THIS PAGE NOT FOR PUBLICATION

Title of Rule:	Revision to the Pharmacy Rule for Determining Reimbursement Rates of Pharmaceuticals, Section 8.800
Rule Number:	MSB 11-11-04-A
Division / Contact / Phone:	Pharmacy / Sonia Sandoval / (303) 866-6338

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 11-11-04-A, Revision to the Pharmacy Rule for Determining Reimbursement Rates of Pharmaceuticals, Section 8.800
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) 8.800.13, Colorado Department of Health Care Policy and Financing, Staff Manual Volume 8, Medical Assistance (10 CCR 2505-10).

5. Does this action involve any temporary or emergency rule(s)? Yes
   If yes, state effective date: 12/09/2011
   Is rule to be made permanent? (If yes, please attach notice of hearing). Yes

PUBLICATION INSTRUCTIONS*

Please replace current text from the first unnumbered paragraph after §8.800.13 through §8.800.13.P.6 and replace with the new text provided. This rule is effective 12/09/2011.

*to be completed by MSB Board Coordinator

THIS PAGE NOT FOR PUBLICATION

Title of Rule:	Revision to the Pharmacy Rule for Determining Reimbursement Rates of Pharmaceuticals, Section 8.800
Rule Number:	MSB 11-11-04-A
Division / Contact / Phone:	Pharmacy / Sonia Sandoval / (303) 866-6338

STATEMENT OF BASIS AND PURPOSE

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

   The proposal is to continue the rule that is currently in place for pharmaceutical reimbursement.

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:

   If this emergency rule is not passed, there will be no pharmaceutical reimbursement rule in place after January 7, 2012.

3. Federal authority for the Rule, if any:

4. State Authority for the Rule:

   25.5-1-301 through 25.5-1-303, C.R.S. (2010);

Initial Review — Final Adoption

Proposed Effective Date **12/09/2011** — Emergency Adoption **12/09/2011**

DOCUMENT # 01

THIS PAGE NOT FOR PUBLICATION

Title of Rule:	Revision to the Pharmacy Rule for Determining Reimbursement Rates of Pharmaceuticals, Section 8.800
Rule Number:	MSB 11-11-04-A
Division / Contact / Phone:	Pharmacy / Sonia Sandoval / (303) 866-6338

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.

   Pharmacies that provide services for fee-for-service outpatient drugs to Medicaid eligible clients will be affected by the proposed rule.

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

   Passage of the proposed rule allows the state to continue to work toward a rule that meets CMS approval. The Department will continue to work with stakeholders through this process.

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 benefit to the proposed rule is that there will be a rule regarding pharmaceutical reimbursement. The cost of inaction would be that with no rule in place, the Department is at risk for auditing, tracking and hearing issues.

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

   N/A.

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 alternative methods for achieving the purpose for the proposed rule due to the loss of AWP information.

8.800.13 REIMBURSEMENT CALCULATION

~~The paragraphs which follow set forth the reimbursement calculation effective September 9, 2011 through September 22, 2011.~~

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

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

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

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

~~1. Based on Average Wholesale Price (AWP):~~

~~a. AWP less 14.5% for brand name drugs; and~~

~~b. AWP less 45% for generic drugs;~~

~~2. Direct price plus 18%;~~

~~3. State MAC; and~~

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

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

~~i) Multiple manufacturers;~~

~~ii) Broad wholesale price span;~~

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

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

~~v) Bioequivalence or interchangeability.~~

~~4. FUL~~

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

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

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

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

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

~~8.800.13.H. Dispensing Fee~~

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

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

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

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

~~5. Government Pharmacies shall receive no dispensing fee.~~

~~6. Dispensing Physicians shall not receive a dispensing fee unless their offices or sites of practice are located more than 25 miles from the nearest participating pharmacy. In that case, the Dispensing Physician shall receive a dispensing fee of $1.89.~~

~~The paragraphs which follow set forth the reimbursement calculation effective September 23, 2011 unless otherwise noted in the paragraph.~~

8.800.13.A~~I~~. Covered drugs for all clients except for Old Age Pension (OAP) State Only clients shall be reimbursed the lesser the provider's Usual and Customary Charge minus the client's copayment, as determined according to 10 C.C.R. 2505-10, Section 8.754,and the allowed ingredient cost plus a dispensing fee minus the client's copayment. Covered drugs for the OAP State Only Programs shall be reimbursed according to 10 C.C.R. 2505-10, Section 8.941.9.

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

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

8.800.13.~~L~~D. The State Maximum Allowable Cost (MAC) price shall be established as:

1. The Average Acquisition Cost (AAC) plus fifty one and one-tenths percent (51.1%) for non-rural pharmacies; and

2. The AAC plus two hundred and thirty-three percent (233%) for rural pharmacies as defined in 8.800.13.~~O~~G.

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

i) A minimum of two readily available manufacturers in the United States;

ii) An Orange Book (bio-equivalency) rating of "A";

iii) The most popular / practical package sizes are used in the review process;

iv) AAC limits are continually reviewed for additions, deletions, increases, decreases and FUL comparison.

8.800.13.~~M~~E. The allowed ingredient cost is determined utilizing different methodologies as applicable.

~~1. Effective September 23, 2011 through September 30, 2011, the allowed ingredient cost will be the lesser of the MAC price as defined in10 C.C.R. 2505-10, Section 8.800.13. L, or submitted ingredient cost. If no MAC price is available, the allowed ingredient cost will be the less of:~~

~~a. Wholesale Acquisition Cost (WAC);~~

~~i) WAC plus two and six-tenths percent (2.6%) for brand drugs; and~~

~~ii) WAC minus one-tenths percent (0.1%) for generic drugs;~~

~~b. Average Wholesale Price (AWP);~~

~~i) AWP less fourteen and five-tenths percent (14.5%) for brand drugs; and~~

~~ii) AWP less forty five percent (45%) for generic drugs;~~

~~c. Submitted ingredient cost;~~

~~d. Federal Upper Limit (FUL) rates.~~

~~2. Effective October 1, 2011, t~~The allowed ingredient cost will be the lesser of the MAC price as defined in10 C.C.R. 2505-10, Section 8.800.13. ~~L,~~D or submitted ingredient cost. If no MAC price is available, the allowed ingredient cost will be the lesser of:

a. Wholesale Acquisition Cost (WAC);

i) WAC plus two and six-tenths percent (2.6%) for brand drugs; and

ii) WAC minus one-tenths percent (0.1%) for generic drugs;

b. Submitted ingredient cost.

8.800.13.~~N~~F. The MAC Price List is~~will be~~ posted on the Department's web site (~~-~~www.colorado.gov/hcpf) on a weekly basis. ~~beginning September 23, 2011.~~

8.800.13.~~O~~G. Any pharmacy, except a Mail Order Pharmacy, that is the only pharmacy within a twenty ~~-~~ mile radius may submit a letter to the Department requesting to become a Rural Pharmacy. If approved as a Rural Pharmacy, the reimbursement shall be calculated according to the following pricing methodologies:

~~Effective September 23, 2011 through September 30, 2011, a rural pharmacy will be reimbursed the MAC price as defined in 10 C.C.R. 2505-10, Section 8.800.13. L. If no MAC price is available, the allowed ingredient cost will be AWP minus twelve percent (12.0%).~~

~~Effective October 1, 2011, a~~ ~~r~~Rural pharmac~~ies~~~~y~~ will be reimbursed using the MAC price as defined in 10 C.C.R. 2505-10, Section 8.800.13. ~~L~~E. If no MAC price is available, the WAC price plus thirty and four-tenths percent (30.4%) will be the allowed ingredient cost.

8.800.13.~~P~~H. Dispensing Fee

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

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

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

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

5. Government Pharmacies shall receive no dispensing fee.

6. Dispensing Physicians shall not receive a dispensing fee unless their offices or sites of practice are located more than 25 miles from the nearest participating pharmacy. In that case, the Dispensing Physician shall receive a dispensing fee of $1.89.

THIS PAGE NOT FOR PUBLICATION

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: Revision to the Medical Assistance Rule Concerning Services for Clients in Psychiatric Residential Treatment Facilities or Residing in Therapeutic Residential Child Care Facilities, 8.765.4.A.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) 8.765.4.A.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)? Yes
   If yes, state effective date: 01/01/2012
   Is rule to be made permanent? (If yes, please attach notice of hearing). <Select One>

PUBLICATION INSTRUCTIONS*

Please delete text at the very end of the sentence in §8.765.4.A.5. All other text is for clarification purposes only. This change is effective 01/01/2012.

*to be completed by MSB Board Coordinator

THIS PAGE NOT FOR PUBLICATION

Title of Rule:	Revision to the Medical Assistance Rule Concerning Services for Clients in Psychiatric Residential Treatment Facilities or Residing in Therapeutic Residential Child Care Facilities
Rule Number:	MSB 11-11-21-A
Division / Contact / Phone:	Medicaid Program Division / Amanda Belles / 303-866-2830

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 change eliminates the requirement for a Department of Human Services Trails system level C determination to be eligible for placement into a Psychiatric Residential Treatment Facility (PRTF).

As of January 1, 2012, a thorough medical necessity evaluation known as a Colorado Client Assessment Record (CCAR) will be done once a client has been enrolled into a PRTF. This information will be housed in a Division of Behavioral Health (DBH) system instead of the Trails system, and does not use a "levels" system. Therefore, this requirement is no longer relevant.

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:

   Section 8.765.4.A.5 needs to be revised because it still requires that a level C must be reached for a child to be placed into a PRT. This requirement is irrelevant since the level system is no longer used as a placement tool. Further, by having this requirement in rule, it will make it impossible for any placement into a PRTF.
   For the preservation of public health, safety, and welfare of both the children that require the level of services attained at a PRTF and for the safety and interest of the general public, this section needs to be revised to remove the level C requirement for placement.

3. Federal authority for the Rule, if any:

4. State Authority for the Rule:

   25.5-1-301 through 25.5-1-303, C.R.S. (2011);

Initial Review		Final Adoption	
Proposed Effective Date	**01/01/2012**	Emergency Adoption	**12/09/2011**

DOCUMENT # 02

THIS PAGE NOT FOR PUBLICATION

Title of Rule:	Revision to the Medical Assistance Rule Concerning Services for Clients in Psychiatric Residential Treatment Facilities or Residing in Therapeutic Residential Child Care Facilities
Rule Number:	MSB 11-11-21-A
Division / Contact / Phone:	Medicaid Program Division / Amanda Belles / 303-866-2830

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 classes of persons who will be affected by this proposed revision of section 8.765.4.A.5, include the Department of Health Care Policy and Financing, the Department of Human Services, the Division of Behavioral Health, PRTFs, and clients who require PRTF services but are not able to be placed into a PRFT because of the unnecessary level C requirement.

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

   The probable quantitative and qualitative impact of not revising this section, as previously stated would be that it would make it impossible for any placements into PRTFs. For the preservation of public health, safety, and welfare of both the children that require the level of services attained at a PRTF and for the safety and interest of the general public, this section needs to be revised to remove the level C requirement for placement.

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.

   We do not anticipate that this proposed rule change will increase the utilization or costs to the Department or to any agency associated with this rule change. Nor do we anticipate that this rule change will affect state revenues.

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

   The probable cost of not revising section 8.765.4.A.5 as previously stated would be that it would make it impossible for any placement into a PRTF, which would be a detriment to clients who require the level of services offered at a PRTF.

   Te probable benefit of revising this section, would be that clients who require the level of services offered at a PRTF would still be able to be placed into the PRTF facility to receive these services.

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

We see the process of revising this section as the least costly and least intrusive method for ensuring that clients who require the level of services offered at a PRTF may still be placed into a PRTF to receive these services.

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.

   We do not foresee any alternative methods for achieving the purpose.

8.765.4 PRTF CLIENT ELIGIBILITY [Emer. Rule eff. 9/8/06; Perm. Rule eff. 10/1/06]

8.765.4.A. To receive benefits in a PRTF, the client shall:

1. Be between the ages of three and twenty-one.

2. Be certified to need PRTF level of care by an Independent Team. The Team shall certify that:

   a. Ambulatory care resources available in the community do not meet the treatment needs of the client.

   b. Proper treatment of the client's mental illness condition requires services on an inpatient basis under the direction of a physician.

   c. The services can reasonably be expected to improve the client's mental health or prevent further regression so that the services shall no longer be needed.

3. Be certified to have a diagnosis of a psychiatric disorder classified as a Diagnostic Statistical Manual (DSM) IV Text Revision, Fourth Edition, diagnosis that is the primary reason for placement from one of the following diagnostic categories:

   295 Schizophrenic disorders

   296 Affective psychoses

   297 Paranoid states

   298 Other nonorganic psychoses

   300 Neurotic disorders

   301 Personality disorders

   307 Eating Disorders, Tic Disorders and Sleep Disorders

   308 Acute reaction to stress

   309 Adjustment reaction

   311 Depressive disorder, not elsewhere classified

   312 Disturbance of conduct, not elsewhere classified

   313 Disturbance of emotions specific to childhood and adolescence

   314 Hyperkinetic syndrome of childhood

4. Be certified to have a DSM Axis 5 GAF score of 40 or less.

5. Be assessed using a current valid Colorado Client Assessment Record (CCAR) that supports medical necessity. ~~and scores at a level C.~~