DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Rule Concerning Federally Qualified Health Center Reimbursement, Section 8.700.6
Rule Number: MSB 16-09-21-A
Division / Contact / Phone: Payment Reform / Kevin Martin / 303-866-2842

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 16-09-21-A, Revision to the Medical Assistance Rule Concerning Federally Qualified Health Center Reimbursement, Section 8.700.6
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) Section 8.700.6, 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*

Replace the current text at 8.700.6.A with the proposed text starting at 8.700.6.A through the end of 8.700.6.D. The effective date of the rule change is March 30, 2017.

*to be completed by MSB Board Coordinator

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Rule Concerning Federally Qualified Health Center Reimbursement, Section 8.700.6
Rule Number: MSB 16-09-21-A
Division / Contact / Phone: Payment Reform / Kevin Martin / 303-866-2842

STATEMENT OF BASIS AND PURPOSE

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

   This rule will specify a methodology for calculating an updated Prospective Payment system rate following a change in the scope-of-service for a federally qualified health center. Section 1902(bb) of the Social Security Act specifies that States must adjust the PPS to take into account a change in the scope-of-services. The Colorado State Plan states what qualified a change in the scope-of-services and a general methodology for updating the PPS. It is important to include the specific methodology that the Department plans to use in the State rules so that federally qualified health centers know and understand how their rates are being changed.

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:

   BIPA Sec. 702(b) 42 U.S.C. § 1396a (bb)

4. State Authority for the Rule:

   25.5-1-301 through 25.5-1-303, C.R.S. (2015);
   Section 25.5-4-401 (1)(a), C.R.S.

Initial Review	**01/10/17**	Final Adoption	**02/10/17**
Proposed Effective Date	**03/30/17**	Emergency Adoption	

DOCUMENT #02

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Rule Concerning Federally Qualified Health Center Reimbursement, Section 8.700.6
Rule Number: MSB 16-09-21-A
Division / Contact / Phone: Payment Reform / Kevin Martin / 303-866-2842

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.

   This rule will affect the 417,922 Medicaid members that receive medical services at Federally Qualified Health Centers.

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

   Total expenditures for services received at FQHCs during the last fiscal year was $169,420,600.13 or approximately $405.39 per member. This rule change could potentially increase the rates paid to FQHCs if the recalculated PPS is greater than the APM since our policy is to choose the greater of the PPS and APM rate. However, Federal regulations stipulate that a change in the scope of services must be taken into account the PPS should be adjusted based on the change in costs and visits seen at an FQHC.

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

   If the adjusted PPS rate is greater than the APM rate, the rate paid to the FQHC will be higher than it was before the PPS was adjusted.

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

   The probable costs are that an FQHCs rate could be higher than it previously was due to a PPS rate that is higher than the APM rate. The benefits to the proposed rule are that it will better align the Department with Federal Law and will set a Prospective Payment System rate that is better aligned with the Federally Qualified Health Center's current costs and visits.

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

There are no less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

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 seriously considered a State Plan Amendment to achieve the purpose of this rule. However, it was determined that the State Plan already details the definition and methodology for calculating a rate adjustment due to a change in the scope-of-service so a State Plan Amendment is not necessary. The proposed rule was written to define the exact methodology being used to calculate a rate adjustment due to a change in the scope-of-service.

8.700.6 REIMBURSEMENT

8.700.6.A FQHCs shall be reimbursed a per visit encounter rate based on 100% of reasonable cost. An FQHC may be reimbursed for up to three separate encounters with the same client occurring in one day and at the same location, so long as the encounters submitted for reimbursement are any combination of the following: medical encounter, dental encounter, or mental health encounter. Duplicate encounters of the same service category occurring on the same day and at the same location are prohibited unless it is a distinct mental health encounter, which is allowable only when rendered services are covered and paid by a contracted BHO.

8.700.6.B A medical encounter, a dental encounter, and a mental health encounter on the same day and at the same location shall count as three separate visits.

1. Encounters with more than one health professional, and multiple encounters with the same health professional that take place on the same day and at a single location constitute a single visit, except when the client, after the first encounter, suffers illness or injury requiring additional diagnosis or treatment.

2. Distinct mental health encounters are allowable only when rendered services are covered and paid by a contracted BHO.

8.700.6.C Encounter rate calculation

a) Effective July 1, 2014, the encounter rate shall be the higher of the Prospective Payment System (PPS) rate or the alternative payment rate.

1. The PPS rate is defined by Section 702 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act (BIPA) included in the Consolidated Appropriations Act of 2000, Public Law 106-554, Dec. 21, 2000. BIPA is incorporated herein by reference. No amendments or later editions are incorporated.

   Copies are available for a reasonable charge and 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, CO 80203. Any material that has been incorporated by reference in this rule may be examined at any state publications depository library.

2. a) The alternative payment rate shall be the lower of the annual rate or the base rate. The annual rate and the base rate shall be calculated as follows:

   1.~~a)~~ Annual rates shall be the FQHCs current year's calculated inflated rate, after audit.

   2.~~b)~~ The new base rate shall be the calculated, inflated weighted average encounter rate, after audit, for the past three years. Beginning July 1, 2004 the base encounter rate shall be inflated annually using the Medicare Economic Index to coincide with the federal reimbursement methodology for FQHCs. Base rates shall be recalculated (rebased) every three years.

3. a) New FQHCs shall file a preliminary FQHC Cost Report with the Department. Data from the preliminary report shall be used to set a reimbursement base rate for the first year. The base rate shall be calculated using the audited cost report showing actual data from the first fiscal year of operations as a FQHC. This shall be the FQHCs base rate until the next rebasing period.

b) New base rates may be calculated using the most recent audited Medicaid FQHC cost report for those FQHCs that have received their first federal Public Health Service grant with the three years prior to rebasing, rather than using the inflated weighted average of the most recent three years audited encounter rates.

4. a) The Department shall audit the FQHC cost report and calculate the new annual and base reimbursement rates. If the cost report does not contain adequate supporting documentation, the FQHC shall provide requested documentation within ten (10) business days of request. Unsupported costs shall be unallowable for the calculation of the FQHCs new encounter rate.

b) Freestanding FQHCs shall file the Medicaid cost reports with the Department on or before the 90th day after the end of the FQHCs' fiscal year. Freestanding FQHCs shall use the Medicaid FQHC Cost Report developed by the Department to report annual costs and encounters. Failure to submit a cost report within 180 days after the end of a freestanding FQHCs' fiscal year shall result in suspension of payments.

c) The new reimbursement rate for freestanding FQHCs shall be effective 120 days after the FQHCs fiscal year end. The old reimbursement rate (if less than the new audited rate) shall remain in effect for an additional day above the 120 day limit for each day the required information is late; if the old reimbursement rate is more than the new rate, the new rate shall be effective the 120th day after the freestanding FQHCs fiscal year end.

d) The new reimbursement rate for hospital-based FQHCs shall be effective January 1 of each year.

e) If a hospital-based FQHC fails to provide the requested documentation, the costs associated with those activities shall be presumed to be non-primary care services and shall be settled using the Outpatient Hospital reimbursement rate.

f) All hospital-based FQHCs shall submit separate cost centers and settlement worksheets for primary care services and non-primary care services on the Medicare Cost Report for their facilities. Non-primary care services shall be reimbursed according to Section 8.300.632.

5. a) If a FQHC changes its scope of service after the year in which its base PPS rate was determined, the Department will adjust the FQHC's PPS rate in accordance with section 1902(bb) of the Social Security Act.

b) A FQHC must apply to the Department for an adjustment to its PPS rate whenever there is a documented change in the scope of service of the FQHC. The documented change in the scope of service of the FQHC must meet all of the following conditions:

1. The increase or decrease in cost is attributable to an increase or decrease in the scope of service that is a covered benefit, as described in Section 1905(a)(2)(C) of the Social Security Act, and is furnished by the FQHC.

2. The cost is allowable under Medicare reasonable cost principles set forth in 42 CFR Part 413.5.

3. The change in scope of service is a change in the type, intensity, duration, or amount of services, or any combination thereof.

4. The net change in the FQHC's per-visit encounter rate equals or exceeds 3% for the affected FQHC site. For FQHCs that file consolidated cost reports for

multiple sites in order to establish the initial PPS rate, the 3% threshold will be applied to the average per-visit encounter rate of all sites for the purposes of calculating the cost associated with a scope-of-service change.

5. The change in scope of service must have existed for at least a full six (6) months.

c) A change in the cost of a service is not considered in and of itself a change in scope of service. The change in cost must ~~be subject to~~meet the conditions set forth in Section 8.700.6.C.5.b and the change in scope of service must include at least one of the following to prompt a scope-of-service rate adjustment. If the change in scope of service does not include at least one of the following, the change in the cost of services will not prompt a scope-of-service rate adjustment.

1. The addition of a new service not incorporated in the baseline PPS rate, or deletion of a service incorporated in the baseline PPS rate;

2. The addition or deletion of a covered Medicaid service under the State Plan;

3. Changes necessary to maintain compliance with amended state or federal regulations or regulatory requirements;

4. Changes in service due to a change in applicable technology and/or medical practices utilized by the FQHC;

5. Changes resulting from the changes in types of patients served, including, but not limited to, populations with HIV/AIDS, populations with other chronic diseases, or homeless, elderly, migrant, or other special populations that require more intensive and frequent care;

6. Changes resulting from a change in the provider mix, including, but not limited to:

i. A transition from mid-level providers (e.g. nurse practitioners) to physicians with a corresponding change in the services provided by the FQHC;

ii. The addition or removal of specialty providers (e.g. pediatric, geriatric, or obstetric specialists) with a corresponding change in the services provided by the FQHC (e.g. delivery services);

iii. Indirect medical education adjustments and a direct graduate medical education payment that reflects the costs of providing teaching services to interns and/or residents; or,

iv. Changes in operating costs attributable to capital expenditures (including new, expanded, or renovated service facilities), regulatory compliance measures, or changes in technology or medical practices at the FQHC, provided that those expenditures result in a change in the services provided by the FQHC.

d) The following items do not prompt a scope-of-service rate adjustment:

1. An increase or decrease in the cost of supplies or existing services;

2. An increase or decrease in the number of encounters;

3. Changes in office hours or location not directly related to a change in scope of service;

4. Changes in equipment or supplies not directly related to a change in scope of service;

5. Expansion or remodel not directly related to a change in scope of service;

6. The addition of a new site, or removal of an existing site, that offers the same Medicaid-covered services;

7. The addition or removal of administrative staff;

8. The addition or removal of staff members to or from an existing service;

9. Changes in salaries and benefits not directly related to a change in scope of service;

10. Change in patient type and volume without changes in type, duration, or intensity of services;

11. Capital expenditures for losses covered by insurance; or,

12. A change in ownership.

e) A FQHC must apply to the Department by written notice within ninety (90) days of the end of the FQHCs fiscal year in which the change in scope of service occurred, in conjunction with the submission of the FQHC's annual cost report. ~~For a scope-of-service rate adjustment to be considered, the change in scope of service must have existed for at least a full six (6) months.~~ Only one scope-of-service rate adjustment will be calculated per year. However, more than one type of change in scope of service may be included in a single application.

f) Should the scope-of-service rate application for one year fail to reach the threshold described in Section 8.700.6.C.5.b.4, the FQHC may combine that year's change in scope of service with a valid change in scope of service from the next year or the year after. For example, if a valid change in scope of service that occurred in FY 2016 fails to reach the threshold needed for a rate adjustment, and the FQHC implements another valid change in scope of service during FY2018, the FQHC may submit a scope-of-service rate adjustment application that captures both of those changes. A FQHC may only combine changes in scope of service that occur within a three-year time frame, and must submit an application for a scope-of-service rate adjustment as soon as possible after each change has been implemented. Once a change in scope of service has resulted in a successful scope-of-service rate adjustment, either individually or in combination with another change in scope of service, that change may no longer be used in an application for another scope-of-service rate adjustment.

g) The documentation for the scope-of-service rate adjustment is the responsibility of the FQHC. Any FQHC requesting a scope-of-service rate adjustment must submit the following to the Department:

1. The Department's application form for a scope-of-service rate adjustment, which includes:

i. The provider number(s) that is/are affected by the change(s) in scope of service;

ii. A date on which the change(s) in scope of service was/were implemented;

iii. A brief narrative description of each change in scope of service, including how services were provided both before and after the change;

iv. Detailed documentation such as cost reports that substantiate ~~Supporting data that details~~ the change in total costs, total health care costs, and total visits associated with the change(s) in scope; and

v. An attestation statement that certifies the accuracy, truth, and completeness of the information in the application signed by an ~~duly appointed~~ officer or administrator of the FQHC;

~~2. Detailed documentation such as cost reports that substantiate the supporting data in the aforementioned form; and,~~

2~~3~~. Any additional documentation requested by the Department. If the Department requests additional documentation to calculate the rate for the change(s) in scope of service, the FQHC must provide the additional documentation within thirty (30) days. If the FQHC does not submit the additional documentation within the specified timeframe, the Department, at its discretion, may postpone the implementation of the scope-of-service rate adjustment.

h) The reimbursement rate for a scope-of-service change applied for January 30, 2017 or afterwards will be calculated as follows:

1. The Department will first verify the total costs, the total covered health care costs, and the total number of visits before and after the change in scope of service. The Department will also calculate the Adjustment Factor (AF = covered health care costs/total cost of FQHC services) associated with the change in scope of service of the FQHC. If the AF is 80% or greater, the Department will accept the total costs as filed by the FQHC. If the AF is less than 80%, the Department will reduce the costs other than covered health care costs (thus reducing the total costs filed by the FQHC) until the AF calculation reaches 80%. These revised total costs will then be the costs used in the scope-of-service rate adjustment calculation.

2. The Department will then use the appropriate costs and visits data to calculate the adjusted PPS rate. The adjusted PPS rate will be the average of the costs/visits rate before and after the change in scope of service, weighted by visits.

3. The Department will calculate the difference between the current PPS rate and the adjusted PPS rate. The “current PPS rate” means the PPS rate in effect on the last day of the reporting period during which the most recent scope-of-service change occurred.

4. The Department will check that the adjusted PPS rate meets the 3% threshold described above. If it does not meet the 3% threshold, no scope-of-service rate adjustment will be implemented.

5. Once the Department has determined that the adjusted PPS rate has met the 3% threshold, the adjusted PPS rate will then be increased by the Medicare Economic Index (MEI) to become the new PPS rate.

i) The Department will review the submitted documentation and will notify the FQHC in writing within one hundred twenty (120) days from the date the Department received the application as to whether a PPS rate change will be implemented. Included with the notification letter will be a rate-setting statement sheet, if applicable. The new PPS rate will take effect one hundred twenty (120) days after the FQHC's fiscal year end.

j) Changes in scope of service, and subsequent scope-of-service rate adjustments, may also be identified by the Department through an audit or review process ~~at the request of the Department~~.

1. If the Department identifies a change in scope of services, the Department may request the documentation as described in Section 8.700.6.C.5.g from the FQHC. The FQHC must submit the documentation within ninety (90) days from the date of the request.

2. The rate adjustment methodology will be the same as described in Section 8.700.6.C.5.h.

3. The Department will review the submitted documentation and will notify the FQHC by written notice within one hundred twenty (120) days from the date the Department received the application as to whether a PPS rate change will be implemented. Included with the notification letter will be a rate-setting statement sheet, if applicable.

4. The effective date of the scope-of-service rate adjustment will be one hundred twenty (120) days after the end of the fiscal year in which the change in scope of service occurred.

k) A FQHC may request a written informal reconsideration of the Department's decision of the PPS rate change regarding a scope-of-service rate adjustment within thirty (30) days of the date of the Department's notification letter. The informal reconsideration must be mailed to the Department of Health Care Policy and Financing, 1570 Grant St, Denver, CO 80203. To request an informal reconsideration of the decision, a FQHC must file a written request that identifies specific items of disagreement with the Department, reasons for the disagreement, and a new rate calculation. The FQHC should also include any documentation that supports its position. A provider dissatisfied with the Department's decision after the informal reconsideration may appeal that decision through the Office of Administrative Courts according to the procedures set forth in 10 CCR 2505-10 Section 8.050.3, PROVIDER APPEALS.

6~~5~~. The performance of physician and mid-level medical staff shall be evaluated through application of productivity standards established by the Centers for Medicare and Medicaid Services (CMS) in CMS Publication 27, Section 503; "Medicare Rural Health Clinic and FQHC Manual". If a FQHC does not meet the minimum productivity standards, the productivity standards established by CMS shall be used in the FQHCs' rate calculation.

8.700.6.D The Department shall notify the FQHC of its rate.

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Rule Concerning Medical Eligibility for Individuals Residing in Community Correction Facilities and Inmates of Correctional Institutions, Sections 8.100.3.B.1, 8.100.3.G.1.b and 8.100.5.C.5
Rule Number: MSB 16-08-16-A
Division / Contact / Phone: Eligibility Policy / Eric Stricca / 303-866-4475

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 16-08-16-A, Revision to the Medical Assistance Rule Concerning Medical Eligibility for Individuals Residing in Community Correction Facilities and Inmates of Correctional Institutions, Sections 8.100.3.B.1, 8.100.3.G.1.b and 8.100.5.C.5
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) 8.100.3.B.1, 8.100.3.G.1.b and 8.100.5.C.5, 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*

Replace the current text at 8.100.3.B with the proposed text starting at 8.100.3.B.1 through the end of 8.100.3.B.5. Replace the current text at 8.100.3.G with the proposed text starting at 8.100.3.G.1 through the end of 8.100.3.G.1.g.v.3. Replace the current text at 8.100.C.5 with the proposed text starting at 8.100.5.C.1 through the end of 8.100.5.C.5. This rule is effective March 30, 2017.

*to be completed by MSB Board Coordinator

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Rule Concerning Medical Eligibility for Individuals Residing in Community Correction Facilities and Inmates of Correctional Institutions, Sections 8.100.3.B.1, 8.100.3.G.1.b and 8.100.5.C.5
Rule Number: MSB 16-08-16-A
Division / Contact / Phone: Eligibility Policy / Eric Stricca / 303-866-4475

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).

   On April 28, 2016, CMS issued guidance letter SHO#16-007, which clarified that federal financial participation may now be drawn for Medicaid-covered services for individuals who reside in community corrections facilities (halfway houses) that have freedom of movement. This is a reversal from prior guidance and now these individuals are no longer considered to be incarcerated and can be fully enrolled in Medicaid if all eligibility criteria are met. The Department of Public Safety has determined that all community corrections facilities meet the freedom of movement requirement except Gateway Through the Rockies in Colorado Springs. The eligibility policy rules are being updated to reflect this guidance.

   Additionally, the rule that allows for individuals who are inmates of correctional facilities, if eligible, to be enrolled in Medicaid while having their benefits limited to a 24+ hour inpatient stay in a medical institution, will be clarified.

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:

   State Health Official directive #16-007, dated April 28, 2016, Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS)

4. State Authority for the Rule:

   25.5-1-301 through 25.5-1-303, C.R.S. (2015);
   25.5-4-102, 25.5-4-205.5, C.R.S. 2016

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Rule Concerning Medical Eligibility for Individuals Residing in Community Correction Facilities and Inmates of Correctional Institutions, Sections 8.100.3.B.1, 8.100.3.G.1.b and 8.100.5.C.5
Rule Number: MSB 16-08-16-A
Division / Contact / Phone: Eligibility Policy / Eric Stricca / 303-866-4475

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 rule change will benefit individuals who are residents in Colorado Community Corrections facilities, excluding Gateway Through the Rockies, by allowing them to be able to enroll into Medicaid if they meet eligibility requirements. The rule change only affects individuals who would otherwise be eligible for a non-MAGI eligibility category; individuals who are otherwise eligible for MAGI eligibility categories and are residents in Colorado Community Corrections facilities are already eligible to enroll in Medicaid under 8.100.3.G.1.b and per State Health Official guidance letter #16-007.

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

   Residents of Community Corrections facilities who would otherwise be eligible for non-MAGI eligibility categories will be eligible for Medicaid under this rule change and be able to gain access to health care that they previously could not. This will improve the health outcomes of these individuals and may reduce recidivism that is caused by lack of access to behavioral health medications and physical health care services (some individuals may recidivate just for access to health care coverage provided by county jails and Department of Corrections).

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.

   This rule change is a clarification of the Department's existing policy to cover individuals who would otherwise be eligible for Medicaid and are living in Community Corrections facilities. Individuals eligible for MAGI populations who are living in these facilities are already eligible to enroll in Medicaid under 8.100.3.G.1.b and per State Health Official guidance letter #16-007. This rule change extends the policy to individuals who would otherwise be eligible for non-MAGI populations. It is not certain how many individuals will be newly eligible for Medicaid under this rule, but as there is an employment requirement while living in a community corrections

environment, the affected population is likely reasonably small and limited to individuals in the Working Adults with Disabilities Non-MAGI group who are earning more than the income limit for MAGI populations.

Under the rule change, the Department would incur costs related to covering the newly eligible individuals while they are residing in Community Corrections facilities, which would result in six to seven additional months of coverage on average. The Department assumes that there would be offsetting savings for covering clients for this additional time because without Medicaid coverage, the affected clients would incur costs related to the following: 1) receiving more costly care in the inpatient setting while at the Community Corrections facilities, and 2) receiving more costly care once they leave the facility and become eligible for Medicaid due to the exacerbation of medical conditions while they were without health insurance.

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

   The benefit of allowing residents of Community Corrections continuity of health care coverage is that the individual will have an increase in their quality of health and life and possibly enhance their chances of completing the program and re-entering the general population. Inaction could decrease the quality of health of these individuals which could cost the state more in future Medicaid costs due to the exacerbation of conditions or if the individual returned to custody of Department of Corrections to receive medical services.

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 alternatives.

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.

   There are no alternatives to allowing eligible individuals to enroll in Medicaid.

8.100.3.B. Residency Requirements

1. Individuals shall make application in the county in which they live. ~~Individuals held in correctional facilities or who are held in community corrections programs shall apply for the Medical Assistance Program in the county specified as the county of residence upon release~~. Individuals who reside in a county but who do not reside in a permanent dwelling nor have a fixed mailing address shall be considered eligible for the Medical Assistance Program, provided all other eligibility requirements are met. In no instance shall there be a durational residency requirement imposed upon the applicant, nor shall there be a requirement for the applicant to reside in a permanent dwelling or have a fixed mailing address. If an individual without a permanent dwelling or fixed mailing address is hospitalized, the county where the hospital is located shall be responsible for processing the application to completion. If the individual moves prior to completion of the eligibility determination the origination eligibility site completes the determination and transfers the case as applicable.

a. For applicants in Long Term Care institutions - The county of domicile for all Long Term Care clients is the county in which they are physically located and receiving services.

2. A resident of Colorado is defined as a person that is living within the state of Colorado and considers Colorado to be their place of residence at the time of application. For institutionalized individuals who are incapable of indicating intent as to their state of residence, the state of residence shall be where the institution is located unless that state determines that the individual is a resident of another state, by applying the following criteria:

a. for any institutionalized individual who is under age 21 or who is age 21 or older and incapable of indicating intent before age 21, the state of residence is that of the individual's parent(s) or legally appointed guardian at the time of placement;

b. for any institutionalized individual who became incapable of indicating intent at or after age 21, (1) the state of residence is the state in which the person was living when he or she became incapable of indicating intent, or (2) if this cannot be determined, the state of residence is the state in which the person was living when he or she was first determined to be incapable of indicating intent;

c. upon placement in another state, the new state is the state of residence unless the current state of residence is involved in the placement. If a current state arranged for an individual to be placed in an institution located in another state, the current state shall be the individual's state of residence, irrespective of the individual's indicated intent or ability to indicate intent;

d. in the case of conflicting opinions between states, the state of residence is the state where the individual is physically located.

3. For purposes of this section on establishing an individual's state of residence, an individual is considered incapable of indicating intent if:
   a. the person has an I.Q. of 49 or less or has a mental age of 7 or less, based on standardized tests as specified in the persons in medical facilities section of this volume;

   b. the person is judged legally incompetent; or

c. medical documentation, or other documentation acceptable to the eligibility site, supports a finding that the person is incapable of indicating intent.

4. Residence shall be retained until abandoned. A person temporarily absent from the state, inside or outside the United States, retains Colorado residence. Temporarily absent means that at the time he/she leaves, the person intends to return.

5. A non-resident shall mean a person who considers his/her place of residence to be other than Colorado. Any person who enters the state to receive Medical Assistance or for any other reason is a non-resident, so long as they consider their permanent place of residence to be outside of the state of Colorado.

8.100.3.G. General and Citizenship Eligibility Requirements

1. To be eligible to receive Medical Assistance, an eligible person shall:

a. Be a resident of Colorado;

b. Meet the following requirements while being an inmate, in-patient or resident of a public institution:

i). The following individuals, if eligible, may be enrolled for Medical Assistance

1. Patients in a public medical institution

2. Residents of a Long-Term Care Institution

3. Prior inmates who have been paroled

4. Resident of a publicly operated community residence which serves no more than 16 residents

5. Individuals participating in community corrections programs or residents in community corrections facilities ("halfway houses") who have freedom of movement and association which includes individuals who:

a) are not precluded from working outside the facility in employment available to individuals who are not under justice system supervision;

b) can use community resources (e.g., libraries, grocery stores, recreation, and education) at will;

c) can seek health care treatment in the broader community to the same or similar extent as other Medicaid enrollees in the state; and/or

d) are residing at their home, such as house arrest, or another location

ii). Inmates who are incarcerated in a correctional institution such as a city, county, state or federal prison may be enrolled, if eligible, with benefits limited to an in-patient stay of 24 hours or longer in a medical institution.

~~b. Not be an inmate of a public institution, except as a patient in a public medical institution or as a resident of an Long Term Care Institution or as a resident of a publicly operated community residence which serves no more than 16 residents~~

8.100.5.C. Effective Date of Eligibility

1. Eligibility for the Aged, Blind and Disabled categories shall be approved effective on the later of:
   a. The first day of the month of the Single Streamlined Application for Medical Assistance; or
   b. The first day of the month the person becomes eligible for Medical Assistance.
2. The date that eligibility begins for Long-Term Care Medical Assistance is defined in section 8.100.7.A and B.
3. For the Medicaid Buy-In Program for Children with Disabilities, any child who is determined to be eligible for Medical Assistance at any time during a calendar month shall be eligible for benefits during the entire month.
4. Clients applying for Medical Assistance under the Aged, Blind and Disabled category shall be reviewed for retroactive eligibility as described at 8.100.3.E. When reviewing for retroactive eligibility for an individual who is SSI eligible or applied and became SSI eligible in each of the retroactive months, the applicant must:
   a. Be aged at least 65 years; or
   b. Meet the Social Security Administration definition of disability by:
      i) Being approved as eligible to receive either SSI or SSDI, on or prior to the date of a medical service; or
      ii) Having a disability onset date determined on or prior to the date of a medical service; and
   c. Meet the financial requirements as described at 8.100.5.E.
5. ~~Individuals held in correctional facilities or who are held in community corrections programs that are determined eligible for Medical Assistance shall be approved effective as of the individual's date of release. Individuals participating in a Community Corrections program who are residing at their home, such as house arrest, or another location that is not a Community Corrections facility that are determined eligible for Medical Assistance shall be approved effective as of the date the individual meets all financial eligibility requirements. All individuals on Parole who are determined eligible for Medical Assistance shall be approved effective as of the date the individual meets all financial eligibility requirements~~

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Program Pharmacy Benefit Rules Concerning Pharmaceuticals, Section 8.800
Rule Number: MSB 16-10-24-A
Division / Contact / Phone: Client and Clinical Care Office / January Montano / (303)866-6977

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 16-10-24-A, Revision to the Medical Assistance Program Pharmacy Benefit Rules Concerning Pharmaceuticals, Section 8.800
3. This action is an adoption of: new rules
4. Rule sections affected in this action (if existing rule, also give Code of Regulations number and page numbers affected):

   Sections(s) 8.800, 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*

Replace the current text at 8.800 with the proposed text starting at 8.800.1 through the end of 8.800.18.E. This rule is effective March 30, 2017.

*to be completed by MSB Board Coordinator

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Program Pharmacy Benefit Rules Concerning Pharmaceuticals, Section 8.800
Rule Number: MSB 16-10-24-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).

   A Regulatory Efficiency Review was performed at 10 CCR 2505-10, Section 8.800, pursuant to Executive Order D2012-002 in 2015. Several revisions requiring technical clean-up of the rules at 8.800 were identified. The revisions to Section 8.800 represent a technical clean-up only and do not include any substantive changes. Therefore, the rules at 10 C.C.R. 2505-10, Sections 8.800, are being revised.

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:

   42 U.S.C. Section 1396r-8(d)

   42 U.S.C. Section 256b

   42 U.S.C. Section 1395w-102(e)

   42 C.F.R. Sections 447.512-447.516

   42 C.F.R. Section 456.716(d)

   42 C.F.R. Section 423.100

4. State Authority for the Rule:

   25.5-1-301 through 25.5-1-303, C.R.S. (2015);

Initial Review **01/13/17** Final Adoption **02/10/17**
Proposed Effective Date **03/30/17** Emergency Adoption

DOCUMENT #05

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C.R.S. Sections 25.5-5-501, 25.5-5-502, 25.5-505 (2016)

Initial Review **01/13/17** Final Adoption **02/10/17**

Proposed Effective Date **03/30/17** Emergency Adoption

DOCUMENT #05

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Program Pharmacy Benefit Rules Concerning Pharmaceuticals, Section 8.800
Rule Number: MSB 16-10-24-A
Division / Contact / Phone: Client and Clinical Care Office / January Montano / (303)866-6977

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.

   There are no costs associated with the proposed rule. There are no impacts to members, providers or local governments.

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

   None.

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.

   None.

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

   The rule revisions at 10 CCR 2505-10, Section 8.800, are technical only and as such create no potential costs.

   The benefits of the proposed revisions are up-to-date and efficacious pharmaceutical rules.

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

   None.

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.

   None.

8.800 PHARMACEUTICALS

8.800.1 DEFINITIONS

~~A.~~ 340B Pharmacy means any pharmacy that participates in the Federal Public Health Service's 340B Drug Pricing Program as described in Title 42 of the United States Code, Section 256b (2014). Title 42 of the United States Code, Section 256b (2014) ~~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. *Title 42 of the United States Code Section 256b (201)*~~ is hereby incorporated by reference into this rule. Such incorporation, however, excludes later amendments to or editions of the referenced material. ~~These regulations are available~~This statute is available for public inspection at the Department of Health Care Policy and Financing, 1570 Grant Street, Denver, CO 80203. Pursuant to C.R.S. §24-4-103(12.5)(V)(b), the agency shall provide certified copies of the material incorporated at cost upon request or shall provide the requestor with information on how to obtain a certified copy of the material incorporated by reference from the agency of the United States, this state, another state, or the organization or association originally issuing the code, standard, guideline or rule.

A.

B. 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.

C. 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.

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

E. 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.

F. Dispensing ~~Physician~~ Prescriber means a health care professional ~~licensed physician~~ who, as licensed by Colorado state law, prepares, dispenses and instructs ~~clients~~ members to self-~~-~~administer medication.

G. Drug Class means a group composed of drugs that -all treat a particular disease, ~~-or~~ symptom or indication.~~and are in the same therapeutic class.~~

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

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

~~J.~~ Fiscal agent means a contractor that supports and operates the pharmacy benefit management system ~~processes or pays vendor claims~~ on behalf of the Medical Assistance Program~~id agency~~.

J.

~~K. 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.~~

~~L.~~ Federal Upper Limit (FUL) means the upper limit for multiple source drugs as set by the Centers for Medicare and Medicaid Services pursuant to Title 42 of the Code of Federal Regulations, Part 447.512-447.516 (2016). Title 42 of the Code of Federal Regulations, Part 447.512-447.516 (2016) ~~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 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. *Title 42 of the Code of Federal Regulations, Part 447.512-447.516 (201)*~~ is hereby incorporated by reference into this rule. Such incorporation, however, excludes later amendments to or editions of the referenced material. ~~These regulations are available~~This statute is available for public inspection at the Department of Health Care Policy and Financing, 1570 Grant Street, Denver, CO 80203. Pursuant to C.R.S. §24-4-103(12.5)(V)(b), the agency shall provide certified copies of the material incorporated at cost upon request or shall provide the requestor with information on how to obtain a certified copy of the material incorporated by reference from the agency of the United States, this state, another state, or the organization or association originally issuing the code, standard, guideline or rule.

K.

~~M.~~L. 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.

~~N.~~M. 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.

~~O.~~N. Government Pharmacy means any pharmacy whose primary function is to provide drugs and services to ~~client~~members 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.

~~P.~~O. 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.

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

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

~~S.~~R. Medical Assistance Program shall have the meaning defined in Section 25.5-1-103(5), C.R.S. (20~~08~~16).

~~T.~~S. 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~~member's copayment as determined according to 10 C.C.R. 2505-10, Section 8.754.

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

~~U.~~ Medicare Part D means the prescription drug benefit provided to Part D ~~Eligible Individual~~eligible individuals pursuant to the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

U.

~~V.~~ Medicare Part D Drugs means drugs defined at Title 42 of the United States Code, Section 1395w-102(e) (2014) and Title 42 of the Code of Federal Regulations, Section 423.100 (2015). ~~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.~~Title 42 of the United States Code, Section 1395w-102(e) (2014) and Title 42 of the Code of Federal Regulations, Section 423.100 (2015) are hereby incorporated by reference into this rule. Such incorporation, however, excludes later amendments to or editions of the referenced material. ~~These regulations are available~~This statute is available for public inspection at the Department of Health Care Policy and Financing, 1570 Grant Street, Denver, CO 80203. Pursuant to C.R.S. §24-4-103(12.5)(V)(b), the agency shall provide certified copies of the material incorporated at cost upon request or shall provide the requestor with information on how to obtain a certified copy of the material incorporated by reference from the agency of the United States, this state, another state, or the organization or association originally issuing the code, standard, guideline or rule.

V.

W. Non-preferred Drug means a drug that ~~-~~is designated as non-preferred by the Medical Director pursuant to 10 CCR 2505-10, Section 8.800.16, and requires prior-authorization before being payable by the Medical Assistance Program. ~~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.~~

X. 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.

~~X.~~Y. Over-the-Counter (OTC) means ~~a drug that can be purchased without a physician's prescription.~~ ~~means~~ a drug that is appropriate for use without the supervision of a health care professional such as a physician, and which can be purchased by a consumer without a prescription.

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

AA. 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.~~

BB. Preferred Drug means a drug that is designated preferred by the Medical Director pursuant to 10 CCR 2505-10, Section 8.800.16.B, 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 members.

~~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.~~

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

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

~~AA.~~EE. Retail Pharmacy means any pharmacy that is not a 340B Pharmacy, Government Pharmacy, Institutional Pharmacy, Mail Order Pharmacy, or Rural Pharmacy.

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

~~CC.~~GG. 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.

~~DD.~~HH. 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.

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

~~FF.~~JJ. 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~~Prescriber, whether in-state or out-of-state, that submits claims for reimbursement must be enrolled in the ~~Colorado Medicaid~~Medical Assistance program in accordance with 8.040.1 and 8.013.1. The Department may deny a provider~~n~~ application, and the Department may terminate or not renew ~~for~~ a provider agreement~~, terminate or not renew a provider agreement~~ in accordance with 10 C.C.R. 2505-10, Sections 8.076, 8.125, and 8.1~~3~~30.

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

8.800.3 MAIL ORDER

8.800.3.A. Only Maintenance Medications may be delivered through the mail.

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;

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"; exceptexpect for the following:

a. Stiripentol and clobazam (prior to availability of Onfi in the US) may qualify for coverage (generic coverage, if available, brand coverage if no generic is available) for clients up through age 20, if the coverage has been ordered by the child's physician, has been determined medically necessary by the Colorado Medical Assistance Program Medical Director (or clinical appointee of the Executive Director), and has been authorized for the specific child's use by the U.S. Food & Drug Administration.

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

7. Medicare Part D Drugs for Part D Eligible Individualeligible 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. Title 42 of the United States Code, Section 1396r-8(d)(2014). Title 42 of the United States Code, Section 1396r-8(d)(2014) is hereby incorporated by reference into this rule. Such incorporation, however, excludes later amendments to or editions of the referenced material. These regulations are availableThis statute is available for public inspection at the Department of Health Care Policy and Financing, 1570 Grant Street, Denver, CO 80203. Pursuant to C.R.S. §24-4-103(12.5)(V)(b), the agency shall provide certified copies of the material incorporated at cost upon request or shall provide the requestor with information on how to obtain a certified copy of the material incorporated by reference from the agency of the United States, this state, another state, or the organization or association originally issuing the code, standard, guideline or rule.

1. 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~~F. 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 Individual~~eligible individuals in the same manner as they are covered for all other eligible Medical Assistance Program ~~client~~members.

8.800.4.~~H~~G. Generic drugs shall be dispensed to ~~client~~members 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. Mental Illness;

~~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 c~~Cancer;

c. ~~Treatment of e~~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~~member 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~~member 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~~ shall not bill for any products that ~~shall be~~are administered in a physician's office or clinic.

8.800.5.B. ~~Dispensing Physician~~Dispensing Prescribers whose offices or sites of practice are located ~~more than~~within 25 miles from the nearest participating pharmacy ~~may~~shall not be reimbursed for drugs or services 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~~member'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~~member 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~~Member 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~~member for proper treatment. The pharmacist may call the p~~P~~rior A~~a~~uthorization ~~H~~help desk ~~Desk~~ to receive override approval. ~~.~~ Prescriptions dispensed under the override approval are eligible for reimbursement.

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~~member 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~~member 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~~Member Counseling

1. A pharmacist or pharmacist designee ~~pharmacy intern~~ shall offer drug therapy counseling to each Medical Assistance Program ~~client~~member or the caregiver of such ~~client~~member with a new prescription or with a refill prescription if the pharmacist or pharmacist designee~~y intern~~ believes that it is in the best interest of the ~~client~~member. 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 pharma~~cy intern~~cist designee shall review the ~~client~~member's record and then discuss with the ~~client~~member or the ~~client~~member's caregiver those matters that, in the exercise of his or her professional judgment, the pharmacist or pharmac~~y intern~~ist designee 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~~member;

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

4. ~~Client~~Member counseling by a pharmacist or pharmac~~y intern~~ist designee as described in this section shall not be required for ~~client~~members of a hospital or institution where other licensed health care professionals administer the prescribed drugs pursuant to a chart order.

5. A pharmacist or pharmac~~y intern~~ist designee shall not be required to counsel a ~~client~~member or caregiver when the ~~client~~member or caregiver refuses such consultation. The pharmacist or pharmac~~y intern~~ist designee 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 ~~client~~member<u>s</u> 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.~~ Title 42 of the Code of Federal Regulations, Section 456.716(d)(2015). Title 42 of the Code of Federal Regulations, Section 456.716(d)(2015) are hereby incorporated by reference into this rule. Such incorporation, however, excludes later amendments to or editions of the referenced material. ~~These regulations are available~~This statute is available for public inspection at the Department of Health Care Policy and Financing, 1570 Grant Street, Denver, CO 80203. Pursuant to C.R.S. §24-4-103(12.5)(V)(b), the agency shall provide certified copies of the material incorporated at cost upon request or shall provide the requestor with information on how to obtain a certified copy of the material incorporated by reference from the agency of the United States, this state, another state, or the organization or association originally issuing the code, standard, guideline or rule.

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~~member, 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~~member information from the ~~client~~member 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~~member's pharmaceutical care as described in the Prospective Drug Review and ~~Client~~Member 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 ~~client~~members 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~~member; 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; or

~~4.~~

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

~~5~~f. 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):

i~~a.~~) Inpatient hospital services;

ii~~b.~~) Hospice services;

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

iv)~~d.~~ Physician services;

v)~~e.~~ Outpatient hospital services;

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

vii)~~g.~~ Other laboratory and x-ray services; or

viii)~~h.~~ Renal dialysis.

~~4~~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.

~~5~~7. When a Medical Assistance Program ~~client~~member 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~~member was determined eligible. Prescriptions that are filled or refilled after the ~~client~~member 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~~member'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~~member or agent of the ~~client~~member.

2. Pharmacies using a chronological log shall review all Medical Assistance Program prescriptions in shall-call status (filled but not released to the ~~client~~member or the ~~client~~member'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 ~~client~~members 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 ~~client~~members except for OAP State Only clients shall be reimbursed the lesser of:

1. The Usual and Customary Charge minus the ~~client~~member'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~~member'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 8.941.9~~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 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 or designated vendor as indicated on the Average Acquisition Cost Inquiry Worksheet. 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 R~~r~~ural P~~p~~harmacy. 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%~~

~~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 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 Physician~~Dispensing Prescribers who dispense medications that are reimbursed as a pharmacy benefit pursuant to 8.800 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. (20~~08~~16), 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; and

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 Preferred or Non-preferred and designates prior authorization criteria to protect the health and safety of members, 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 efficacy, safety and appropriate prior authorization criteria for Preferred and Non-preferred Drugs to ensure the health and safety of members.

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 ~~client~~members.

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 ~~client~~members 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 ~~client~~members shall be exempted, on an annual basis, from prior authorization requirements for all Non-preferred Drugs if:

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

b. A ~~client~~member'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~~member 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 ~~client~~members 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~~member 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 ~~client~~members.

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~~which 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 ~~client~~members the opportunity to meet with a pharmacist to review the ~~client~~member'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~~member 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 ~~client~~members 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

3. ~~Client~~Members may participate in the program if they are a fee-for-service ~~client~~member 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~~member within ten days of the referral. If the ~~client~~member 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~~member drug histories.

c. Hold face-to-face or telephonic consultations with ~~client~~members.

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

e. Provide the ~~client~~member 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 ~~client~~members participating in the program in writing that a pharmacist has been assigned to review the ~~client~~member's records and that the pharmacist will contact the ~~client~~member 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~~member, 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~~member.

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