DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Program Rule Concerning Outpatient Fee-For-Service Substance Use Disorder Treatment Services, Section 8.746
Rule Number: MSB 16-06-28-B
Division / Contact / Phone: Health Programs Benefits & Operations Division / Amanda Forsythe / x6459

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 16-06-28-B, Revision to the Medical Assistance Program Rule Concerning Outpatient Fee-For-Service Substance Use Disorder Treatment Services, Section 8.746
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) 8.746 and 8.700-8.799 Appendix A, 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). <Select One>

PUBLICATION INSTRUCTIONS*

Replace all current text starting at 8.746.A through the end of 8.746.A with the new text provided. Delete all current text beginning at 8.746 Appendix A. This revision is effective 11/01/2016.

*to be completed by MSB Board Coordinator

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Title of Rule: Revision to the Medical Assistance Program Rule Concerning Outpatient Fee-For-Service Substance Use Disorder Treatment Services, Section 8.746
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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 proposed revision removes Section 8.746, Appendix A: Outpatient Fee-For-Service Substance Use Disorder Treatment Benefit Coverage Standard, and inserts its content into the body of the rule at Section 8.746. The proposed rule revision is primarily technical; it makes minor changes to the language in order to best conform to standard rule formatting. However, the changes to the language do not substantively alter the Department's current Outpatient Fee-For-Service Substance Use Disorder Treatment benefit policy.

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. § 1396d(a)(2)(A); 42 C.F.R. § 440.230

4. State Authority for the Rule:

   25.5-1-301 through 25.5-1-303, C.R.S. (2015);
   C.R.S. 25.5-5-202(1)(s)(I)

Initial Review **08/12/2016** Final Adoption **09/09/2016**
Proposed Effective Date **11/01/2016** Emergency Adoption

DOCUMENT #03

Title of Rule: Revision to the Medical Assistance Program Rule Concerning Outpatient Fee-For-Service Substance Use Disorder Treatment Services, Section 8.746
Rule Number: MSB 16-06-28-B
Division / Contact / Phone: Health Programs Benefits & Operations Division / Amanda Forsythe / x6459

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.

   Currently, the language at Section 8.746 refers readers to Appendix A: Outpatient Fee-For-Service Substance Use Disorder Treatment Services Benefit Coverage Standard, which is located at the end of the entire Section 8.700. As a result of the current format, readers are required to follow multiple steps in order to locate the policy language for this benefit.

   By inserting the language from the Benefit Coverage Standard into the body of the rule at Section 8.746, the proposed revision is aimed at simplifying the organization of the Department's rules, while also increasing their readability.

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.

   N/A

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 or less intrusive methods for achieving the purpose of the proposed rule revision.

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.

8.746 OUTPATIENT FEE-FOR-SERVICE SUBSTANCE USE DISORDER TREATMENT

~~8.746.A. Outpatient Fee-for Service Substance Use Disorder Treatment benefits are provided in accordance with the provisions of Appendix A, which details the benefit coverage standards.~~

8.746.1 DEFINITIONS

Community Behavioral Health Services Program means the program described at 10 CCR 2505-10 Section 8.212, by which program-enrolled Medicaid clients receive behavioral health treatment services.

Day Treatment Program means a non-residential treatment program designed for children and adolescents under the age of 21 who have an emotional, behavioral, and neurobiological, or substance use disorder diagnosis, and may be at high risk for out-of-home placement. Day Treatment Program services include family, group, and individual psychotherapy; parent-child education; skill and socialization training focused on improving functional and behavioral deficits; and intensive coordination with schools or other child service agencies.

Health First Colorado is Colorado's Medicaid Program, the free or low cost public health insurance program that provides health care coverage to low-income individuals, families, children, pregnant women, seniors, and people with disabilities. Colorado Medicaid is funded jointly by the federal and state government, and is administered by the Colorado Department of Health Care Policy and Financing.

Intensive Outpatient Psychiatric Rehabilitation Services are those that focus on maintaining and improving functional abilities for the client through a time-limited, multi-faceted approach to treatment.

Masters Level Clinician means a provider who is clinical social worker licensed pursuant to CRS 12-43-404, marriage and family therapist licensed pursuant to CRS 12-43-504, professional counselor licensed pursuant to CRS 12-43-603, or advanced practice nurse licensed pursuant to CRS 12-38-111.5.

Peer Advocate Services means a scheduled therapeutic activity led by a trained client who is self-identified as receiving behavioral health services.

Psychologist, Psy.D/PhD means a provider who has a doctoral degree from an accredited program offering psychology courses approved by the American Psychological Association and is licensed as a psychologist by the State Board of Psychologist Examiners pursuant to CRS 12-43-304.

Physician Assistant means a provider who is a graduate of an education program accredited by the Accreditation Review Commission on Education for the Physician Assistant, certified by the National Commission on Certification of Physician Assistants, and licensed as a physician assistant pursuant to CRS 12-36-107.4.

Residential Treatment means a short-term residential treatment program offering 24-hour intensive residential treatment, habilitative, and rehabilitative services for up to 30 days in a highly structured, community-oriented environment.

State Fiscal Year (SFY) is July 1 – June 30.

8.746.2 ELIGIBLE PROVIDERS

1. Providers eligible to render services are limited to the following:

    a. Licensed physicians who are also:

i) Certified in addiction medicine by the American Society of Addiction Medicine (ASAM); or

ii) Certified as Certified Addiction Counselors (CAC II or CAC III) or Licensed Addiction Counselors (LAC) by the Department of Regulatory Agencies (DORA); or

iii) Certified as National Certified Addiction Counselors II (NCAC II) or Master Addiction Counselors (MAC) by the National Association of Alcohol and Drug Abuse Counselors (NAADAC); or

iv) Certified in addiction psychiatry by the American Board of Psychiatry and Neurology certified in Addiction Psychiatry (ABPN).

b. Licensed non-physicians who are also:

i) Psychologists (PhD, PsyD),

ii) Nurse Practitioners,

iii) Licensed Addiction Counselors, or

iv) Master's Level Clinicians:

1) Licensed Clinical Social Worker (LCSW)

2) Licensed Professional Counselor (LPC)

3) Licensed Marriage and Family Therapist (LMFT)

4) Licensed Advanced Practice Nurse (LAPN)

and either:

i) Certified by DORA as a CAC II or CAC III; or

ii) Certified by NAADAC as an NCAC II or MAC.

c. Licensed facilities that are supervised by one or more licensed physicians or non-physicians; supervised professional personnel who are:

i) Working at a facility licensed by the Office of Behavioral Health to provide substance use disorder treatment services; and

ii) Supervised by one or more licensed physicians or licensed non-physicians found in Part 1 or 2 of this Eligible Providers section.

8.746.3 TREATMENT PLANNING

8.746.3.A. An approved treatment plan must be in place for each client prior to the client receiving services. An initial assessment is required to establish a treatment plan. Treatment plans require approval from a licensed provider indicated in Section 8.746.2 with the authority to approve treatment plans within their scope of practice.

8.746.3.B. All rendered services must be medically necessary, as defined in Section 8.076.1.8., and must be detailed in the client's treatment plan and progress notes. Initial substance use disorder assessments are exempt from inclusion in the treatment plan.

8.746.4 ELIGIBLE CLIENTS

1. To be eligible for the Outpatient Fee-for-Service Substance Use Disorder Treatment benefit, client:

    a. Must currently be enrolled in Colorado Medicaid; and

    b. Must not be enrolled in the Community Behavioral Health Services program pursuant to 10 C.C.R. 2505-10 Section 8.212.

        i) All Colorado Medicaid clients are automatically enrolled in the Community Behavioral Health Services program, unless one of the following is true:

            1) Client is not eligible for enrollment in the Community Behavioral Health Services program, per 10 CCR 2505-10 Section 8.212.1.A.; or

            2) Client is approved for an individual enrollment exemption, as set forth at 10 CCR 2505-10 Section 8.212.2.

8.746.5 LIMITATIONS

1. Clients are not required to obtain a referral from their Primary Care Physician (PCP) or Primary Care Medical Provider (PCMP) to receive these services.

2. Clients must have a treatment plan that is approved by a licensed practitioner listed in Section 8.746.2.

3. Outpatient Fee-for-Service Substance Use Disorder Treatment services may only be rendered by providers outlined in Section 8.746.2, with an exception for certain providers of Medication Assisted Treatment described below.

4. Services are covered only when client has been diagnosed with at least one of the following:

    a. Alcohol use or induced disorder

    b. Amphetamine use or induced disorder

    c. Cannabis use or induced disorder

    d. Cocaine use or induced disorder

    e. Hallucinogen use or induced disorder

    f. Inhalant use or induced disorder

    g. Opioid use or induced disorder

    h. Phencyclidine use or induced disorder

i. Sedative Hypnotic or Anxiolytic use or induced disorder

j. Tobacco use disorder

8.746.6 COVERED SERVICES

8.746.6.A. Substance Use Disorder Assessment

1. A substance use disorder assessment is an evaluation designed to determine the most appropriate level of care based on criteria established by the American Society of Addiction Medicine (ASAM), the extent of drug or alcohol use, abuse, or dependence and related problems, and the comprehensive treatment needs of a client with a substance use disorder diagnosis.

    a. Course of treatment and changes in level of care must be based on best practices as defined by the current ASAM Patient Placement Criteria.

    b. Re-assessments must be spaced appropriately throughout the course of treatment to ensure the treatment plan is effectively managing the client's changing needs.

    c. Substance use disorder assessments are limited to two encounter-based units of service per State Fiscal Year. Each complete assessment corresponds to one unit of service.

    d. An assessment may involve more than one session and may span multiple days. If the assessment spans multiple days, the final day of the assessment is reported as the date of service.

8.746.6.B. Individual and Family Therapy

1. Individual and family therapy is the planned treatment of a client's problem(s) as identified by an assessment and listed in the treatment/service plan. The intended outcome is the management and reduction, or resolution of the identified problem(s).

2. Individual and family therapy is limited to one client per session.

3. Individual and family therapy is limited to a combined 35 sessions per State Fiscal Year, and billed at 15 minutes per unit, with up to four units (one hour) per session.

    a. A session is considered a single encounter with the client that can encompass multiple timed units.

4. Family therapy must be directly related to the client's treatment for substance use disorder or dependence.

5. Individual therapy and family therapy sessions are allowed on the same date of service.

8.746.6.C. Group Therapy

1. Group therapy refers to therapeutic substance use disorder counseling and treatment services, administered through groups of people who have similar needs, such as progression of disease, stage of recovery, and readiness for change.

2. Group therapy must include more than one patient.

3. Group therapy is limited to 36 sessions per State Fiscal Year.

a. A session of group therapy may last up to three hours and is billed in units of one hour each (e.g., a three hour group session would consist of three units).

b. A unit of service may be billed separately for each client participating in the group therapy session.

8.746.6.D. Alcohol / Drug Screening and Counseling

1. Alcohol / drug screening and counseling is the collection of urine followed by a counseling session with the client to review and discuss the results of the screening.

a. The laboratory analysis of the urine specimen (urinalysis) must be billed by a laboratory using that laboratory's Medicaid Provider ID.

b. Substance use disorder providers will only be reimbursed for collecting the urine specimen and providing a counseling session to review and discuss the results of the urinalysis. Claims submitted for the collection of the urine sample without the subsequent counseling of urinalysis results will not be reimbursed.

i) If the client does not return for the counseling of their urinalysis results, the collection of the sample cannot be claimed.

c. Substance use disorder counseling services to discuss and counsel the client on the test results must be provided by an eligible rendering provider, as outlined in Section 8.746.2.

d. The counseling portion of the service may be conducted during a session of individual or family therapy.

e. Multiple urine collections per date of service are not additionally reimbursed.

f. Alcohol / drug screening and counseling is limited to 52 specimen collections per State Fiscal Year.

g. Alcohol / drug screening and counseling is limited to one unit per date of service.

i) A unit of service is the single collection and subsequent counseling session.

8.746.6.E. Targeted Case Management

1. Targeted case management refers to coordination and planning services provided with, or on behalf of, a client with a substance use disorder diagnosis.

a. The client does not need to be physically present for this service to be performed if it is done on the client's behalf.

2. Targeted case management services are limited to service planning, advocacy, and linkage to other appropriate medical services related to substance use disorder diagnosis, monitoring, and care coordination.

3. Targeted case management services are limited to:

a. 52 units of service per State Fiscal Year.

b. Up to four units of service per date of service.

4. A unit of service equals one 30-minute sessions of targeted case management, and consists of at least one documented contact with a client or person acting on behalf of a client, identified during the case planning process.

8.746.6.F. Social / Ambulatory Detoxification

1. Facilities licensed by the Office of Behavioral Health (OBH) are the only provider type eligible to render social / ambulatory detoxification services.

2. Social / ambulatory detoxification services:

a. Include supervision, observation, and support from qualified personnel for clients exhibiting intoxication or withdrawal symptoms.

b. Are provided when there is minimal risk of severe withdrawal (including seizures and delirium tremens) and when any co-occurring mental health or medical conditions can be safely managed in an ambulatory setting.

3. Social / ambulatory detoxification is limited to five sessions per State Fiscal Year.

a. A session is defined as the continuous treatment time from the first day to the last day of social/ambulatory detoxification.

b. Each session may last a maximum of three days.

4. Room and board is not a covered social / ambulatory detoxification service. Claims billed for room and board will not be reimbursed.

5. Social / ambulatory detoxification is divided into four distinct services—physical assessment of detoxification progress, evaluation of level of motivation, safety assessment, and provision of daily living needs—with corresponding procedure codes, which may be provided and billed on the same date of service if medically necessary, as defined in rule at 10 CCR 2505-10 Section 8.076.1.8.

8.746.6.G. Medication-Assisted Treatment (MAT)

1. Medication Assisted Treatment (MAT) is a benefit for opioid addiction that includes a medication approved by the U.S. Food and Drug Administration (FDA) for opioid addiction detoxification or maintenance treatment.

2. For the purposes of the Outpatient Fee-for-Service Substance Use Disorder Treatment benefit, MAT is defined as the administration, acquisition, and dispensing of Methadone to the client.

a. Only licensed physicians, physician assistants, or nurse practitioners are eligible to administer MAT. All providers must comply with the Office of Behavioral Health's Opioid Medication Assisted Treatment program requirements set forth at 2 C.C.R. 502-1 21.320.

b. MAT is limited to one unit per date of service. A unit is a single dose administered to the client.

c. Take-home dosing is permitted in accordance with Office of Behavioral Health rules at 2 CCR 502-1 21.320.8. Therefore, one unit of MAT must be reported for each date of service the client ingests the dose of methadone.

d. If the client ingests their dose at the facility, the place of service must be reported as office. If the client ingests their dose at home, the place of service must be reported as home. Records must include documentation to substantiate claims for take-home doses.

e. Ongoing counseling and therapy services associated with MAT have the same respective benefit limitations as individual, family, and group therapy services listed in Sections 8.746.6.B. and 8.746.6.C.

8.746.7 PRIOR AUTHORIZATION REQUIREMENTS

8.746.7.A. There are no prior authorization requirements for Outpatient Fee-for-Service Substance Use Disorder Treatment benefit.

8.746.8 NON-COVERED SERVICES

8.746.8.A. The following services are not covered under the Outpatient Fee-for-Service Substance Use Disorder Treatment benefit:

1. Day Treatment Program Services

2. Intensive Outpatient Psychiatric Rehabilitation

3. Peer Advocate Services

4. Residential treatment services, with the exception of those provided in a Residential Child Care Facility, as set forth in Section 8.765.

5. Court-ordered DUI services that are independent of a substance use disorder diagnosis.

6. Services provided by a third party that is under contract with the provider.

7. Any substance use disorder treatment service not specified as covered in Section 8.746.6.

10 CCR 2505-10 § 8.746, APPENDIX A: OUTPATIENT FEE-FOR-SERVICE SUBSTANCE USE DISORDER TREATMENT SERVICES BENEFIT COVERAGE STANDARD

Capitalized terms within this Benefit Coverage Standard that do not refer to the title of a benefit, program, or organization, have the meaning specified in the Definitions section.

BRIEF COVERAGE STATEMENT

This Benefit Coverage Standard describes Outpatient Fee-For-Service (FFS) Substance Use Disorder (SUD) Treatment Services benefits for Colorado Medicaid clients who are not enrolled in the Community Behavioral Health Services program.

CONTENTS

RELATED BENEFITS ADDRESSED IN OTHER BENEFIT COVERAGE STANDARDS

1. Outpatient Fee-For-Service Mental Health
2. Laboratory Services
3. Pharmacy
4. Physician Services
5. Inpatient Hospital

ELIGIBLE PROVIDERS

Providers eligible to render services are limited to the following:

1. Licensed physicians who are also:
    a. Certified in addiction medicine by the American Society of Addiction Medicine (ASAM); or
    b. Certified as Certified Addiction Counselors (CAC II or CAC III) or Licensed Addiction Counselors (LAC) by the Department of Regulatory Agencies (DORA); or
    c. Certified as National Certified Addiction Counselors II (NCAC II) or Master Addiction Counselors (MAC) by the National Association of Alcohol and Drug Abuse Counselors (NAADAC); or
    d. Certified in addiction psychiatry by the American Board of Psychiatry and Neurology certified in Addiction Psychiatry (ABPN).
2. Licensed non-physicians who are also:
    a. Psychologists (PhD, PsyD),
    b. Nurse Practitioners,

c. Licensed Addiction Counselors, or

d. Master's Level Clinicians

i) Licensed Clinical Social Worker (LCSW)

ii) Licensed Professional Counselor (LPC), or

iii) Licensed Marriage and Family Therapist (LMFT);

and either:

a. Certified by DORA as a CAC II or CAC III; or

b. Certified by NAADAC as an NCAC II or MAC.

3. Licensed facilities that are supervised by one or more licensed physicians or non-physicians; supervised professional personnel who are:

a. Working at a facility licensed by the Office of Behavioral Health to provide substance use disorder treatment services; and

b. Supervised by one or more licensed physicians or licensed non-physicians found in Part 1 or 2 of this Eligible Providers section.

TREATMENT PLANNING

An approved treatment plan must be in place for each client prior to the client receiving services. An initial assessment is required to establish a treatment plan. Treatment plans require approval from the licensed provider indicated in the Eligible Providers section with the authority to approve treatment plans within their scope of practice.

All rendered services must be medically necessary, as defined in Colorado Medical Assistance Program rule at 10 C.C.R. 2505-10 Section 8.076.1.8., and must be detailed in the client's treatment plan and progress notes. Initial SUD Assessments are exempt from inclusion in the treatment plan.

ELIGIBLE MEDICAID CLIENTS

1. To be eligible for the FFS SUD Treatment Services benefit, client:

a. Must currently be enrolled in Colorado Medicaid; and

b. Must not be enrolled in the Community Behavioral Health Services program pursuant to 10 C.C.R. 2505-10 Section 8.212.

2. All Colorado Medicaid clients are automatically enrolled in the Community Behavioral Health Services program, unless one of the following is true:

   a. Client is not eligible for enrollment in the Community Behavioral Health Services program, per 10 CCR 2505-10 Section 8.212.1; or

   b. Client is approved for an individual enrollment exemption, as set forth at 10 CCR 2505-10 Section 8.212.2

LIMITATIONS

1. Clients are not required to obtain a referral from their Primary Care Physician (PCP) or Primary Care Medical Provider (PCMP) to receive these services.

2. Clients must have a treatment plan that is approved by a licensed practitioner listed in the Eligible Providers section.

3. FFS SUD services may only be rendered by providers outlined in the Eligible Providers section, with an exception for certain providers of Medication Assisted Treatment described below.

4. Services are covered only when client has been diagnosed with at least one of the following:

   a. Alcohol (use or induced) disorders

   b. Amphetamine (use or induced) disorders

   c. Cannabis (use or induced) disorders

   d. Cocaine (use or induced) disorders

   e. Hallucinogen (use or induced) disorders

   f. Inhalant (use or induced) disorders

   g. Opioid (use or induced) disorders

   h. Phencyclidine (use or induced) disorders

   i. Sedative Hypnotic or Anxiolytic (use or induced) disorders

   j. Tobacco Use Disorder

5. Additional medical and laboratory services, such as physical health monitoring, therapeutic drug monitoring, and alcohol/drug screenings, are covered services under the Physician Service benefit or Laboratory benefit, which are separate from the FFS SUD benefit.

COVERED SERVICES

Substance Use Disorder Assessment

SUD assessment is an evaluation designed to determine the most appropriate level of care based on criteria established by the American Society of Addiction Medicine (ASAM), the extent of drug/alcohol use, abuse, or dependence and related problems, and the comprehensive treatment needs of a client with a SUD diagnosis.

a. Course of treatment and changes in level of care must be based on best practices as defined by the current ASAM Patient Placement Criteria.

b. Re-assessments must be spaced appropriately throughout the course of treatment to ensure the treatment plan is effectively managing the client's changing needs.

c. SUD assessments are limited to two encounter-based units of service per State Fiscal Year. Each complete assessment corresponds to one unit of service.

d. An assessment may involve more than one session and may span multiple days. If the assessment spans multiple days, the final day of the assessment is reported as the date of service.

Individual and Family Therapy

Individual and family therapy is the planned treatment of a client's problem(s) as identified by an assessment and listed in the treatment/service plan. The intended outcome is the management and reduction, or resolution of the identified problem(s).

a. Family therapy must be directly related to the client's treatment for SUD and/or dependence.

b. Individual and family therapy is limited to one client per session.

c. Individual and family therapy is limited to a combined 35 sessions per State Fiscal Year, and billed at 15 minutes per unit, with up to four units (one hour) per session. A session is considered a single encounter with the client that can encompass multiple timed units.

d. Individual therapy and family therapy sessions are allowed on the same date of service.

Group Therapy

Group therapy refers to therapeutic SUD counseling and treatment services, administered through groups of people who have similar needs, such as progression of disease, stage of recovery, and readiness for change.

a. Group therapy must include more than one patient.

b. Group therapy is limited to 36 sessions per State Fiscal Year. A session of group therapy may last up to three hours and is billed in units of one hour each (e.g., a three hour group session would consist of three units). A unit of service may be billed separately for each client participating in the group therapy session.

Alcohol/Drug Screening Counseling

Alcohol/drug screening counseling is the collection of urine followed by a counseling session with the client to review and discuss the results of the screening.

a. The laboratory analysis of the urine specimen (urinalysis) must be billed by a laboratory using that laboratory's Medicaid Provider ID.

b. SUD providers will only be reimbursed for collecting the urine specimen and providing a counseling session to review and discuss the results of the urinalysis. Claims submitted for the collection of the urine sample without the subsequent counseling of urinalysis results will not be reimbursed.

c. SUD counseling services to discuss and counsel the client on the test results must be provided by an eligible rendering provider, as outlined in the above Eligible Providers section.

d. If the client does not return for the counseling of their urinalysis results, the collection of the sample cannot be claimed.

e. The counseling portion of the service may be conducted during a session of individual or family therapy.

f. Multiple urine collections per date of service are not additionally reimbursed.

g. Alcohol/ drug screening counseling is limited to 52 specimen collections per State Fiscal Year.

h. Alcohol/ drug screening counseling is limited to one unit per date of service. A unit of service is the single collection and subsequent counseling session.

Targeted Case Management

Targeted case management refers to coordination and planning services provided with, or on behalf of, a client with a SUD diagnosis. The client does not need to be physically present for this service to be performed if it is done on their behalf.

a. Services are limited to service planning, advocacy, and linkage to other appropriate medical services related to SUD diagnosis, monitoring, and care coordination.

b. SUD targeted case management services are limited to 52 units of service per State Fiscal Year.

i) A unit of service consists of at least one documented contact with a client or person acting on behalf of a client, identified during the case planning process.

ii) A unit of service equals one 30-minute session of targeted case management. Up to four units of service may be rendered per date of service.

Social/Ambulatory Detoxification

Facilities licensed by the Office of Behavioral Health (OBH) are the only provider type eligible to render social/ambulatory detoxification services.

a. Social/ambulatory detoxification services:

i) Include supervision, observation, and support from qualified personnel for clients exhibiting intoxication or withdrawal symptoms.

ii) Are provided when there is minimal risk of severe withdrawal (including seizures and delirium tremens) and when any co-occurring mental health or medical conditions can be safely managed in an ambulatory setting.

b. Social/ambulatory detoxification is limited to five sessions per State Fiscal Year.

i) A session is defined as the continuous treatment time from the first day to the last day of social/ambulatory detoxification.

ii) Each session may last a maximum of three days.

c. Room and board is not a covered social/ambulatory detoxification service. Claims billed for room and board will not be reimbursed.

d. Social/ambulatory detoxification is divided into four distinct services—physical assessment of detoxification progress, evaluation of level of motivation, safety assessment, and provision of daily living needs—with corresponding procedure codes, which may be provided and billed on the same date of service if medically necessary, as defined in rule at 10 CCR 2505-10 Section 8.076.1.8.

Medication-Assisted Treatment (MAT)

MAT is a benefit for opioid addiction that includes a medication approved by the U.S. Food and Drug Administration (FDA) for opioid addiction detoxification or maintenance treatment.

For the purposes of the FFS SUD Treatment Services benefit, MAT is defined as the administration, acquisition, and dispensing of Methadone to the client.

a. Only licensed physicians, physician assistants, or nurse practitioners are eligible to administer MAT. All providers must comply with the Opioid Medication Assisted Treatment program requirements set forth by Office of Behavioral Health in rule at 2 C.C.R. 502-1 21.320.

b. MAT is limited to one unit per date of service. A unit is a single dose administered to the client.

c. Take-home dosing is permitted in accordance with OBH rules at 2 CCR 502-1 21.320.8. Therefore, one unit of MAT must be reported for each date of service the client ingests the dose of methadone.

d. If the client ingests their dose at the facility, the place of service must be reported as office. If the client ingests their dose at home, the place of service must be reported as home. Records must include documentation to substantiate claims for take-home doses.

e. Ongoing counseling and therapy services associated with MAT have the same respective benefit limitations as individual, family, and group therapy services listed previously in COVERED SERVICES, INDIVIDUAL AND FAMILY THERAPY, and GROUP THERAPY.

SPECIAL PROVISION: EXCEPTION TO POLICY LIMITATIONS FOR CLIENTS AGED 20 AND YOUNGER

For Medicaid clients ages 20 and younger, FFS SUD Treatment Services are covered in accordance with the provisions of the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) program found at 10 CCR 2505-10 Section 8.280.

PROCEDURE CODING

Current procedure coding is detailed in the Outpatient Behavioral Health FFS Billing Manual, found in the Billing Manual section of the Department of Health Care Policy and Financing website at colorado.gov/hcpf.

PRIOR AUTHORIZATION REQUIREMENTS

There are no prior authorization requirements for FFS SUD Treatment services.

SERVICES NOT COVERED BY THE OUTPATIENT FEE-FOR-SERVICE SUBSTANCE USE DISORDER TREATMENT BENEFIT

1. Day Treatment Program Services
2. Intensive Outpatient Psychiatric Rehabilitation
3. Peer Advocate Services
4. Residential treatment services, with the exception of Residential Child Care Facilities
5. Court-ordered DUI services that are independent of a substance use disorder diagnosis.
6. Services provided by a third party that is under contract with the provider.
7. Any SUD treatment service not specified as covered in this Benefit Coverage Standard.

The majority of Colorado Medicaid clients are enrolled in the Community Behavioral Health Services program and must receive services from a BHO network provider. The FFS SUD Treatment benefit is available to the small percentage of clients who are not enrolled in the Community Behavioral Health Service program, and whose service claims must be submitted to the Department of Health Care Policy and Financing's fiscal agent.

DEFINITIONS

The following definitions are applicable only within the scope of this Benefit Coverage Standard.

Colorado Medicaid. The free or low cost public health insurance program that provides health care coverage to low-income individuals, families, children, pregnant women, seniors, and people with disabilities. Colorado Medicaid is funded jointly by the federal and state government, and is administered by the Colorado Department of Health Care Policy and Financing.

Community Behavioral Health Services Program. The program described in rule at 10 CCR 2505-10 Section 8.212, by which program-enrolled Medicaid clients receive behavioral health treatment services.

Day Treatment Program Services. A non-residential treatment program designed for children and adolescents under the age of 21 who have emotional, behavioral, and neurobiological or SUD problems and may be at high risk for out-of-home placement. Day Treatment Program Services include family, group, and individual psychotherapy; parent-child education; skill and socialization training focused on improving functional and behavioral deficits; and intensive coordination with schools and/or other child service agencies.

Inpatient Hospital SUD Treatment. Organized service delivered by medical and nursing professionals in a facility licensed as a hospital by the state. Provides for 24-hour medically directed evaluation and withdrawal management in an acute care inpatient setting, specifically designed for acute medical detoxification. This is considered an inpatient hospital benefit and is not part of the FFS SUD benefit.

Intensive Outpatient Psychiatric Rehabilitation Services. Services that focus on maintaining and improving functional abilities for the client through a time-limited, multi-faceted approach to treatment.

Masters Level Clinician. A provider who is clinical social worker licensed pursuant to CRS 12-43-404, marriage and family therapist licensed pursuant to CRS 12-43-504, professional counselor licensed pursuant to CRS 12-43-603, or advanced practice nurse licensed pursuant to CRS 12-38-111.5.

Medicaid Provider ID. The unique eight-digit number assigned to a provider who enrolls in the Colorado Medical Assistance Program.

Peer Advocate Services. A scheduled therapeutic activity led by a trained client who is self-identified as receiving behavioral health services.

Psychologist, Psy.D/PhD. A provider who has a doctoral degree from an accredited program offering psychology courses approved by the American Psychological Association and is licensed as a psychologist by the State Board of Psychologist Examiners pursuant to CRS 12-43-304.

Physician Assistant. A provider who is a graduate of an education program accredited by the Accreditation Review Commission on Education for the Physician Assistant, certified by the National Commission on Certification of Physician Assistants, and licensed as a physician assistant pursuant to CRS 12-36-107.4.

Physician/Psychiatrist. A provider who has a Doctor of Medicine or Osteopathic Medicine degree, engages in the practice of medicine as defined by, and is licensed as a physician pursuant to CRS 12-36-107.

provider who serves as a medical home for Accountable Care Collaborative (ACC) Members. A PCMP may be a federally qualified health center, regional health center, clinic or other group practice that provides the majority of an ACC Member's comprehensive primary, preventive and sick care. A PCMP may also be individual or pods of PCMPs that are physicians, advanced practice nurses or physician assistants with a focus on primary care, general practice, internal medicine, pediatrics, geriatrics or obstetrics and gynecology.

Primary Care Physician (PCP). A physician who provides the majority of a Colorado Medicaid client's primary care.

Residential Child Care Facility (RCCF). A facility licensed to provide twenty-four-hour group care and treatment for five or more children operated under private, public, or nonprofit sponsorship. RCCF includes community-based residential child care facilities, shelter facilities, and therapeutic residential child care facilities as defined in rule by the state board, and psychiatric residential treatment facilities as defined in CRS 25.5-4- 103 (19.5). A RCCF may be eligible for designation by the executive director of the state department pursuant to Article 65 of Title 27, C.R.S.

Residential Treatment. A short-term residential treatment program offering 24-hour intensive residential treatment, habilitative, and rehabilitative services for up to 30 days in a highly structured, community-oriented environment.

State Fiscal Year (SFY). July 1 – June 30.

Targeted Case Management. Medically necessary coordination and planning services provided with or on behalf of a client with a substance use disorder diagnosis.

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Nursing Facility Rule Concerning Fair Rental Allowance For Capital-Related Assets, 10 CCR 2505-10, Section 8.443.9
Rule Number: MSB 16-04-28-A
Division / Contact / Phone: Long Term Services and Support / Bryan Fife / 2798

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 16-04-28-A, Modification to 10 CCR 2505-10, Section 8.443.9.A.1.a tp define "Appraised Value" as the Boeckh Commerical System and Section 8.443.9.A.1.h to define "Index" as RS Means Square Foot Cost Book
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) 8.443.9.A.1.a & 8.443.9.A.1.h, 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 all current text beginning at 8.443.9.A.1 through the end of 8.443.9.A.1.i with the new text provided. This revision is effective 10/30/2016.

*to be completed by MSB Board Coordinator

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Nursing Facility Rule Concerning Fair Rental Allowance For Capital-Related Assets, 10 CCR 2505-10, Section 8.443.9
Rule Number: MSB 16-04-28-A
Division / Contact / Phone: Long Term Services and Support / Bryan Fife / 2798

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 Department intends to modify 10 CCR 2505-10, section 8.443.9.A.1.h by defining "Index" as Square Foot Cost Book published by R.S. Means Company and "Appraised Value" as the Boeckh Commerical System. This is a technical changes to correct the improper incorporation by reference that were removed by HB16-1257.

   • The modification's purpose is to clarify C.R.S. 25.5-6-201(19) by identifying Index as RSMeans and Appraised Value as Boeckh Commerical System. This modification does not have any impact on clients or providers. This update remedies the impropoer incorporations and aligns the rule with Section 25.5-6-201 C.R.S.

   • In response to Office of Legislative Legal Services, the Department worked with OLLS and Colorado Attorney's Generals Office (COAG) to develop a solution to correct the improper incorporation. The solution was to delete the incorporation by reference provision and define "Index" by referencing R.S. Means Square Foot Cost Book and "Appraised Value" by referencing Boeckh Commerical System.

2. An emergency rule-making is imperatively necessary

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

   Explain:

3. Federal authority for the Rule, if any:

4. State Authority for the Rule:

   25.5-1-301 through 25.5-1-303, C.R.S. (2015);
   25.5-6-201, CRS (2015)

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

DOCUMENT #04

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Nursing Facility Rule Concerning Fair Rental Allowance For Capital-Related Assets, 10 CCR 2505-10, Section 8.443.9
Rule Number: MSB 16-04-28-A
Division / Contact / Phone: Long Term Services and Support / Bryan Fife / 2798

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.

   None

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

   N/A

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.

   None

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.

   N/A

8.443.9.A. FAIR RENTAL ALLOWANCE: DEFINITIONS AND SPECIFICATIONS

1. For purposes of this section concerning fair rental allowance, the following definitions shall apply:

a. ~~a.~~ [Expired 05/15/2016 per House Bill 16-1257].

b. Appraised Value means the determination by a qualified appraiser who is a member of an institute of real estate appraisers or its equivalent, the depreciated cost of replacement of a capital-related asset to its current owner. The depreciated replacement appraisal shall be based on the most recent edition of the Boeckh™ Commercial Building Valuation System available on December 31st of the year preceding the year in which the appraisals are to be performed.

c. ~~b.~~ Base Value means the value of the capital related assets as determined by the most current appraisal report completed by the Department or its designee and any additional information considered relevant by the Department. For each year in which an appraisal is not done, base value means the most recent appraisal value increased or decreased by fifty percent (50%) of the change in the Index. Under no circumstances shall the base value exceed $25,000 per bed plus the percentage rate of change referred to as the per bed limit.

d. ~~c.~~ Capital-Related Asset means the land, buildings and fixed equipment of a participating facility.

e. ~~d.~~ Fair Rental Allowance means the product obtained by multiplying the base value of a capital-related asset by the rental rate.

f. ~~e.~~ Fair Rental Allowance Per Diem Rate means the fair rental allowance described above, divided by the greater of the audited patient days on the provider's annual cost report or ninety percent (90%) of licensed bed capacity on file. This calculation applies to both rural and urban facilities.

g. ~~f.~~ Fiscal Year means the State fiscal year from July 1 through June 30.

h. ~~g.~~ Fixed equipment means building equipment as defined under the Medicare principle of reimbursement as specified in the Medicare provider reimbursement manual, part 1, section 104.3. Specifically, building equipment includes attachments to buildings, such as wiring, electrical fixtures, plumbing, elevators, heating systems, air conditioning systems, etc. The general characteristics of this equipment are:

i) ~~i)~~ Affixed to the building and not subject to transfer; and

ii) ~~ii)~~ A fairly long life but shorter than the life of the building to which it is affixed.

i. ~~h.~~ [Expired 05/15/2016 per House Bill 16-1257]

j. Index means the square foot construction costs for nursing facilities in the Means Square Foot Costs Book, which shall be the most recent publication of R.S.Means Company, Inc. that is updated quarterly (section M.450, "Nursing Home"), hereafter referred to as the Means Index.

k. Rental Rate means the average annualized composite rate for United States treasury bonds issued for periods of ten years and longer plus two percent; except that the rental rate shall not exceed ten and three-quarters percent nor fall below eight and one-quarter percent.

~~i. Rental Rate means the average annualized composite rate for United States treasury bonds issued for periods of ten years and longer plus two percent; except that the rental rate shall not exceed ten and three-quarters percent nor fall below eight and one-quarter percent.~~

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Home and Community Based Services for Elderly Blind and Disabled Rule Concerning Non-Medical Transportation Section 8.494
Rule Number: MSB 16-07-14-A
Division / Contact / Phone: LTSS / Cassandra Keller / 866-5181

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 16-07-14-A, Revision to the Medical Assistance Home and Community Based Services for Elderly Blind and Disabled Rule Concerning 8.494 Non-Medical Transportation
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) 8.494 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 all current text starting at 8.494.10 through the end of 8.494.50 with the new text provided. This revision is effective 10/30/2016.

*to be completed by MSB Board Coordinator

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Home and Community Based Services for Elderly Blind and Disabled Rule Concerning Non-Medical Transportation Section 8.494
Rule Number: MSB 16-07-14-A
Division / Contact / Phone: LTSS / Cassandra Keller / 866-5181

STATEMENT OF BASIS AND PURPOSE

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

The purpose of this correspondence is to request clearance of the rule change for Non-Medical Transportation service. The rule is found at 10 CCR 2505-10 §8.494. This rule change is in response to a statutory change. The legislature passed HB16-1097, which created a new category of transportation permits administered by the Public Utilities Commission. This rule change is needed to come into compliance with the legislative mandate.

This new category of Medicaid Client Transport (MCT) permits will be administered to NMT and NEMT providers, upon the completion of several requirements, which includes, but is not limited to, a criminal background check and vehicle inspections.

The rule outlines the new requirements for providers, how new and existing providers become qualified, and requirements for background checks for drivers. This rule does not drive any additional cost for the Department and increases oversight of a critical service.

The Department has worked closely with the PUC to develop the changes to this section of the rule, and has received buy-in on these changes, as well as with the NMT stakeholder workgroup.

2. An emergency rule-making is imperatively necessary

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

   Explain:

3. Federal authority for the Rule, if any:

4. State Authority for the Rule:
   25.5-6-303, C.R.S. (2015); 25.5-1-301 through 25.5-1-303, C.R.S. (2015)

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

DOCUMENT #05

Title of Rule: Revision to the Medical Assistance Home and Community Based Services for Elderly Blind and Disabled Rule Concerning Non-Medical Transportation Section 8.494
Rule Number: MSB 16-07-14-A
Division / Contact / Phone: LTSS / Cassandra Keller / 866-5181

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.

   Individuals who will be affected by this rule are individuals who use the NMT service. They will benefit from this rule change due the new requirements, but they will not bear any cost from this rule change. NMT providers may have a slight additional administrative burden but the Department does not anticipate any bearing any additional cost.

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

   All LTSS waiver clients who use NMT will benefit from the new requirements additional oversight it will bring to the program.

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.

   There will not be a cost increase to the Department.

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

   The clarification of the new requirements to LTSS providers significantly outweighs any additional administrative burdens on the part of the providers.

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 available.

6. Describe any alternative methods for achieving the purpose for the proposed rule that were seriously considered by the Department and the reasons why they were rejected in favor of the proposed rule.
   No alternative methods were considered.

8.494 NON-MEDICAL TRANSPORTATION

8.494.10 DEFINITIONS

.11

Non-Mmedical Ttransportation (NMT) services means transportation which enable eligible clients to gain personal physical access to non-medical community services and resourcessupports, as required by the care plan to prevent institutionalization.

.12 Non-Mmedical Ttransportation pProvider (provider) means a provider agency that has met all of the standards and requirements as specified in subsection 8.494.40 of this regulation. as defined at 10 CCR 2505-10 section 8.484.50.P which has met all the certification standards for transportation providers listed below.

Medicaid Client Transport (MCT) Permit means a permit that is issued to a Non-Medical Transportation provider by the Public Utilities Commission (PUC).

8.494.20 INCLUSIONS

.21 Non-Mmedical transportation Transportation services shall include, but not be limited to, transportation between the client's home and non-medical services or resources supports such as Aadult Dday Center's, services, shopping, activities that encourage community integration, therapeutic swimming, dentist appointments, counseling sessions not covered by State Plan, and other services as required by the care plan to prevent institutionalization.

8.494.30 EXCLUSIONS

.31 Non-medical Medical transportation Transportation services shall not be used to substitute for medical transportation, which is subject to reimbursement under 10 CCR 2505-10 sections 8.680 through 8.691.

.32 Non-Mmedical transportation Transportation services shall only be used after the case manager has determined that free transportation is not available to the client.

8.494.40 CERTIFICATION PROVIDER STANDARDS FOR NON-MEDICAL TRANSPORTATION SERVICES

.41 Transportation providers shall conform to all general certification standards and procedures set forth within Department regulations at 10 CCR 2505-10 sections 8.494 and 8.487 with the following exceptions:

A. Existing Non-Medical Transportation providers have until January 1st, 2018 to fully comply with section 8.494 regarding the new Medicaid Provider and MCT Permit applications.

.42 Transportation providers shall assure that:

.42 A. Transportation providers shall ensure that Aall drivers shall possess a valid Colorado driver's license, are shall be free of physical or mental impairment that would adversely affect

driving performance, and have not had two or more convictions or chargeable accidents within the past two years.

.43 ~~B.~~ Transportation providers shall ensure that ~~A~~all vehicles and related auxiliary equipment shall meet all applicable federal, state, and local safety inspection and maintenance requirements, and transportation providers shall be in compliance with ~~state automobile~~commercial liability insurance requirements and PUC financial responsibility requirements, as set forth in section 40-10.1-107, C.R.S.

.44~~3~~ Provider and Driver Qualifications:

A. Each Provider must have and maintain a valid MCT Permit from the PUC, as required by section 40-10.1-302, C.R.S.; and

B. Each Provider must maintain safe and functioning vehicles, free of deficiencies, and in compliance with PUC safety rules as required by 4 C.C.R. 723-6, § 6100-6199; and

~~C~~C. Each Provider shall ensure that all drivers, prior to providing NMT services, have been qualified based upon the results of the statutorily required criminal history record check as conducted via the PUC, as outlined in Section 40-10.1-110, C.R.S.

8.494.50 LIMITATIONS AND REIMBURSEMENT

.51 Reimbursement for non-medical transportation shall be the lower of billed charges or the prior authorized unit cost at a rate not to exceed the cost of providing medical transportation services.

.52 A provider's submitted charges shall not exceed those normally charged to the general public, other public or private organizations, or non-subsidized rates negotiated with other governmental entities.

.53 ~~No payment shall be made for charges when the recipient is not actually in the vehicle~~Provider charges shall not accrue when the recipient is not physically present in the vehicle.

.54 Providers shall not bill for services before they are an approved Medicaid provider and may bill only for those NMT services performed by a driver that has been qualified based upon the results of the statutorily required criminal history record check.

~~.54 Effective 2/1/99, t~~There shall be no reimbursement under this section for non-medical transportation services provided to clients residing in uncertified congregate facilities. Case managers may submit a written request to the Department for a waiver not to exceed six months for clients receiving services in uncertified congregate facilities prior to the effective date of this rule. After that time, services shall be discontinued.

.55 ~~Effective 12/01/2009, e~~Excluding transportation to HCBS Adult Day facilities, a client may not receive more than the equivalent of two (2) round trip services per week, or 104 round trip

services per annual certification period utilizing NMT, unless otherwise authorized by the Department.

DO NOT PUBLISH THIS PAGE

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

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 16-05-31-A, Revision to the Medical Assistance Pharmacy Rule Concerning Medicaid Option For Prescribed Drugs By Mail, Section 8.800Medicaid Option For Prescribed Drugs By Mail
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, 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 current text beginning at 8.800.2.B through the end of 8.800.3.A with the new text provided.

*to be completed by MSB Board Coordinator

DO NOT PUBLISH THIS PAGE

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

STATEMENT OF BASIS AND PURPOSE

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

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

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

2. An emergency rule-making is imperatively necessary

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

   Explain:

3. Federal authority for the Rule, if any:

4. State Authority for the Rule:

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

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

DOCUMENT #05

DO NOT PUBLISH THIS PAGE

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

REGULATORY ANALYSIS

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

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

   Pharmacies are the affected provider group.

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

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

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

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

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

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

   The Department's estimated net savings was calculated from reduced dispensing fees and annual cost-shifting. The Department will reimburse pharmacies one dispensing fee for a 90-day supply of prescriptions through the mail, rather than three dispensing fees for three fills of a 30-day supply. Cost-shifting was included in

estimated savings, as costs for a portion of the medication will shift forward into the year when the 90-day supply is purchased and avoided in the next year while it is being consumed.

External agencies will not be effected by this rule change.

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

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

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

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

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

6. Describe any alternative methods for achieving the purpose for the proposed rule that were seriously considered by the Department and the reasons why they were rejected in favor of the proposed rule.

   No alternative methods were considered by the Department as the mail delivery change is pursuant to the passing of SB 16-027 on June 1, 2016. The Department must promulgate the proposed rule in order to come into compliance with state statute.

8.800 PHARMACEUTICALS

8.800.1 DEFINITIONS

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

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

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

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

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

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

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

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

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

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

Federal Upper Limit (FUL) means the upper limit for multiple source drugs as set by the Centers for Medicare and Medicaid Services pursuant to 42 C.F.R. 447. 512 - 447.516 (2011). 42 C.F.R. 447.512 - 447.516 (2011) is hereby incorporated by reference into this rule. This rule does not include any later amendments or editions of the code. A copy of the code is available for public inspection at the Colorado Department of Health Care Policy and Financing, 1570 Grant Street, Denver, CO 80203 where a copy of the code provision is available for a reasonable charge. A copy is also available, for a reasonable charge from U.S. Government Printing Office, P.O. Box 979050, St. Louis, MO 63197-9000.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Physical Hardship means any physiological disorder or condition, cosmetic disfigurement, or anatomical loss affecting one or more of the following body systems: neurological, musculoskeletal, special sense organs, respiratory (including speech organs), cardiovascular, reproductive, digestive, genitourinary,

hemic and lymphatic, skin, and endocrine; or, any mental or psychological disorder, such as mental retardation, organic brain syndrome, emotional or mental illness, and specific learning disabilities.

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

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

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

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

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

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

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

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

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

8.800.2 CONDITIONS OF PARTICIPATION

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

8.800.2.B. Any pharmacy or Dispensing Physician, whether in-state or out-of-state, that submits claims for reimbursement must be ~~first submit an application for participation to the~~enrolled in the Colorado Medicaid program in accordance with 8.040.1 and 8.013.1. ~~Department. The provider shall be notified whether or not the application is accepted and, if accepted, the effective date. An accepted application must be on file with the Department before reimbursement shall be made. An application may be d~~DThe Department may deny~~ied~~ an application for a provider agreement, terminate~~d~~ or not renew a provider agreement ~~ed for any of the grounds set forth~~ in accordance with 10 C.C.R. 2505-10, Sections ~~8.050 or~~ 8.076, 8.125, ~~or~~ and 8.I30.

8.800.2.C. An ~~An out-of-state pharmacy may enroll~~ out-of-state pharmacy may enroll as a Medical Assistance Program provider subject to the same conditions of participation as an in-state pharmacy.~~as a provider and receive payment for dispensed drugs under any of the following circumstances:~~

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

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

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

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

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

8.800.3 MAIL ORDER

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

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

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

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

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

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

8.800.4 DRUG BENEFITS

8.800.4.A. Only those drugs designated by companies participating in the federally approved Medical Assistance Program drug rebate program and not otherwise excluded according to these rules are regular drug benefits. Notwithstanding the foregoing, drugs not covered by rebate agreements may be reimbursed if the Department has made a determination that the availability of the drug is essential, such drug has been given an "A" rating by the U. S. Food and Drug Administration (FDA), and a prior authorization has been approved. Reimbursement of any drugs that are regular drug benefits may be restricted as set forth in these rules.

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

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

2. Agents when used to promote fertility;

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

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

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

6. Non-prescription Drugs;

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

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

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

1. Spirituous liquors of any kind;

2. Dietary needs or food supplements;

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

4. Medical supplies;

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

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

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

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

8.800.4.E. Restrictions may be placed on drugs in accordance with 42 U.S.C. Section 1396r-8(d) (2007), which is incorporated herein by reference. No amendments or later editions are incorporated. Copies of 42 U.S.C. Section 1396r-8(d) (2007) are available for inspection at the following address: Colorado Department of Health Care Policy and Financing, 1570 Grant Street, Denver, Colorado 80203-1818. Without limiting the foregoing, restrictions may be placed on drugs for which it has been deemed necessary to address instances of fraud or abuse, potential for, and history of, drug diversion and other illegal utilization, overutilization, other inappropriate utilization or the availability of more cost-effective comparable alternatives.

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

8.800.4.G. To the extent the drug categories listed in Section 8.800.4.B are not Medicare Part D Drugs, they shall be covered for Part D Eligible Individuals in the same manner as they are covered for all other eligible Medical Assistance Program clients.

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

1. Only a brand name drug is manufactured.

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

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

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

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

    b. Treatment of cancer;

    c. Treatment of epilepsy; or

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

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

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

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

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

8.800.5 DRUGS ADMINISTERED OR PROVIDED IN PHYSICIAN OFFICES OR CLINICS

8.800.5.A. Any drugs administered in a physician's office or clinic are considered part of the physician's services and not a pharmacy benefit. Such drugs shall be billed on the physician claim form. Pharmacies may not bill for any products that shall be administered in a physician’s office or clinic.

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

8.800.6 COMPOUNDED PRESCRIPTIONS

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

8.800.7 PRIOR AUTHORIZATION REQUIREMENTS

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

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

2. Name of the drug(s) requested;

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

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

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

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

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

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

8.800.8 LIMIT REQUIREMENTS

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

8.800.8.B. The Department shall solicit and maintain a list of any interested parties who wish to comment on any proposed limits on drugs. The list of interested parties shall be notified of any proposal and shall be given reasonable time, not to exceed 30 days, to comment or recommend changes before any such drugs are limited. Notwithstanding the foregoing, if a new drug is

approved by the FDA and that drug is in a class of drugs already subject to limits, the new drug shall also be subject to limits without any comment period.

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

8.800.9 DRUG UTILIZATION REVIEW

8.800.9.A. Prospective Drug Utilization Review

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

    a. Over-utilization or under-utilization;

    b. Therapeutic duplication;

    c. Drug-disease contraindications;

    d. Drug-drug interactions;

    e. Incorrect drug dosage or duration of drug treatment;

    f. Drug-allergy interactions; and

    g. Clinical abuse/misuse.

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

8.800.9.B. Client Counseling

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

2. If the offer to counsel is accepted, a pharmacist or pharmacy intern shall review the client’s record and then discuss with the client or the client’s caregiver those matters that, in the exercise of his or her professional judgment, the pharmacist or pharmacy intern considers significant including the following:

    a. The name and description of the drug;

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

    c. Intended use of the drug and expected action;

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

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

f. Techniques for self-monitoring drug therapy;

g. Proper storage;

h. Prescription refill information; and

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

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

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

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

8.800.9.C. Retrospective Drug Utilization Review

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

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

8.800.9.D. Drug Utilization Review (DUR) Board

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

a. Approving the application of standards;

b. Conducting retrospective DUR;

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

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

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

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

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

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

   a. The clinically appropriate prescribing of covered outpatient drugs;

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

   c. Drug utilization review, evaluation and intervention; or

   d. Medical quality assurance.

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

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

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

   b. A summary of the interventions used;

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

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

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

8.800.10 BILLING PROCEDURES

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

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

8.800.11 PRESCRIPTION RECORD REQUIREMENTS

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

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

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

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

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

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

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

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

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

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

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

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

i) Void/Illegal/Copy Pantograph with or with the Reverse Rx feature. The word “Void”, “Illegal”, or “Copy” appears when the prescription is photocopied. If the paper has the Reverse Rx feature, the Rx symbol must disappear when photocopied at light setting. The Reverse Rx feature is not allowed as a feature by itself.

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

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

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

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

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

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

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

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

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

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

vi) Pre-printed refill indicator where the number of refills allowed is marked or no refills or “NR” is marked when no refills are authorized. Refill

information must be completed by the prescriber for the prescription to be valid.

vii) Characters surrounding the authorized dispensing quantity and the number of refills. Special characters such as a series of asterisks must be repeated on both sides of the numbers indicating the quantity and the number of refills authorized (e.g., Quantity ***50*** Refill ***3***). This is acceptable only for prescriptions that are generated by a computer, electronic medical records system or other electronic means.

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

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

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

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

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

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

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

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

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

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

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

a. Inpatient hospital services;

b. Hospice services;

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

d. Physician services;

e. Outpatient hospital services;

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

g. Other laboratory and x-ray services; or

h. Renal dialysis.

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

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

8.800.11.E. Prescription tracking and claim reversals

1. The pharmacy shall keep:

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

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

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

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

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

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

8.800.12 BASIS FOR REIMBURSEMENT

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

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

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

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

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

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

8.800.13 REIMBURSEMENT CALCULATION

8.800.13.A. Covered drugs for all clients except for OAP State Only clients shall be reimbursed the lesser of:

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

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

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

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

8.800.13.C. AAC rates shall be rebased monthly using invoices and/or purchase records provided to the Department through a representative group of pharmacies. If the Department cannot establish a process to obtain invoices and/or purchase records on a monthly basis, the Department shall survey one-fourth (1/4) of all Medicaid enrolled pharmacies every quarter to rebase AAC rates.

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

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

8.800.13.F. Any pharmacy, except a Mail Order Pharmacy, that is the only pharmacy within a twenty mile radius may submit a letter to the Department requesting the designation as a rural pharmacy. If the designation is approved by the Department, the allowed ingredient cost shall be AAC. If AAC is not available, the allowed ingredient cost shall be WAC.

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

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

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

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

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

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

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

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

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

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

8.800.14 PRESCRIPTION QUANTITIES

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

8.800.15 REIMBURSEMENT FROM PHARMACIES REDISPENSING UNUSED MEDICATION

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

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

8.800.16 PREFERRED DRUG LIST

8.800.16.A. ESTABLISHING THE PREFERRED DRUG LIST

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

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

   b. Refer selected drugs and Drug Classes to the P&T Committee for clinical reviews performed without consideration of drug cost-effectiveness. The P&T Committee shall make recommendations pursuant to 10 C.C.R. 2505-10, Section 8.800.17.C.

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

      i) Drug safety;

      ii) Drug efficacy;

      iii) The recommendations of the P&T Committee;

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

      v) Cost-effectiveness;

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

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

2. After the P&T Committee meets, the Medical Director shall review the recommendations of the P&T Committee and the Department and determine whether a reviewed drug is designated a Preferred Drug or a Non-preferred Drug.

3. After the Medical Director has designated a reviewed drug as Non-preferred, the Department shall refer that drug to the DUR Board for recommendations on prior authorization criteria.

4. After the DUR Board meets, the Medical Director shall review the recommendations of the P&T Committee, the DUR Board and the Department and determine the prior authorization criteria for Non-preferred Drugs.

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

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

8.800.16.B. NEW DRUGS

1. Notwithstanding any other provision of this section, a new drug entity, including new generic drugs and new drug product dosage forms of existing drug entities, in a Drug Class already included on the PDL:

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

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

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

2. The Preferred or Non-preferred designation for a new drug shall continue until the relevant Drug Class is reviewed and the designation is changed pursuant to 10 C.C.R. 2505-10, Section 8.800.16.A.

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

1. The following exclusions are intended to promote good health outcomes and clinically appropriate drug utilization and to protect the most vulnerable Medical Assistance Program clients.

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

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

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

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

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

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

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

8.800.16.D. AUTHORITY OF THE EXECUTIVE DIRECTOR

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

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

8.800.16.E. SUPPLEMENTAL REBATES The Department may enter into supplemental rebate agreements with drug manufacturers for Preferred Drugs. The Department may contract with a vendor and/or join a purchasing pool to obtain and manage the supplemental rebates.

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

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

1. Atypical and typical antipsychotic drugs;

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

3. Drugs used for the treatment of hemophilia; and

4. Drugs used for the treatment of cancer.

8.800.17 PHARMACY AND THERAPEUTICS COMMITTEE

8.800.17.A. MEMBERSHIP

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

a. The P&T Committee membership shall include:

i) Four pharmacists;

ii) Two client representatives;

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

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

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

vi) Four physicians from any other medical specialty.

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

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

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

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

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

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

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

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

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

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

a. The clinically appropriate prescribing of covered outpatient drugs;

b. The clinically appropriate dispensing of outpatient drugs;

c. Drug use review, evaluation and intervention;

d. Medical quality assurance; or

e. The treatment of Medical Assistance Program clients.

8.800.17.B. CONFLICT OF INTEREST

1. P&T Committee members must complete and sign a conflict of interest disclosure form, prior to their appointment to the P&T Committee, that discloses any financial or other

affiliation with organizations that may have a direct or indirect interest in business before the P&T Committee.

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

8.800.17.C. DUTIES

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

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

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

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

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

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

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

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

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

8.800.17.D. NOTICE/OPEN MEETINGS

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

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

8.800.18 PRESCRIPTION DRUG CONSUMER INFORMATION AND TECHNICAL ASSISTANCE PROGRAM

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

8.800.18.B. REQUIREMENTS FOR PARTICIPATION IN THE PROGRAM

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

2. Pharmacists shall:

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

   b. Maintain liability insurance; and

   c. Complete an application; and

   d. Enter into a contract with the Department; and

   e. Meet one of the following qualifications:

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

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

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

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

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

8.800.18.C. SERVICES

1. Pharmacists participating in the program shall:

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

   b. Collect and review client drug histories.

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

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

e. Provide the client with information regarding:

i) The prudent use of prescription drugs.

ii) How to avoid dangerous drug interactions.

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

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

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

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

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

DO NOT PUBLIS THIS PAGE

Title of Rule: Revision to the Medical Assistance Rates Section Rule Concerning the Adding Definitions of Hospital Services, Section 8.300.1; and Payments For Outpatient Hospital Services, Section 8.300.6
Rule Number: MSB 16-06-20-A
Division / Contact / Phone: Payment Reform / Andrew Abalos / 2130

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 16-06-20-A, Revision to the Medical Assistance Rates Section Rule Concerning the Adding Definitions of Hospital Services, Section 8.300.1; and Payments For Outpatient Hospital Services, Section 8.300.6

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) 8.300.6, 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*

Insert new text beginning at 8.300.1 paragraph 10 through the end of paragraph 10. Replace the current text beginning at 8.300.1 paragraph 20 through the end of paragraph 20 with the new text provided. Replace the current text beginning at 8.300.1 paragraph 28 through the end of paragraph 28 with the new text provided. Replace the current text beginning at 8.300.6.A.1.k through the end of 8.300.6.A.2 with the new text provided. This revision is effective 10/30/2016.

DO NOT PUBLIS THIS PAGE

Title of Rule: Revision to the Medical Assistance Rates Section Rule Concerning the Adding Definitions of Hospital Services, Section 8.300.1; and Payments For Outpatient Hospital Services, Section 8.300.6
Rule Number: MSB 16-06-20-A
Division / Contact / Phone: Payment Reform / Andrew Abalos / 2130

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 proposed rule will allow the Department to pay hospitals for outpatient services provided to Medicaid clients under a prospective payment methodology. Currently, the rule describes a methodology which relies on the Medicare cost reports that are made available years after services are provided. As such, interim payments are made and are later reconciled based on the Department's contracted cost report auditor's findings. This methodology presents difficulties in budget planning and payment consistency for both the Department and its hospital providers. The proposed rule allows a methodology to be used which is based on fixed payments calculated using state-wide average costs and payment will no longer require reconciliation. Additionally, the proposed rule allows payment under a methodology which provides incentives for effiiency and minimization of upcoding to generate higher payments. In order to accommodate the implementation of this methodology, updates will also be requred to the rule's definitions.

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. 1396a(a)(30)(A);

   42 C.F.R. 447.321

4. State Authority for the Rule:

   25.5-1-301 through 25.5-1-303, C.R.S. (2015);
   25.5-4-402.3(4)(B)(I) C.R.S (2014); 10 CCR 2505-10 8.300.6;

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

DOCUMENT #08

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 proposed rule will allow Hospitals will receive payment for outpatient services provided to Medicaid clients under a prospective payment methodology. The implementation of the methodology is budget neutral and is accounted for in the state budget. While the proposed rule is budget neutral long-term, the proposed rule would result in temporary savings for the first several fiscal years as the Department would continue to reconcile hospital cost reports from fiscal years prior to FY 2016-17.

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 proposed rule fixes the payment amount for outpatient services provided to Medicaid clients based on state-wide average costs. As such, the economic impact for each hospital provider is dependent on the expended resources for classification of services provided. In anticipation of these variances, the proposed rule applies a risk corridor to each hospital during the rate-setting process. Hospital base rates are set such that projected gains or losses will be mitigated to 10% of what the hospitals would have received without implementation of the proposed rule.

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

   The proposed rule is budget neutral long-term and therefore accounted for in the state budget. There are no additional costs to the Department or any other agency due to the implementation and enforcement of the proposed rule.

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

   The proposed rule will allow both the Department and its Hospital providers to more accurately plan budgets based on providing outpatient services to Medicaid clients. The proposed rule will also provide a transition away from the current reimbursement methodology based on interim payments which generally results in overpayments to hospitals which later have to be reconciled.

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

The proposed rule is budget neutral long-term and therefore accounted for in the state budget. There are no methods for achieving the purpose of the proposed rule that are less costly or less intrusive.

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.

   A payment methodology for outpatient hospitals based on Medicare's Ambulatory Payment Classifications (APCs) was considered. The Department and its contractor solicited feedback from Colorado Hospital Association (CHA) and Hospital representatives, but determined that the proposed prospective payment system was better designed to address the needs of the Colorado Medicaid population.

8.300 HOSPITAL SERVICES

8.300.1 Definitions

Abbreviated Client Stay means an Inpatient stay ending in client death or in which the client leaves against medical advice.

Concurrent Review means a review of quality, Medical Necessity and/or appropriateness of a health care procedure, treatment or service during the course of treatment.

Continued Stay Review means a review of quality, Medical Necessity and appropriateness of an Inpatient health care procedure, treatment or service.

Department means the Department of Health Care Policy and Financing.

Diagnosis Related Group (DRG) means a cluster of similar conditions within a classification system used for Hospital reimbursement. It reflects clinically cohesive groupings of Inpatient hospitalizations that utilize similar amounts of Hospital resources.

DRG Hospital means a Hospital that is reimbursed by the Colorado Medicaid program based on a system of DRGs. Those Hospitals reimbursed based on a DRG system are: General Hospitals, Critical Access Hospitals, Pediatric Hospitals, Rehabilitation Hospitals, and Long-Term Care Hospitals.

Diagnostic Services means any medical procedures or supplies recommended by a licensed professional within the scope of his/her practice under state law to enable him/her to identify the existence, nature, or extent of illness, injury or other health condition in a client.

Disproportionate Share Hospital (DSH) Factor is a percentage add-on adjustment that qualified Hospitals receive for serving a disproportionate share of low-income clients.

Emergency Care Services, for the purposes of this rule, means services for a medical condition, including active labor and delivery, manifested by acute symptoms of sufficient severity, including severe pain, for which the absence of immediate medical attention could reasonably be expected to result in: (1) placing the client's health in serious jeopardy, (2) serious impairment to bodily functions or (3) serious dysfunction of any bodily organ or part.

Enhanced Ambulatory Patient Group (EAPG) means a cluster of similar procedures within a classification system used for Hospital reimbursement. It reflects clinically cohesive groupings of services performed during Outpatient visits that utilize similar amounts of Hospital resources.

Hospital means an institution that is (1) primarily engaged in providing, by or under the supervision of physicians, Inpatient medical or surgical care and treatment, including diagnostic, therapeutic and rehabilitation services, for the sick, disabled and injured; (2) licensed, when located in Colorado, as a Hospital by the Colorado Department of Public Health and Environment (CDPHE); and, when not located in Colorado, by the state in which it is located; and (3) certified for participation in the Centers for Medicare and Medicaid Services (CMS) Medicare program. Hospitals can have multiple satellite locations as long as they meet the requirements under CMS. For the purposes of the Colorado Medicaid program, distinct part units and satellite locations are considered part of the Hospital under which they are licensed. Transitional Care Units (TCUs) are not considered part of the Hospital for purposes of the Colorado Medicaid program. Types of Hospitals are:

A General Hospital is licensed and CMS-certified as a General Hospital that, under an organized medical staff, provides Inpatient services, emergency medical and surgical care, continuous nursing services, and necessary ancillary services. A General Hospital may also offer and provide Outpatient services, or any other supportive services for periods of less than twenty-four hours per day.

A Critical Access Hospital (CAH) is licensed and CMS-certified as a Critical Access Hospital. CAHs offer emergency services and limited Inpatient care. CAHs may offer limited surgical services and/or obstetrical services including a delivery room and nursery.

A Pediatric Hospital is licensed as a General Hospital and CMS-certified as a children's Hospital providing care primarily to populations aged seventeen years and under.

A Rehabilitation Hospital is licensed and CMS-certified as a Rehabilitation Hospital which primarily serves an Inpatient population requiring intensive rehabilitative services including but not limited to stroke, spinal cord injury, congenital deformity, amputation, major multiple trauma, fracture of femur, brain injury, and other disorders or injuries requiring intensive rehabilitation.

A Long-Term Care Hospital is licensed as a General Hospital and CMS-certified as a Long-Term Care Hospital. In general, Long-Term Care Hospitals have an average length of stay of greater than twenty-five (25) days.

A Psychiatric Hospital is licensed and CMS-certified as a Psychiatric Hospital to plan, organize, operate, and maintain facilities, beds, and treatment, including diagnostic, therapeutic and rehabilitation services, over a continuous period exceeding twenty-four (24) hours, to individuals requiring early diagnosis, intensive and continued clinical therapy for mental illness; and mental rehabilitation. A Psychiatric Hospital can qualify to be a state-owned Psychiatric Hospital if it is operated by the Colorado Department of Human Services.

Inpatient means a person who is receiving professional services at a Hospital; the services include a room and are provided on a continuous 24-hour-a-day basis. Generally, a person is considered an Inpatient by a physician's order if formally admitted as an Inpatient with the expectation that the client will remain at least overnight and occupy a bed even though it later develops that the client can be discharged or transferred to another Hospital and does not actually use a bed overnight.

Inpatient Hospital Services means preventive, therapeutic, surgical, diagnostic, medical and rehabilitative services that are furnished by a Hospital for the care and treatment of Inpatients and are provided in the Hospital by or under the direction of a physician.

Medical Necessity is defined at Section 8.076.1.~~Medically Necessary, or Medical Necessity, means a Medicaid service that will, or is reasonably expected to prevent, diagnose, cure, correct, reduce or ameliorate the pain and suffering, or the physical, mental, cognitive or developmental effects of an illness, injury, or disability; and for which there is no other equally effective or substantially less costly course of treatment suitable for the client's needs.~~

Non-DRG Hospital means a Hospital that is not reimbursed by the Colorado Medicaid program based on a system of DRGs. Psychiatric Hospitals are considered Non-DRG Hospitals since their reimbursement is based on a per diem rate.

Observation Stay means a stay in the Hospital for no more than forty-eight hours for the purpose of (a) evaluating a client for possible Inpatient admission; or (b) treating clients expected to be stabilized and released in no more than 24 hours; or (c) extended recovery following a complication of an Outpatient procedure. Only rarely will an Observation Stay exceed twenty-four hours in length.

Outlier Days mean the days in a Hospital stay that occur after the Trim Point Day.

Outpatient means a client who is receiving professional services at a Hospital, which is not providing him/her with room and board and professional services on a continuous 24-hour-a-day basis.

Outpatient Hospital Services means preventive, diagnostic, therapeutic, rehabilitative, or palliative services that are furnished to Outpatients; and are furnished by or under the direction of a physician or dentist.

Prospective Review means a review of quality, Medical Necessity and/or appropriateness of a health care procedure, treatment or service prior to treatment.

Rehabilitative Services means any medical or remedial services recommended by a physician within the scope of his/her practice under state law, for maximum reduction of physical or mental disability and restoration of a client to his/her best possible functional level.

Relative Weight (DRG weight or EAPG weight) means a numerical value which reflects the relative resource consumption for the DRG or EAPG to which it is assigned. Modifications to these Relative Weights are made when needed to ensure payments reasonably reflect the average cost ~~of claims~~ for each DRG or EAPG. Relative Weights are intended to be cost effective, and based upon Colorado data as available.

Retrospective Review means a review of quality, Medical Necessity and/or appropriateness of a health care procedure, treatment or service following treatment. A Retrospective Review can occur before or after reimbursement has been made.

Rural Hospital means a Hospital not located within a metropolitan statistical area (MSA) as designated by the United States Office of Management & Budget.

State University Teaching Hospital means a Hospital which provides supervised teaching experiences to graduate medical school interns and residents enrolled in a state institution of higher education; and in which more than fifty percent (50%) of its credentialed physicians are members of the faculty at a state institution of higher education.

Swing Bed Designation means designation of Hospital beds in a Rural Hospital with less than 100 beds for reimbursement under Medicare for furnishing post-hospital extended care services to Medicare beneficiaries in compliance with the Social Security Act, Sections 1883 and 1866. Such beds are called “swing beds.”

Trim Point Day (Outlier Threshold Day) means the day which would occur 2.58 standard deviations above the mean (average) length of stay (ALOS) for each DRG.

Urban Hospital means a Hospital located within a MSA as designated by the United States Office of Management & Budget.

Urban Safety Net Hospital means an Urban, General Hospital for which the Medicaid Inpatient eligible days plus Colorado Indigent Care Program (CICP) Inpatient days relative to total Inpatient days, rounded to the nearest percent are equal to or exceed sixty-five percent. To qualify as an Urban Safety Net Hospital, a Hospital must submit its most current information on Inpatient days by March 1 of each year for the Inpatient rates effective on July 1 of that same year. The Department may rely on other data sources for the calculation if there are discrepancies between the data submitted by the Hospital and alternative data sources such as claims or cost report data.

8.300.6 Payments For Outpatient Hospital Services

8.300.6.A Payments to DRG Hospitals for Outpatient Services

1. Payments to In-Network Colorado DRG Hospitals

Excluding items that are reimbursed according to the Department's fee schedule, Outpatient Hospital Services are reimbursed on an interim basis at actual billed charges multiplied by the Medicare cost-to-charge ratio less 28%. When the Department determines that the Medicare cost-to-charge ratio is not representative of a Hospital's Outpatient costs, the cost-to-charge ratio may be calculated using historical data. A periodic cost audit is done and any necessary retrospective adjustment is made to bring reimbursement to the lower of actual audited Medicaid cost less 28% or billed charges less 28%.

Effective September 1, 2009, Outpatient Hospital Services are reimbursed on an interim basis at actual billed charges times the Medicare cost-to-charge ratio less 29.1 percent (29.1%). When the Department determines that the Medicare cost-to-charge ratio is not representative of a hospital's outpatient costs, the cost-to-charge ratio may be calculated using historical data. A periodic cost audit is done and any necessary retrospective adjustment is made to bring reimbursement to the lower of actual audited cost less 29.1 percent (29.1%) or billed charges less 29.1 percent (29.1%).

Effective January 1, 2010, Outpatient Hospital Services are reimbursed on an interim basis at actual billed charges times the Medicare cost-to-charge ratio less 30 percent (30%). When the Department determines that the Medicare cost-to-charge ratio is not representative of a hospital's outpatient costs, the cost-to-charge ratio may be calculated using historical data. A periodic cost audit is done and any necessary retrospective adjustment is made to bring reimbursement to the lower of actual audited cost less 30 percent (30%) or billed charges less 30 percent (30%).

Effective July 1, 2010, Outpatient Hospital Services are reimbursed on an interim basis at actual billed charges times the Medicare cost-to-charge ratio less 30.7 percent (30.7%). When the Department determines that the Medicare cost-to-charge ratio is not representative of a hospital's outpatient costs, the cost-to-charge ratio may be calculated using historical data. A periodic cost audit is done and any necessary retrospective adjustment is made to bring reimbursement to the lower of actual audited cost less 30.7 percent (30.7%) or billed charges less 30.7 percent (30.7%).

Effective July 1, 2011, Outpatient Hospital Services are reimbursed on an interim basis at actual billed charges times the Medicare cost-to-charge ratio less 31.2 percent (31.2%). When the Department determines that the Medicare cost-to-charge ratio is not representative of a hospital's outpatient costs, the cost-to-charge ratio may be calculated using historical data. A periodic cost audit is done and any necessary retrospective adjustment is made to bring reimbursement to the lower of actual audited cost less 31.2 percent (31.2%) or billed charges less 31.2 percent (31.2%).

Effective July 1, 2013, Outpatient Hospital Services are reimbursed on an interim basis at actual billed charges times the Medicare cost-to-charge ratio less 29.8 percent (29.8%). When the Department determines that the Medicare cost-to-charge ratio is not representative of a hospital's outpatient costs, the cost-to-charge ratio may be calculated

using historical data. A periodic cost audit is done and any necessary retrospective adjustment is made to bring reimbursement to the lower of actual audited cost less 29.8 percent (29.8%) or billed charges less 29.8 percent (29.8%).

Effective July 1, 2014, Outpatient Hospital Services are reimbursed on an interim basis at actual billed charges times the Medicare cost-to-charge ratio less 28.4 percent (28.4%). When the Department determines that the Medicare cost-to-charge ratio is not representative of a hospital's outpatient costs, the cost-to-charge ratio may be calculated using historical data. A periodic cost audit is done and any necessary retrospective adjustment is made to bring reimbursement to the lower of actual audited cost less 28.4 percent (28.4%) or billed charges less 28.4 percent (28.4%).

Effective July 1, 2015, Outpatient Hospital Services are reimbursed on an interim basis at actual billed charges times the Medicare cost-to-charge ratio less 28 percent (28%). When the Department determines that the Medicare cost-to-charge ratio is not representative of a hospital's outpatient costs, the cost-to-charge ratio may be calculated using historical data. A periodic cost audit is done and any necessary retrospective adjustment is made to bring reimbursement to the lower of actual audited cost less 28 percent (28%) or billed charges less 28 percent (28%).

Effective October 31, 2016, DRG Hospitals will be reimbursed for Outpatient Hospital Services based on a system of Enhanced Ambulatory Patient Grouping and a Hospital-specific Medicaid Outpatient base rate. The reimbursement for Outpatient Hospital Services shall be referred to as the EAPG Payment.

a. The EAPG Payment will be equal to the EAPG Weight multiplied by the Hospital-specific Medicaid Outpatient base rate for that hospital as calculated in 10 CCR 2505-10 Section 8.300.6.A.1.k. If the EAPG Weight is modified due to any action impacting payment as described in sections 8.300.6.A.1.d-j, the modified EAPG Weight will be referred to as the EAPG Adjusted Weight. EAPG Payment will then be equal to the EAPG Adjusted Weight multiplied by the Hospital-specific Medicaid Outpatient base rate. If the billed amount is less than the EAPG Payment, reimbursement will be the billed amount.

b. The EAPG Payment is calculated for each detail on the claim. Claim details with the same dates of service are grouped into a visit. Claims containing details describing charges for emergency room, treatment room services or patients placed under observation will have all its details grouped into a single visit.

c. Each detail on a claim is assigned an EAPG. EAPGs can have the following types:

    (1) Per Diem

    (2) Significant Procedure. Subtypes of Significant Procedures Are:

        (a) General Significant Procedures

        (b) Physical Therapy and Rehabilitation

        (c) Mental Health and Counseling

        (d) Dental Procedure

(e) Radiologic Procedure

(f) Diagnostic Significant Procedure

(3) Medical Visit

(4) Ancillary

(5) Incidental

(6) Drug

(7) Durable Medical Equipment

(8) Unassigned

d. A detail will be subject to EAPG Consolidation when it is assigned the same Significant Procedure EAPG as a detail not already subjected to EAPG Consolidation for that visit. EAPG Consolidation will also occur for details assigned EAPGs considered to be clinically similar to another EAPG during the visit. Details subject to EAPG Consolidation will have an EAPG Payment calculated using an EAPG Weight of 0.

e. A detail will be subject to EAPG Packaging when its assigned EAPG is considered an ancillary service to a Significant Procedure EAPG or Medical Visit EAPG present on the claim for that visit. Details describing additional undifferentiated medical visits and services will be exempt from EAPG Packaging. A detail is also subject to EAPG Packaging when it is assigned a Medical Visit EAPG while a Significant Procedure EAPG is present on the claim for that visit. Details assigned Significant Procedure EAPGs that are of subtypes Physical Therapy and Rehabilitation and Radiologic Significant Procedure do not cause details with Medical Visit EAPGs to be subject to EAPG Packaging. Details subject to EAPG Packaging will be calculated using an EAPG Weight of 0.

f. A detail will qualify for Multiple Significant Procedure Discounting when a Significant Procedure of the same subtype is present on the claim for that visit. Details qualifying for Multiple Significant Procedure Discounting are ordered by their EAPG Weight, by visit. Per visit, the qualifying detail with the greatest EAPG Weight will have its EAPG Payment calculated at 100 percent (100%) of its EAPG Weight. The qualifying detail for that visit with the next greatest EAPG Weight will have its EAPG Payment calculated at 50 percent (50%) of its EAPG Weight. All other qualifying details for that visit will have its EAPG Payment calculated at 25 percent (25%) of its EAPG Weight.

g. Details assigned the same Ancillary EAPG on the same visit will qualify for Repeat Ancillary Discounting. EAPG Payment for the first occurrence of a detail qualifying for Repeat Ancillary Discounting for that visit and EAPG is calculated using 100 percent (100%) of its EAPG Weight. EAPG Payment for the second occurrence of a detail qualifying for Repeat Ancillary Discounting for that visit and EAPG is calculated using 50 percent (50%) of its EAPG Weight. EAPG Payment for all other details qualifying for Repeat Ancillary Discounting for that visit and EAPG will be calculated using 25 percent (25%) of their EAPG Weights.

h. Details describing terminated procedures will be subject to Terminated Procedure Discounting. EAPG Payment for a detail subject to Terminated Procedure Discounting is calculated using 50 percent (50%) of the EAPG Weight. Terminated procedures are not subject to other types of discounting.

i. Details describing bilateral services will have EAPG Payment calculated using 150 percent (150%) of the EAPG Weight or the EAPG Payment not resulting from Terminated Procedure Discounting.

j. Details describing 340B Drugs will have an EAPG Payment calculated using 50 percent (50%) of the EAPG Weight or the EAPG Payment not resulting from Terminated Procedure Discounting.

k. The Hospital-specific Medicaid Outpatient base rate for the year of the methodology implementation for each hospital is calculated using the following method.

(1) Assign each hospital to one of the following peer groups based on hospital type and location:

(a) Pediatric Hospitals

(b) Urban Hospitals

(c) Rural Hospitals

~~(1)~~(2) Process Medicaid outpatient hospital claims from state fiscal year 2015, known as the Base Year, through the methodology described in 8.300.6.A.1.a-~~k~~ j using ~~the~~ Colorado's EAPG Relative Weights. For lines with incomplete data, estimations of EAPG Adjusted Weights will be used.

~~(a) For the calculation of the Hospital-specific Medicaid Outpatient base rate for out-of-state hospital providers, all out-of-state hospital providers are treated as a single hospital. The resulting Hospital-specific Medicaid Outpatient base rate calculated through the remainder of this process shall be used for all out-of-state hospital providers.~~

~~(2)~~(3) ~~Develop utilization trend factor for projecting from the Base Year to the fiscal year of EAPG implementation. The annual utilization trend factor is developed based on the claims data ranging from state fiscal years 2011 to 2013.~~Calculate costs from hospital charge data using the computation of the ratio of costs to charges from the CMS-2552-10 Cost Report. After the application of inflation factors to account for the difference in cost and caseload from state fiscal year 2015 to the implementation period, costs and EAPG Adjusted Weights are aggregated by peer group and are used to form peer group base rates. Each hospital is assigned the peer group base rate depending on their respective peer group assigned in 8.300.6.A.1.k.(1).

~~(3)~~(4) ~~Aggregate the line item EAPG Adjusted Weights for the Base Year of claims that were processed through the EAPG grouper by hospital. The annual utilization trend factor is then applied to the aggregated weights of each hospital. For lines with incomplete data, estimations of EAPG~~

~~Adjusted Weights will be used.~~For each hospital, calculate the projected EAPG payment by multiplying its peer group base rate by its hospital-specific EAPG Adjusted Weights as calculated in 8.300.6.A.1.k.(2). If the projected payment exceeds a +/-10% difference in payment from the prior outpatient hospital reimbursement methodology, the hospital will receive an adjustment to their base rate to cap its resulting gains or losses in projected EAPG payments to 10%.

~~(4) Calculate a standard base rate by dividing outpatient hospital budget by the sum of the aggregated weights per hospital. This quotient is then adjusted to meet budget constraints.~~

~~(5) Calculate a unique base rate for hospitals with projected payments that exceed a +/- 10% threshold based on the projected payments that would have been made under the prior outpatient hospital reimbursement methodology. If necessary, the standard base rate is adjusted to meet budget constraints. If the projected payments for a hospital are within the +/-10% threshold, the hospital receives the standard base rate.~~

2. Payments to Out-of-Network DRG Hospitals

Excluding items that are reimbursed according to the Department's fee schedule, border-state Hospitals and out-of-network Hospitals, including out-of-state Hospitals, shall be paid 30% of billed charges for Outpatient Hospital Services. Consideration of additional reimbursement shall be made on a case-by-case basis in accordance with supporting documentation submitted by the Hospital.

Effective October 31, 2016, Out-of-Network PPS Hospitals will be reimbursed for Outpatient Hospital Services based the system of Enhanced Ambulatory Patient Grouping described in 10 CCR 2505-10 Section 8.300.6.A.1. Such hospitals will be assigned to a Rural or Urban peer group depending on hospital location and will receive a base rate of 90% of the respective peer group base rate as calculated 8.300.6.A.1.k.(3).