisition cost for like drugs grouped by Generic Code Number (GCN). For GCNs with both generic and brand drugs, the Department shall determine two separate AAC rates for the GCN. One AAC rate shall be based on the average acquisition cost for all generic drugs while the other shall be based on the average acquisition cost for all brand drugs.

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 Fee means the reimbursement amount for costs associated with filling a prescription. Costs include salary costs, pharmacy department costs, facility costs, and other costs.

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. 512 - 447.516 (2011). 42 C.F.R. 447.512 - 447.516 (2011) is hereby incorporated by reference into this rule. This rule does not

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include any later amendments or editions of the code. A copy of the code is available for public inspection at the Colorado Department of Health Care Policy and Financing, 1570 Grant Street, Denver, CO 80203 where a copy of the code provision is available for a reasonable charge. A copy is also available, for a reasonable charge from U.S. Government Printing Office, P.O. Box 979050, St. Louis, MO 63197-9000.

Generic Code Number (GCN) means a standard number to group together drugs that have the same ingredients, route of administration, drug strength, and dosage form.

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 any 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 any pharmacy whose primary function is to provide drugs and services to hospitalized patients and others receiving health care provided by the facility with which the pharmacy is associated.

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. Section 1395w-102(e) (2012) and 42 C.F.R. Section 423.100 (2012). This rule does not include any later amendments or editions of the code. A copy of the code is available for public inspection at the Colorado Department of Health Care Policy and Financing, 1570 Grant Street, Denver, CO 80203 where a copy of the code provision is available for a reasonable charge. A copy is also available, for a reasonable charge from Superintendent of Documents, U.S. Government Printing Office, P.O. Box 371954, Pittsburgh, PA 15250-79524.

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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 340B Pharmacy, Government Pharmacy, Institutional Pharmacy, Mail Order Pharmacy, or Rural Pharmacy.

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

Submitted Ingredient Cost means a pharmacy’s calculated ingredient cost. For drugs purchased through the Federal Public Health Service’s 340B Drug Pricing Program, the Submitted Ingredient Cost means the 340B purchase price.

Total Prescription Volume means all new and refill prescriptions dispensed for all payer types. Payer types include but are not limited to Medicaid, Medicare, commercial, third-party, and uninsured.

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

Wholesale Acquisition Cost (WAC) means with respect to a drug or biological, the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

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 be ~~first submit an application for participation to the~~enrolled in the Colorado Medicaid program in accordance with 8.040.1 and 8.013.1. ~~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 d~~~~D~~The Department may den~~yied~~ an application for a provider agreement, terminate~~d~~ or not renew a provider agreement ~~ed for any of the grounds set forth~~ in accordance with 10 C.C.R. 2505-10, Sections ~~8.050 or~~ 8.076, 8.125, ~~or~~ and 8.l30.

8.800.2.C. An ~~An out-of-state pharmacy may enroll~~ out-of-state pharmacy may enroll as a Medical Assistance Program provider subject to the same conditions of participation as an in-state pharmacy.~~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.~~

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~~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. Only Maintenance Medications may be delivered through the mail.[MJ1]

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

6. Non-prescription Drugs;

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7. 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; and

8. 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 of 42 U.S.C. Section 1396r-8(d) (2007) are available for inspection at the following address: Colorado Department of Health Care Policy and Financing, 1570 Grant Street, Denver, Colorado 80203-1818. 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. To the extent the drug categories listed in Section 8.800.4.B are not Medicare Part D Drugs, they 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:

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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

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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

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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;

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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.

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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

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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.

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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

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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

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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.

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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.

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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.

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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 the lesser of:

1. The Usual and Customary Charge minus the client's copayment, as determined according to 10 C.C.R. 2505-10, Section 8.754; or

2. The allowed ingredient cost plus a Dispensing Fee minus the client's copayment, as determined according to 10 C.C.R. 2505-10, Section 8.754.

Covered drugs for the OAP State Only Program shall be reimbursed according to 10 C.C.R. 2505-10, Section 8.941.10.

8.800.13.B. The allowed ingredient cost for Retail Pharmacies, 340B Pharmacies, Institutional Pharmacies, Government Pharmacies and Mail Order Pharmacies shall be the lesser of AAC, or Submitted Ingredient Cost. If AAC is not available, the allowed ingredient cost shall be the lesser of WAC, or Submitted Ingredient Cost.

8.800.13.C. AAC rates shall be rebased monthly using invoices and/or purchase records provided to the Department through a representative group of pharmacies. If the Department cannot establish a process to obtain invoices and/or purchase records on a

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monthly basis, the Department shall survey one-fourth (1/4) of all Medicaid enrolled pharmacies every quarter to rebase AAC rates.

8.800.13.D. A pharmacy wanting to inquire about a listed AAC rate shall complete the Average Acquisition Cost Inquiry Worksheet posted on the Department's website. The pharmacy shall email the completed worksheet with a copy of the receipt invoice and Medicaid billed claim for the drug in question to Colorado.SMAC@hcpf.state.co.us. The Department shall have five (5) days to provide an inquiry response to the pharmacy. If the AAC rate requires revision, the Department shall then have 5 additional days to update the AAC rate.

8.800.13.E. To address weekly fluctuations in drug prices, the Department shall apply a percent adjustment to existing AAC rates for drugs experiencing significant changes in price. The percent adjustment shall be determined using weekly changes in price based on national pricing benchmarks. Every week, the Department shall post an updated AAC price list, with the adjusted AAC rates, on the Department's website (www.colorado.gov/hcpf). A percent adjustment shall only be applied to an AAC rate until the Department can rebase the rate through the process discussed in 10 C.C.R. 2505-10, 8.800.13.C.

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 the designation as a rural pharmacy. If the designation is approved by the Department, the allowed ingredient cost shall be AAC. If AAC is not available, the allowed ingredient cost shall be WAC.

1. To reduce the burden of transitioning to an AAC reimbursement methodology for rural pharmacies, and to ensure guaranteed Medicaid access in rural communities, the Department shall include a percent increase to AAC and phase the percent increase out over a one-year period. The effective dates and corresponding percent increases shall be:

   a. February 1, 2013 to May 31, 2013 – AAC+60%

   b. June 1, 2013 to September 30, 2013 – AAC+40%

   c. October 1, 2013 to January 31, 2014 – AAC+20%

   d. February 1, 2014 forward – AAC+0%

2. In cases where WAC applies, the Department shall also include a percent increase to WAC and phase the percent increase out over a one-year period. The effective dates and corresponding percent increases shall be:

   a. February 1, 2013 to May 31, 2013 – WAC+60%

   b. June 1, 2013 to September 30, 2013 – WAC+40%

   c. October 1, 2013 to January 31, 2014 – WAC+20%

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d. February 1, 2014 forward – WAC+0%

8.800.13.G. Dispensing Fees shall be determined based upon reported dispensing costs provided through a Cost of Dispensing (COD) survey completed every two fiscal years. The Dispensing Fees for Retail Pharmacies, 340B Pharmacies, Institutional Pharmacies and Mail Order Pharmacies shall be tiered based upon annual Total Prescription Volume. The Dispensing Fees shall be tiered at:

1. Less than 60,000 total prescriptions filled per year = $13.40

2. Between 60,000 and 90,000 total prescriptions filled per year = $11.49

3. Between 90,000 and 110,000 total prescriptions filled per year = $10.25

4. Greater than 110,000 total prescriptions filled per year = $9.31

8.800.13.H. The designation of a pharmacy's Dispensing Fee shall be updated annually. Every October, the Department shall contact a pharmacy requesting the completion of an attestation letter stating the pharmacy's Total Prescription Volume for the period September 1 to August 31. A pharmacy shall have until October 31 to provide the completed attestation letter to the Department. Using the attestation letter, the Department shall update a pharmacy's Dispensing Fee effective January 1. A pharmacy failing to provide the Department an attestation letter on or before October 31, regardless of their previous Dispensing Fee, shall be reimbursed the $9.31 Dispensing Fee.

8.800.13.I. The Department shall determine the Dispensing Fee for a pharmacy enrolling as a Medicaid provider based on the pharmacy's Total Prescription Volume. During the enrollment process, a pharmacy shall provide the Department an attestation letter stating their Total Prescription Volume for the previous twelve (12) months. Using the attestation letter, the Department shall determine the pharmacy's Dispensing Fee effective upon approval of enrollment. If a pharmacy has been open for less than 12 months, the Department shall annualize the Total Prescription Volume to determine the pharmacy's Dispensing Fee. A pharmacy failing to provide the Department an attestation letter during the enrollment process shall be reimbursed the $9.31 Dispensing Fee. The Dispensing Fee shall be used until it can be updated the following year in accordance with 10 C.C.R. 2505-10, 8.800.13.H.

8.800.13.J. In November of each year, the Department shall compare a pharmacy's Total Prescription Volume and Medicaid percent provided with the attestation letter to their Medicaid claims data. If the Department identifies any inconsistencies, the Department shall request a pharmacy to provide documentation that substantiates their Total Prescription Volume for the period September 1 to August 31 within thirty (30) days. If the Department determines that the pharmacy incorrectly reported their Total Prescription Volume, the pharmacy shall be reimbursed at the correct tier based on their actual Total

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Prescription Volume. If a pharmacy does not provide the documentation to the Department within the 30 days, the pharmacy shall be reimbursed the $9.31 Dispensing Fee.

8.800.13.K. The tiered Dispensing Fee shall not apply to Government Pharmacies which shall instead be reimbursed a $0.00 Dispensing Fee.

8.800.13.L. The tiered Dispensing Fee shall not apply to Rural Pharmacies which shall instead be reimbursed a $14.14 Dispensing Fee.

8.800.13.M. 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 instead be reimbursed a $1.89 Dispensing Fee.

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.

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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.

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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:

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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.

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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.

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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.

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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

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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

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.

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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.

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