DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Long-Term Services and Supports HCBS Benefit Rule Concerning Adult Day Services, Section 8.491
Rule Number: MSB 18-05-25-A
Division / Contact / Phone: Benefits and Services Division / 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 18-05-25-A, Revision to the Medical Assistance Long-Term Services and Supports HCBS Benefit Rule Concerning Adult Day Services, Section 8.491

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) 8.491, Colorado Department of Health Care Policy and Financing, Staff Manual Volume 8, Medical Assistance (10 CCR 2505-10).

5. Does this action involve any temporary or emergency rule(s)? No
   If yes, state effective date:
   Is rule to be made permanent? (If yes, please attach notice of hearing). Yes

PUBLICATION INSTRUCTIONS*

Replace the text at 8.491 with the proposed text beginning at 8.491.1 through the end of 8.491.5. This rule is effective October 31, 2018.

*to be completed by MSB Board Coordinator

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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).

   The intention of this rule is to ensure providers meet both State and Federal guidelines for critical incident reporting, care planning, and the HCBS Final Settings Rule. The new regulations will make clear the new requirements for the providers. This will help to ensure the Department is in compliance with federal regulations, as well as better align policies with our sister agencies. That collaboration will lead to improved oversight of adult day centers as well as more comprehensive inspections by the Department of Public Health and Environment (DPHE).

   Additionally, the revised criteria for specialized adult day services, food safety regulations, and updated language and clarification throughout will provide more comprehensive regulations and safer settings for the HCBS waiver participants and clarity for providers.

   The Department has worked closely with DPHE, providers, participants and the trade groups to revise these regulations.

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. (2017);
   25.5-6-313, C.R.S.

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REGULATORY ANALYSIS

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

   Individuals who will be affected by this rule are individuals who attend Adult Day Centers on the Elderly Blind and Disabled (EBD), Community Mental Health Supports (CMHS), and Spinal Cord Injury (SCI) Waivers. They will benefit from this rule change due to improved critical incident reporting; revised criteria for specialized adult day services; care planning requirements; HCBS Final Settings Rule requirements; food safety regulations; and updated language and clarification throughout. They will not bear any cost from this rule change. Adult Day Centers may have a slight additional administrative burden, but the Department does not anticipate the providers bearing any additional costs.

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 EBD, CMHS, and SCI waiver clients who attend Adult Day Centers will benefit from the new requirements and additional oversight it will bring to the program, as described in paragraph one.

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 to the Adult Day rule will significantly benefit participants, which outweighs any additional administrative burdens on the part of the Centers. There are no benefits of inaction in behalf of the Department.

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

The additional requirements in the proposed regulations are required by CMS and must be implemented. The additional regulations and clarifications will require minimal additional output from the Department. There are no less costly or less intrusive methods of achieving the purpose of this rule.

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

   No alternative methods were considered.

8.491 ADULT DAY SERVICES

8.491.1 Definitions

~~.10~~ Adult Day Center is a certified center that provides Basic Adult Day Services and Specialized Adult Day Services to participants.

Adult Day Services (ADS) are provided in an Adult Day Center on a regularly scheduled basis, as specified in the Person Centered Care Plan, promoting social, recreational, physical, and emotional well-being that encompasses the supportive services needed to ensure the optimal wellness of the participant. ~~means health and social services, individual therapeutic and psychological activities furnished on a regularly scheduled basis in an adult day services center, as an alternative to long term nursing facility care.~~

~~.12~~ Basic Adult Day Services (ADS) Center means a community-based entity that provides basic Adult Day Services in conformance with ~~conforms to~~ all state established requirements as described in 10 CCR 2505-10 section 8.130 and 10 CCR 2505-10 section 8.491.~~14.~~

~~.13~~ Specialized Adult Day Services (SADS) Center means a community-based entity ~~determined by the State to be~~ providing Adult Day ~~health supportive~~ ~~s~~Services for participants with a primary diagnosis of ~~Alzheimer's and~~ dementia related ~~disorders~~diseases, Multiple Sclerosis, Brain Injury, chronic mental illness, Intellectual and Developmental Disabilities,~~ty~~ Huntington's Disease, Parkinson's, or post-stroke participants, who require extensive rehabilitative therapies. ~~In order to~~To be designated as specialized, two-thirds of an ADS Center's population must have a diagnosis which is one of any of the above diagnoses. Each diagnosis must be verified by a Licensed Medical Professional, either directly or through Case Management Agency documentation, in accordance with Section 8.491.14.A. ~~be participants whose physician has verified one of the above diagnoses and determined SADS is appropriate for the participant.~~

Care Plan means the individualized goal-oriented plan of services, supports, and preferences developed collaboratively with the participant and/or the designated or legal representative and the service provider, as outlined in 10 CCR 2505-10 8.495.6.F.

Designated Representative means a representative who is designated by the participant to act on the participant's behalf, as defined in 10 CCR 2505-10 Section 8.500.1.

Direct Care Staff means staff who provide hands-on care and services, including personal care, to participants. Direct Care Staff must have the appropriate knowledge, skills and training to meet the individual needs of the participants before providing care and services. Training must be completed prior to the provision of services, as outlined in 10 CCR 2505-10 8.491.4.I.

Director means any person who owns and operates an ADS Center or SADS Center, or is a managing employee with delegated authority by ownership to manage, control, or perform the day-to-day tasks of operating the Center as described in 10 CCR 2505-10 Section 8.491.

Licensed Medical Professional (LMP) means a medical professional that possesses one or more of the following Colorado licenses, which must be active and in good standing: Physician, Physician Assistant, Registered Nurse (RN) or Licensed Practical Nurse (LPN) governed by the Colorado Medical License Act, and as defined in 10 CCR 2505-10 Section 8.503.

Participant means any individual found to be eligible for and enrolled in Adult Day Services regardless of payment source.

Qualified Medication Administration Personnel (QMAP) means an individual that has completed training, passed a competency evaluation, and is included in the Colorado Department of Public Health and Environment's (CDPHE) public list of individuals who have passed the requisite competency evaluation, as outlined in 6 CCR 1011-1 Chapter 24.

Restraint means any physical or chemical device, application of force, or medication, which is designed or used for restricting freedom of movement, and/or modifying, altering, or controlling behavior, excluding medication prescribed by a physician as part of an ongoing treatment plan or pursuant to a diagnosis.

Staff means a paid or voluntary employee or contracted professional of the ADS Center or SADS Center.

Universal Precautions refers to a system of infection control that prevents the transmission of communicable diseases. Precautions include, but are not limited to, disinfecting of instruments, isolation and disinfection of environment, use of personal protective equipment, hand washing, and proper disposal of contaminated waste.

8.491.2 PARTICIPANT BENEFITS

8.491.2.A. Adult Day Services

1. Only participants whose needs can be met by the ~~Adult Day Services~~ ADS Center within its certification category and populations served may be admitted to the ADS Center.
2. ~~Adult Day Services~~ADS shall include, but are not limited to, the following:
   a. Daily monitoring to ensure participants are maintaining activity levels and goals set forth in the Care Plan, pursuant to Section 8.491.4.E; and assistance with activities of daily living (ADL) as needed. (ADLs include but are not limited to eating, ambulation, positioning, transferring, toileting, and incontinence care).
   b. Daily services provided to monitor the participant's health status, monitor or administer medications, and carry out physicians' orders as set forth in participant's individual Care Plan.
   c. Services must be provided in an integrated, community based setting, which, supports participation and engagement in community life and gaining access to the greater community; participants may engage in meaningful activities in integrated and community settings.
   d. Emergency services including written procedures to meet medical crises.
   e. Activities that assist in the development of self-care capabilities, personal hygiene, and social support services.
   f. Nutrition services including therapeutic diets and snacks in accordance with the participant's individual Care Plan and hours of attendance.
   g. Social and recreational supportive services as appropriate for each participant and their needs, as documented in the participant's Care Plan. Activities shall take into consideration individual differences in age, health status, sensory deficits, religious affiliation, interests, abilities, and skills by providing opportunities for a variety of types and levels of involvement.
   h. Participants have the right to choose not to participate in social and recreational activities.

8.491.2.B. Adult Day Service Requirements

1. The participant's ~~individual c~~Care P~~p~~lan must include documentation of their diagnosis(es) and service goals. ~~In addition, each participant's individual Ccare pPlan must include the following:~~

~~A.~~

2. ~~For Medicaid participants, the case manager~~ The ADS Center must ~~forward the most recent copy of page 1 of the participant's ULTC-100.2~~ verify all Medicaid participant's diagnosis(es) using the Professional Medical Information Page (PMIP) which shall be supplied by the case manager, or documentation from the participant's Licensed Medical Professional (LMP). ~~to the ADS Center as documentation of one of the above diagnoses.~~ Documentation must be verified at the time of admission~~,~~ on reassessment by the case manager, or whenever there is a significant change in the participant's condition. Any significant change must be recorded in the participant's record or Care Plan~~.~~

~~B~~a. ~~For~~ For participants from other payment sources, diagnosis(es) ~~and recommended specialized services~~ must be documented in a care plan, or other admission form, and verified by the participant's physician or LMP. This documentation must be verified at the time of admission, and whenever there is a significant change in the participant's condition.

~~C. The Department or its designee will review an Adult Day Services Center's designation as a specialized facility (SADS) on an annual basis.~~

~~.14 Only participants whose needs can be met by the Adult Day Services Center within its certification category and populations served shall be admitted to the Center. Adult Day Services shall include, but are not limited to, the following:~~

~~A. Daily monitoring to assure that participants are maintaining activities prescribed; and assisting with activities of daily living (e.g., eating, dressing, bathing).~~

~~B. Emergency services including written procedures to meet medical crises.~~

C. Activities that assist in the development of self-care capabilities, personal hygiene, and social support services.

D. Nutrition services including therapeutic diets and snacks appropriate to the participant's individual care plan and hours in which the participant is served.

E. Daily services provided to monitor the participant's health status, supervise medications, and carry out physicians' orders in participant's individual care plan as needed.

F. Social and recreational services as prescribed to meet the participant's needs and as documented in the participant's individual care plan. Participants have the right to choose not to participate in social and recreational activities.

G. Adult Day Services Centers certified on or after July 1, 1996, or upon change of ownership, shall provide basic personal care services including bathing in emergency situations.

8.491.15 DEFINITIONS

A. Director means any person who owns and operates an ADS Center, or is a managing employee with delegated authority by ownership to manage, control, or perform the day-to-day tasks of operating the center as described in 10 CCR 2505-10 section 8.491. All Directors hired or designated after January 1, 2016, shall meet the following qualifications:

1. At least a bachelor's degree from an accredited college or university and a minimum of two years of social services or health services experience; or

2. A high school diploma or GED equivalent, a minimum of four years of experience in a social services or health services setting, skills to work with aging adults or adults with functional impairment, and skills to supervise ADS Center staff persons.

B. Participant means any individual found to be eligible for adult day services regardless of payment source.

C. Restraint means any physical or chemical device, application of force, or medication, which is designed or used for the purpose of modifying, altering, or controlling behavior for the convenience of the facility, excluding medication prescribed by a physician as part of an ongoing treatment plan or pursuant to a diagnosis.

D. Staff means a paid or voluntary employee of the facility.

E. Universal Precautions refers to a system of infection control which assumes that every direct contact with body fluids is potentially infectious. This includes any reasonably anticipated skin, eye, mucous membrane or contact with blood-tinged body fluids, or other potentially infectious material.

8.491.320 CERTIFICATION STANDARDSPROVIDER REQUIREMENTS

A. All ADS Centers shall conform to all of the following State established standards:

A1. General

1a. ADS Center providers shall cConforms to all established State standards in the section on general provider participation requirements, as defined in 10 CCR 2505-10 Ssection 8.130., ADS Centers shall has have in effect all necessaryrequired licenses, certifications, and insurance, as applicable. ADS Center providers shall comply with ADS Center regulations and is be in compliance with ADS regulations as and Life Safety Code (LCS) regulations, as determined by the Colorado Division of Fire Protection and Control.determined by the an annual on-site survey conducted by the Colorado Department of Public Health and Environment (CDPHE).

b2.. ADS Center providers shall be Medicaid certified by the Department as an ADS provider, in accordance with 10 CCR, 2505-10 Section 8.487.20. Proof of Medicaid certification consists of a completed Provider Agreement approved by the Department and the Department's fiscal agent, and recommendation for certification bya letter from CDPHE. stating that based on the results of the survey, the provider has been certified and/or recertified.

a. Certification shall be denied, revoked, suspended, or terminated when a Provider is unable to meet, or adequately correct deficiencies relating to, certification standards as defined at 10 CCR 2505-10 section 8.491.

c3. The Department or its designee will review an ADS Center's designation as a Specialized Adult Day Services (SADS) Center at the time of initial approval and during the recertification survey.

4. Denial, termination, or non-renewal of the Provider Agreement shall be for "Good Cause" as defined in 10 CCR 2505-10 section 8.076.

5. All providers of ADS shall operate in full compliance with all applicable federal, State and local laws, ordinances and regulations related to fire, health, safety, zoning, sanitation and other standards prescribed in law or regulations. This includes certification of building use occupancy.

8.491.4 PROVIDER ROLES AND RESPONSIBILITIES

2. Using the State approved Critical Incident Reporting Form, Adult Day Service Center providers shall notify the participant's Single Entry Point (SEP) case manager within 24 hours of any incident or situation including:

a. Death;

b. Abuse/neglect/exploitation;

c. Serious injury to participant or illness of participant;

c. Damage to participant's property/theft;

d. Medication management;

e. Other high risk issues.

BA. Environment

1. 1.All ADS Centers must comply with the Centers for Medicare and Medicaid Services (CMS) Home and Community Based Settings Final Rule requirements, 42 C.F.R. § 441.301(c)(4). This includes:

a. ADS Center must be integrated in and supports full access of individuals to the greater community;

b. ADS Center is selected by the individual from among setting options including non-disability specific settings;

c. ADS Center ensures an individual's rights of privacy, dignity and respect, and freedom from coercion and restraint;

d. ADS Center optimizes individual initiative, autonomy, and independence in making life choices, including, but not limited to, daily activities, physical environment, and with whom to interact; and

e. ADS Center facilitates individual choice regarding services and supports, and who provides them.

1.2. ADS Centers presumed to have institutional qualities will be subject to heightened scrutiny and reviewed by the Department and CMS, per 42 C.F.R. § 441.301(a)(2)(v). Settings in which this may apply include but are not limited to those where:

a. The provision of inpatient institutional treatment within a publicly or privately-operated facility happens within the same building.

b. Located on the grounds of, or adjacent to, a public institution.

c. The effect of isolating participants receiving Medicaid Home and Community Based Services (HCBS) from the broader community.

2. If an ADS Center is subject to heightened scrutiny, Medicaid reimbursement by the Department may not be issued if the center fails CMS's heightened scrutiny review or until CMS approves the center.

3. ADS Centers shall provide a clean and sanitary environment that is~~,~~ free of obstacles that could pose a hazard to participant health and safety, allowing individuals the freedom to safely move about inside and outside the ADS Center.

4~~2~~. ADS Centers shall provide lockers or a safe and secure place for participants' personal items.

5~~3~~. ADS Centers shall provide recreational areas and recreational activities appropriate to the number and needs of the participants, at the times desired by the participants.~~.~~

6. ADS Centers shall ensure the following are physically accessible to the participants at all times during hours of operation:

a~~4~~. Access to drinking water and other beverages;~~Drinking facilities; shall be located within easy access to participants.~~

b. Bathrooms, sinks, and paper towel dispensers or hand dryers;

c. Appliances and equipment used by or in the delivery of activities offered by the ADS Center, such as, tables/desks and chairs at a convenient height and location; and

d. Free from obstructions such as steps, lips in doorways, narrow hallways, limiting individuals' mobility in the ADS Center. If obstructions are present, environmental adaptations are to be made to allow for participant access.

7. ADS Centers must provide for a private shower and/or bathing area located on site to address the emergency hygiene needs of participants as needed.

5~~8~~. To accommodate the activities and program needs of the ADS Center, the center must provide eating and activity areas that are consistent with the number and needs of the participants being served, which is at a minimum of 40 square feet per participant~~person. To accommodate all ADS Center activities and program needs, ADS Centers shall provide a minimum of 40 sq. feet per participant. ADS Centers shall provide eating and resting areas consistent with the number and needs of the participants being served. Centers certified on or after July 1, 1996, shall provide a minimum of 40 sq. feet per participant~~

~~6. ADS Centers shall provide easily accessible toilet facilities, hand-washing facilities and paper towel dispensers. Centers must provide a facility for bathing in emergency situations.~~

~~7. ADS Centers shall be accessible to participants with supportive devices for ambulation or in wheelchairs.~~

~~9. All medications shall be stored in a secured area.~~

9~~10~~. ADS Centers shall maintain a comfortable temperature throughout the center. At no time shall the temperature fall outside the range of 68 degrees to 76 degrees Fahrenheit. ~~ADS Centers shall be heated to at least seventy (70) degrees during hours of operation and no more than 76 degrees in the summer months.~~

10~~1~~. ADS Centers must provide an environment free from restraints~~ as defined at 10 CCR 2505-10 section 8.491.15.C of these rules~~.

11~~2~~. ADS Centers, in accordance with 10 CCR 2505-10 section 8.491.4.A~~14~~ above, must provide a safe environment for all participants, including participants exhibiting behavioral problems, wandering behavior, or limitations in mental/cognitive functioning.

B. Food Safety Requirements

1. ADS Centers shall comply with all applicable local food safety regulations. In addition, all ADS Centers must ensure:

a. ~~Ensure a~~Access to a handwashing sink, soap and disposable paper towels;

b. Food handlers, cooks and servers, including participants engaged in food preparation, ~~must~~ properly wash their hands using proper hand-washing guidelines;

c. The ADS Centers do~~shall~~ not allow any staff or participants who are not in good health and free of communicable disease to handle, prepare or serve food or handle utensils~~ who are~~;

d. Refrigerated foods opened or prepared and not used within 24 hours ~~must be~~are marked with a “use by” or “discard by” date. The “use by” or “discard by” date may not exceed 7 days following opening or preparation, or exceed or surpass the manufacturer’s expiration date for the product or its ingredients;

e. For food service, foods ~~must be~~are maintained at the proper temperatures at all times. Foods that are stored cold must be held at or below 41 degrees Fahrenheit and foods that are stored hot must be held at or above 135 degrees Fahrenheit in order to control the growth of harmful bacteria;

f. Kitchen and food preparation equipment ~~must be~~are maintained in working order and cleanable; and

g. Any equipment or surfaces used in the preparation and service of food ~~must be~~are washed, rinsed and sanitized before use or at least every 4 hours of continual use. Dish detergent must be labeled for its intended purpose. Sanitizer must be approved for use as a no-rinse food contact sanitizer. Sanitizers must be registered with the Environmental Protection Agency (EPA) and used in accordance with labeled instructions.

C. Medication Administration and Monitoring

1. All medications shall be administered by Qualified Medication Administration Personnel (QMAP) staff, LMP staff or self-administered.

2. ADS Centers shall require each staff person who administers medication, that is not a LMP, to have completed training, passed a competency evaluation and be included in the Colorado Department of Public Health and Environment’s (CDPHE) public list of individuals who have passed the QMAP competency evaluation, as outlined in 6 CCR 1011-1 Chapter 24.

3. All medication shall be stored in a locked cabinet when unattended by QMAP or LMP staff.

4. Non-prescription medications shall be labeled with the recipient’s name, and shall not be taken by any other participants.

5. A QMAP shall not conduct feeding or administer medication through a gastrostomy tube or administer intravenous, intramuscular or subcutaneous injections.

D. Records and Information

1. ADS Center providers shall keep ~~such~~ records and information necessary to document the services provided to participants receiving Adult Day Services. Records shall include but not be limited to:

a. Name, address, gender~~sex~~, and date of birth ~~age~~ of each participant;

b. Name, address and telephone number of designated representative and/or emergency contact~~responsible party~~;

c. Name, address and telephone number of primary physician;

d. Documentation of the supervision and monitoring of ~~the~~ services provided;

e. Documentation that all participants ~~or~~ and their designated representatives (if any) ~~responsible parties~~ were oriented to the ADS C~~c~~enter, the policies, and procedures relevant to the ADS Center ~~facility~~ and the services provided;

f. A service agreement signed by the participant and/or ~~his or her~~the designated representative and appropriate center staff; and

g. A copy of the PMIP, or diagnosis documentation from the participant’s ~~Licensed Medical Professional (~~LMP~~)~~.

~~g. For participants from other payment sources, receiving supportive services in a specialized ADS Center, individual care plans must include a primary diagnosis and a physician's signature.~~

E. Care Plan

1. The following information must be documented in the Care Plan and used to direct the participant's care and must beis reviewed annually.

a2. Medical Information included in the care plan:

i. All Mmedications the participant is taking, including those while at the Adult Day Services Center, and whether they are being self-administered;

ii. Special dietary considerations, instructions, or restrictionsneeds, if any;

iii. Services that are administered to the participant while at the ADS Center (may include nursing or medical interventions, speech therapy, physical therapy, or occupational therapy);

iv. Any restrictions on social and/or recreational activities identified by participant's LMP; and physician in the care plan;

d. Documentation of any nursing or medical interventions; physical, speech, and/or occupational therapy administered to participant whose physician has prescribed such services to be included in the participant's individual care plan;

ve. Any other special health or behavioral management services or supports recommended to assist the participant by the participant's LMP.

b. Care Planning Documentation:

i. Documentation that the Center was selected by the individual and/or designated representative or legal representative;

ii. Individual choices, preferences, and needs shall be incorporated into the goals and services outlined in the Care Plan;

iii. All participant information and the Care Plan are considered protected health information and shall be kept confidential; and

iv. Participant and/or designated representative or legal representative must review and sign the Care Plan.

c. Modifications to the Care Plan must be supported by a specific and assessed need. Informed consent and proper documentation in the Care Plan is required for any changes including but not limited to:

i. Identification of the specific and individualized assessed need; and

ii. Documentation of any intervention and/or additional supports offered to support the participant appropriately.

3d. Documentation that the participant and/or other responsible partydesignated representative was provided with written information about thehis/her participant's right to establish an advanced directive. under state law regarding advance directives in accordance with regulations at 10 CCR 2505-10 section 8.130.3

e. Documentation as to whether the participant has executed an advance directives or other declaration regarding medical decisions. Such documentation shall be keptmaintained in the participant's /her case record.

4f. All entries into the record shall be legible, written in ink, dated, and signed with name and title designation, or records shall be maintained electronically with electronic signatures in accordance with standards for electronic medical record keeping practices..

5. Records shall be maintained in such a manner as to ensure safety and confidentiality.

F. Critical Incident Reporting

1. A Critical Incident means an actual or alleged event that creates the risk of serious harm to the health or welfare of a participant. A Critical Incident may endanger or negatively impact the mental and/or physical well-being of a participant. Critical Incidents include, but are not limited to:

a. Death;

b. Abuse/neglect/exploitation;

c. Serious injury to participant or illness of participant;
c. Damage or theft of participant's property;
d. Medication mismanagement;
e. Llost or missing person; and
f. Ccriminal activity.

2. A provider must submit a verbal or written report of a Critical Incident to the HCBS participant's Case Management Agency (CMA) case manager within 24 hours of discovery of the actual or alleged incident. The report must include:
a. Participant name;
b. Participant Medicaid identification number;
c. Waiver;
d. Incident type;
e. Date and time of incident;
f. Location of incident;
g. Persons involved;
h. Description of incident; and
i. Resolution, if applicable.

3. If any of the above information is not available within 24 hours of incident and not reported to the CMA case manager, a follow-up to the initial report must be completed.

GD. Staffing Requirements

1. 1. All ADS Centers must maintain, at a minimum, a staff to participant ratio of 1:8. In addition to minimum staffing ratios, the ADS center must maintain or lower toalways maintainin theIn determining appropriate staffing levels, the ADS Center shall adjust staffing ratios based on the individual acuity and needs of the participants in the Center. At a minimum, staffing must be sufficient in number to provide the services outlined in the Care Plans, considering the individual needs, level of assistance, and risks of accidents. A staff person can have multiple functions, as long as they meet the definition of Direct Care Staff defined at 10 CCR 2505-10, Sections 8.491.1. Staff counted in the staff-participant ratio are those who are trained and able to provide direct services to participants.

a. Staffing at an ADS Center shall be no less than the following standard:

i. A minimum of 1 staff to 8 participants with continuous supervision of participants during program operation.
provide for the needs of the participants population servedthey do staff are not considered when determining ratios. participant , as described above at 10 CCR 2505-10 section 8.491.12 and .13, and shall provide the following:
a. Supervision of participants at all times during the operating hours of the program;

b. b. Staff shall provide the following:

i. Immediate response to emergency situations to assure the safety, health and welfare of participants;
iic. Activities that are planned to support the plans of care for the participantsPrescribed recreational and social activities; and
iiid. Administrative, recreational, social, and supportive functions and duties.

c. Nursing services for regular monitoring of the on-going medical needs of participants and the supervision of medications. These services must be

available a minimum of two hours daily and must be provided by an Registered Nurse (RN) or Licensed Practical Nurse (LPN). Certified Nursing Assistant's (CNA)s may provide these nursing services under the direction of a RN or an LPN, in conformance with nurse delegation provisions outlined in CRS 12-38-132.. Supervision of CNAs must include documented consultation and oversight on a weekly basis or more according to the participant's needs. If the supervising RN or LPN is a ADS Center staff member, with consultation and oversight of CNAs included in the member's job description, the supervising nurse's documented attendance shall be sufficient to document consultation and oversight.

e. Administrative, recreational, social, and supportive functions of the ADS Center.

2. In addition to the above services, Specialized Adult Day Services (SADS) Centers which provideing a restorative model of care shall have sufficient staff to provide nursing services during all hours of operation.– :

a. Nursing services must be provided by a licensed RN or LPN or by a CNA under the supervision of an RN or LPN, as per 10 CCR 2505-10 section 8.491.20.D.1.d,4.G.1.e above and employed or contracted by the SADS Center.

3. The ADS Center shall require any individual seeking employment with the Center to submit to a criminal history record check to ascertain whether the individual seeking employment has been convicted of a felony or misdemeanor that which felony or misdemeanor involves conduct that the Center determines could pose a risk to the health, safety or welfare of participants.

4. The criminal history record check shall, at a minimum, include a search of criminal history in the State of Colorado and be conducted not more than 90 days prior to employment of the individual.

5. In assessing whether to employ an applicant with a felony or misdemeanor conviction, the ADS Center shall consider the following factors:

a. The history of convictions, pleas of guilty or no contest,

b. The nature and seriousness of the crimes;

c. The time that has elapsed since the conviction(s);

d. Whether there are any mitigating circumstances; and

e. The nature of the position for which the applicant would be employed.

6. The ADS Center shall develop and implement policies and procedures regarding the employment of any individual who is convicted of a felony or misdemeanor to ensure that the individual does not pose a risk to the health, safety and welfare of the consumer.

H. Director Qualifications

1. All Directors hired or designated after January 1, 2019, shall meet one of the following qualifications:

a. At least a bachelor's degree from an accredited college or university and a minimum of two years of social services or health services experience and shall have demonstrated ability to perform all aspects of the position; or

b. A licensure by the state of Colorado as a Licensed Practical Nurse or Registered Nurse and completion of two years of paid or volunteer experience in planning or delivering health or social services including experience in supervision and administration; or

c. A high school diploma or GED equivalent, a minimum of four years of experience in a social services or health services setting, skills to work with aging adults or

adults with functional impairment, and skills to supervise ADS Center staff persons.

I~~E~~. Training Requirements

1. All ADS Center staff and volunteers must be trained in the ADS Centers' programmatic policies and procedures.

2. ADS Centers providing medication administration as a service must have ~~qualified persons on their~~ QMAP staff ~~who have been~~ qualified ~~trained~~ in accordance with C.R.S. 6 CCR 1011-1 Chapter 24, unless medications are administered only by LMPs.~~section 25-1.5-302.~~

3~~2~~. All staff and volunteers must be trained in the use of universal precautions and infection control, as defined at 10 CCR 2505-10 section 8.491.1~~5.E~~. ~~Facilities certified prior to the effective date of these rules shall have sixty (60) days to satisfy this training requirement.~~

4~~3~~. The ADS Center ~~operator~~ Director and staff must receive ~~have~~ training specific to the needs and diagnoses of the participants ~~populations~~ served~~. in the Center~~, ~~e.g., elderly, blind and disabled, and as defined in 10 CCR 2505-10 section 8.491.13 of these rules.~~Training may include, but is not limited to: behavioral expression and management techniques, effective communication techniques, redirection, cardiopulmonary resuscitation, validation theory and communication, seizure response, and brain injuries.

a. Documentation of staff member and Director trainings must include, but is not limited to: training provided, who completed trainings, who conducted trainings, and completion date.

5~~4~~. All ADS Center staff ~~and volunteers~~ must be trained in the handling of ~~of emergencies including written procedures to meet medical crises.~~emergency services including written procedures to meet medical crises, and natural and manmade disasters.

6~~5~~. All required training must be documented, and documentation must be maintained in ~~employees'~~ individual staff's personnel files. Each staff person's training must be up-to-date.

J~~F~~. Written Policies

1. The ADS Center shall have ~~a~~ written polic~~ies~~y and procedures relevant to its operation. Such polic~~ies~~y shall include, but not be limited to, statements describing:

a~~.~~. Admission criteria for~~that qualify~~ participants ~~to~~ who can be appropriately served in the ADS ~~c~~Center;

b. ~~Interview~~ Intake procedures conducted for ~~qualified participants~~ participants and/or designated representatives~~family member~~ prior to admission to the ~~c~~ADS Center;

c. The meals and nourishments including special diets that ~~will~~ are provided;

d. The hours and days ~~of~~ the ADS Center is open and services ~~are~~ available to participants, including the availability of nursing services;~~week that the participants will be served in the center and days of the week services will be available;~~

e. Medication administration and storage;

f. The personal items that the participants may bring with them to the ADS ~~c~~Center; and

g. Emergency services including written procedures to meet medical crises, and natural and manmade disasters.

2~~g.~~. There shall be a ~~A~~ written, signed agreement between the participant and/or designated representative ~~responsible party~~ and the ADS C~~c~~enter outlining the rules and responsibilities of the ADS C~~c~~enter and the participant. Each party int~~o~~ the agreement shall be provided a copy.

8.491.5~~30~~ REIMBURSEMENT METHOD FOR ADULT DAY SERVICES

A. Reimbursement for ADS for participants in the HCBS Elderly, Blind and Disabled (EBD) waiver, Community Mental Health Supports waiver (CMHS), and the Spinal Cord Injury (SCI) waiver, shall be based upon a single all-inclusive payment rate per unit of service for each participating

provider which shall be prospectively determined. Units are to be billed in accordance to the current rate schedule:

1. A unit is defined as:
   one (1) unit = a partial day = three (3) to five (5) hours of service
   two (2) units = a full day = more than five (5) hours of service

B. For persons in the HCBS waiver for Persons with a Brain Injury (BI), reimbursement for BI-ADS shall be based upon a single all-inclusive payment rate per unit of service for each participating provider.

1. A unit is defined as:
   one (1) unit = two or more hours per day.

C. ADS Centers are permitted to utilize funding from other Federal sources, such as the Child and Adult Care Food Program (CACFP), in addition to the Medicaid per diem. If such funding is utilized, a Center must acknowledge the use of multiple funding sources and demonstrate that Federal funds are not used in a duplicative manner to Medicaid-funded services.

D. Only providers certified as a Specialized Adult Day Services Center are permitted to receive the SADS reimbursement rate, for participants needing SADS. The SADS reimbursement rate applies to every participant at a SADS Center, even if the participant does not have a specialized diagnosis.

E. Providers shall not bill for services on the same day of service for a participant in an HCBS residential program, unless the following criteria have been met:

1. ADS and residential services have been authorized by the Department and are included on the prior authorization request (PAR);

~~1.~~2. Participant's diagnoses must meet the criteria for a SADS Center;

~~2.~~3. Documentation from the participant's physician demonstrating the required specialized services in the SADS Center are necessary because of the qualifying diagnosis(es), are essential to the care of the participant, and are not included in the residential per diem;

~~3.~~4. Documentation that the extensive rehabilitative therapies and therapeutic needs of the participant are not being met by the residential program and are not included in the residential per diem; and

~~4.~~5. Documentation from the participant's physician recommending SADS and how it will meet the previously mentioned needs.

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Rule concerning Pharmacist Provider Type Addition, Section 8.200.2
Rule Number: MSB 18-09-02-A
Division / Contact / Phone: Health Programs Office / Richard Delaney / 303 866-3436

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 18-09-02-A, Revision to the Medical Assistance Rule concerning Pharmacist Provider Type Addition, Section 8.200.2
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) 8.200.2, 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:	10/31/2018
Is rule to be made permanent? (If yes, please attach notice of hearing).	<Select One>

PUBLICATION INSTRUCTIONS*

Replace the current text at 8.200.2 with the proposed text beginning at 8.200.2.A through the end of 8.200.2.E. This rule is effective October 31, 2018.

*to be completed by MSB Board Coordinator

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Rule concerning Pharmacist Provider Type Addition, Section 8.200.2
Rule Number: MSB 18-09-02-A
Division / Contact / Phone: Health Programs Office / Richard Delaney / 303 866-3436

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 Rule will allow pharmacists to be paid for vaccine administration services. These services are medical services and require reimbursement through the MMIS.

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:

   Title XIX Social Security Act, Section 1905(a)(6) medical care recognized under state law furnished by a licensed practioners within the scoope of their practice as defined by state law.

4. State Authority for the Rule:

   25.5-1-301 through 25.5-1-303, C.R.S. (2016);

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Rule concerning Pharmacist Provider Type Addition, Section 8.200.2
Rule Number: MSB 18-09-02-A
Division / Contact / Phone: Health Programs Office / Richard Delaney / 303 866-3436

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.

   Pharmacists and adults enrolled in Medicaid will be affected. Pharmacists will be able to provide a medical service and adults will be able to receive specific vaccines at more locations in the state.

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

   There is not expected to be any economic impact. There is expected to be expanded access to the vaccines pharmacists can provider with this rule change.

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 is not expected to be any costs to the department. Other states that have implemented the policy of allowing pharmacists to administer vaccines did not incur additional costs

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

   The rule will increase access to the vaccines pharmacists are allowed to administer in Colorado.

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

   There is no other method to allow pharmacists to provide vaccine administration services.

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

   The change is needed to comply with Colorado Statutes.

8.200 PHYSICIAN SERVICES

8.200.2 Providers

8.200.2.A. A doctor of medicine or a doctor of osteopathy may order and provide all medical care goods and services within the scope of their license that are covered benefits of the Colorado Medical Assistance Program.

1. A provider of covered dental care surgery may be enrolled as either a dentist or oral surgeon, but not as both. A dentist may order and provide covered dental care.

8.200.2.B. Physician services that may be provided by non-physician providers without a physician order.

1. Advanced Practice Nurses may provide and order covered goods and services in accordance with the scope of practice as described in the Colorado Department of Regulatory Agencies rules without a physician order.

2. Licensed Psychologists may provide and order covered mental health goods and services in accordance with the scope of practice as described in the Colorado Department of Regulatory Agencies rules without a physician order.

    a. Services ordered by a Licensed Psychologist but rendered by a non-licensed mental health provider ~~shall~~ must be signed and dated by the Licensed Psychologist contemporaneously with the rendering of the service by a non-licensed mental health provider.

3. Optometrists may provide covered optometric goods and services within their scope of practice as described by the Colorado Department of Regulatory Agencies rules without a physician order.

4. Podiatrists may provide covered foot care services within their scope of practice as described by the Colorado Department of Regulatory Agencies rules without a physician order.

5. Licensed dental hygienists may provide unsupervised covered dental hygiene services in accordance with the scope of practice for dental hygienists as described in the Colorado Department of Regulatory Agencies rules without a physician order.

8.200.2.C. Physician services that may be provided by a non-physician provider when ordered by a provider acting under the authority described in Sections 8.200.2.A. and 8.200.2.B.

1. Registered occupational therapists, licensed physical therapists, licensed audiologists, certified speech-language pathologists, and licensed physician assistants may provide services ordered by a physician.

    a. Services must be rendered and supervised in accordance with the scope of practice for the non-physician provider described in the Colorado Department of Regulatory Agencies rules.

2. Licensed pharmacists, in accordance with the scope of practice for pharmacists as described in the Colorado Department of Regulatory Agencies rules 3 CCR 749-1 and C.R.S. 12-42.5-101 et. seq., may provide covered services.

8.200.2.D. Physician services that may be provided by a non-physician provider when supervised by an enrolled provider.

1. With the exception of the non-physician providers described in Sections 8.200.2.A. through 8.200.2.C. and 8.200.2.D.1.a., a non-physician provider may provide covered goods and services only under the Direct Supervision of an enrolled provider who has the authority to supervise those services, according to the Colorado Department of Regulatory Agencies rules. If Colorado Department of Regulatory Agencies rules do not designate who has the authority to supervise, the non-physician provider ~~shall~~ must provide services under the Direct Supervision of an enrolled physician.

a. Registered Nurses (RNs) are authorized to provide delegated medical services within their scope of practice as described in the Colorado Department of Regulatory Agencies rules under General Supervision.

8.200.2.E. Licensure and required certification for all physician services providers ~~shall~~ must be in accordance with their specific specialty practice act and with current state licensure statutes and regulations.

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Rule concerning Immunization Services, Section8.815
Rule Number: MSB 18-06-20-B
Division / Contact / Phone: Operations Section / Whitney McOwen / 303-866-4441

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 18-06-20-B, Revision to the Medical Assistance Rule concerning Immunization Services, Section8.815
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) 8.815, 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:	N/A
Is rule to be made permanent? (If yes, please attach notice of hearing).	<Select One>

PUBLICATION INSTRUCTIONS*

Insert the newly proposed text at 8.815. This rule is effective October 31, 2018.

*to be completed by MSB Board Coordinator

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Rule concerning Immunization Services, Section8.815
Rule Number: MSB 18-06-20-B
Division / Contact / Phone: Operations Section / Whitney McOwen / 303-866-4441

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 immunization services benefit is being converted to rule in order to codify existing practice currently documented in the Immunization Benefit Coverage Standard. The rule will also extend eligibility to administer immunizations to pharmacists. Allowing pharmacists to administer immunizations will increase access for Medicaid clients that are eligible for the vaccines.

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 USC 1396s;

   42 CFR 440.120

4. State Authority for the Rule:

   25.5-1-301 through 25.5-1-303, C.R.S. (2017);

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Rule concerning Immunization Services, Section8.815
Rule Number: MSB 18-06-20-B
Division / Contact / Phone: Operations Section / Whitney McOwen / 303-866-4441

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.

   Pharmacists will benefit from this proposed rule because administering immunizations is within the scope of their licensure. Clients will benefit from adoption of this rule because this rule will increase access to immunization administration services. The Department does not anticipate that this will increase costs associated with immunization services, but will instead shift some utilization from physicians to pharmacists.

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

   Quantitatively, the Department estimates that this change will be budget neutral because some utilization will shift from physicians to pharmacists. Qualitatively, pharmacists will benefit because their eligibility will now align with their eligibility under their licensure, and clients will benefit from an increase in access to immunization administration services.

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 this change will be budget neutral.

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

   This change is estimated to be budget neutral. The benefit of increased access to immunization administration services for clients, outweigh any costs of the proposed rule.

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 to convert existing policy from benefit coverage standard to rule or extend immunization administration eligibility to pharmacists.

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

   The Department did not consider any alternative methods for converting existing policy from benefit coverage standard to rule, or extending immunization administration eligibility to pharmacists.

8.810.5 NON-COVERED SERVICES

8.810.5.A. The following Podiatry services are not covered by Colorado Medicaid:

1. Surgical assistant services (differing from assisting surgeons).
2. Local anesthetics that are billed as a separate procedure.
3. Operating room facility charges for in-office procedures.
4. Treatment of subluxation of the foot.
5. Treatment of flat feet.
6. Routine supplies provided in the office.

8.815 IMMUNIZATION SERVICES

8.815.1 Definitions

8.815.1.A. Advisory Committee on Immunization Practices (ACIP) means a group of medical and public health experts that develops recommendations on how to use vaccines to control diseases in the United States. ACIP was established under Section 222 of the Public Health Service Act (42 U.S.C. § 2l7a).

8.815.1.B. Immunization means the process whereby a person is made immune or resistant to an infectious disease, typically by the administration of a vaccine.

8.815.1.C. School District means any board of cooperative services established pursuant to article 5 of title 22, C.R.S., any state educational institution that serves students in kindergarten through twelfth grade including, but not limited to, the Colorado school for the deaf and blind, created in article 80 of title 22, C.R.S., and any public school district organized under the laws of Colorado except a junior college district.

8.815.1.D. Vaccine means a biological preparation that improves immunity to a particular disease.

8.815.1.E. Vaccine Administration Services means the provision of an injection, nasal absorption, or oral administration of a vaccine product.

8.815.1.F. Vaccines for Children (VFC) means a federally funded program for the purchase and distribution of pediatric vaccines to program-registered providers for the Immunization of vaccine-eligible children 18 years of age and younger.

8.815.2 Client Eligibility

8.815.2.A. All Colorado Medicaid clients are eligible for Immunization and Vaccine Administration Services.

8.815.3 Provider Eligibility

8.815.3.A. Rendering Providers

1. Colorado Medicaid enrolled providers are eligible to administer Vaccines and Vaccine Administration Services as follows:

   a. If it is within the scope of the provider's practice;

   b. In accordance with the requirements at 10 CCR 2505-10, S~~s~~ection 8.200.2.; and

   c. If the provider is administering Vaccines and Vaccine Administration Services to a client 18 years of age or younger, the provider must also be enrolled as a VFC provider.

8.815.3.B. Prescribing Providers

1. Colorado Medicaid enrolled providers are eligible to prescribe Vaccines and Vaccine Administration Services in accordance with Ssection 8.815.3.A.1.a.-b.

8.815.4 Covered Services

8.815.4.A. Vaccines identified in the ACIP Vaccine Recommendations and Guidelines are updated routinely and are covered as follows:

1. For clients 18 years of age and younger, Vaccines are covered by the VFC program.

2. For clients 19 years of age and older, Vaccines are covered by Colorado Medicaid.

8.815.4.B. Administration of Vaccines identified in the ACIP Vaccine Recommendations and Guidelines is a covered service for all clients~~VAS~~.

8.815.4.C. Immunization and V~~v~~accine A~~a~~dministration S~~s~~ervices to groups of clients at nursing facilities, group homes, or residential treatment centers that are provided by home health agencies, physicians, or other non-physician practitioners are covered only as follows:

1. Clients who are residents of nursing facilities and clients receiving home health services may receive Immunization services if ordered by their physician. The skilled nursing component for Immunization administration provided at a nursing facility is included in the facility's rate or part of a regularly scheduled home health service for clients receiving home health services.

2. Clients who are residents of an A~~a~~lternative C~~c~~are F~~f~~acility, as defined at S~~s~~ection 8.495.1, may receive Immunization services from their own physician. They may also receive Immunization services as part of a home health service in accordance with S~~s~~ection 8.815.4.C.1.

8.815.5 Prior Authorization Requirements

8.815.5.A. Prior authorization is not required for this benefit.

8.815.6 Non-covered Services

8.815.6.A. The following services are not covered by Colorado Medicaid:

1. For clients 18 years of age and younger, Vaccines that have been obtained from a source other than VFC;

2. Immunization and Vaccine Administration Services provided by a school district provider; and

3. Travel-related Immunization and Vaccine Administration Services.

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Rule concerning Pharmacist Over the Counter Prescriptive Authority, Section 8.800
Rule Number: MSB 18-03-07-A
Division / Contact / Phone: Client and Clinical Care / Kristina Gould / 303-866-6715

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 18-03-07-A, Revision to the Medical Assistance Rule concerning Pharmacist Over the Counter Prescriptive Authority, Section 8.800

3. This action is an adoption of: an amendment

4. Rule sections affected in this action (if existing rule, also give Code of Regulations number and page numbers affected):

   Sections(s) 8.800.1, 8.800.10.B and 8.800.12.A.2, Colorado Department of Health Care Policy and Financing, Staff Manual Volume 8, Medical Assistance (10 CCR 2505-10).

5. Does this action involve any temporary or emergency rule(s)? No
   If yes, state effective date:
   Is rule to be made permanent? (If yes, please attach notice of hearing). Yes

PUBLICATION INSTRUCTIONS*

Replace the current text at 8.800 with the proposed text beginning at 8.800.1 through the end of 8.800.12. This rules is effective October 31, 2018.

*to be completed by MSB Board Coordinator

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Rule concerning Pharmacist Over the Counter Prescriptive Authority, Section 8.800
Rule Number: MSB 18-03-07-A
Division / Contact / Phone: Client and Clinical Care / Kristina Gould / 303-866-6715

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 rule change is to modify the definitions section to incorporate a new term, "Prescriber". This term will encompass a healthcare professional who, as licensed by Colorado state law, may prescribe and authorize the use of medicine or treatment to a member. This term will include pharmacists, as they are authorized to prescribe over-the-counter (OTC) medications to members, pursuant to Colorado Revised Statutes 25.5-5-322. Additionally, this update incorporates the rules that pharmacists must comply with when prescribing OTC's to members for the purpose of receiving reimbursement under the Medical Assistance Program.

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:

   Social Security Act 1927(k)(4)

4. State Authority for the Rule:

   25.5-1-301 through 25.5-1-303, C.R.S. (2016);
   25.5-5-322, C.R.S. (2017).

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Rule concerning Pharmacist Over the Counter Prescriptive Authority, Section 8.800
Rule Number: MSB 18-03-07-A
Division / Contact / Phone: Client and Clinical Care / Kristina Gould / 303-866-6715

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.

   Pharmacists will be positively impacted by this proposed rule because prescribing over-the-counter (OTC) medications is within their scope of licensure. Members will be positively impacted because they can more easily obtain access to OTC medications; this will decrease doctor and emergency room visits because OTC medications will be more easily attainable. The Department will be positively impacted because any slight increase in expenditures for these OTC drugs is anticipated to offset ED use; in addition to potential reductions in higher cost drugs that are currently prescribed by physicians.

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

   Quantitatively, the estimated impact associated with this change is a decrease of $74,877 total funds in FY 2018-19 and a decrease of $184,280 total funds in FY 2019-20 or one full year of implementation. This estimate is based on the assumption that increases in OTC drug expenditure would be offset by avoided expenditures associated with ED use and pregnancies. Qualitatively, this will positively impact pharmacists because these changes align more closely with what is within their scope of licensure. Members will be positively impacted because they will have increased access to OTC medications.

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 probable costs to the Department are a slight increase in OTC expenditures. The probable costs to other agencies for the implementation and enforcement of this proposed rule are estimated to be none because:

   1. Pharmacists have the option to enroll (i.e. they are not mandated to do so),

   2. The technology needed to submit these claims will be the same as with any other pharmacy claim (i.e. does not require system updates) and,

3. Enrolling with the Department as a pharmacist to prescribe OTC medications will not require an admission fee.

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

   The probable costs to the Department are a slight increase in OTC expenditures. However, the benefits of decreased ED utilization, increased comradery between pharmacists and the Department and increased access to medication for members, far outweigh the potential cost increases related to OTC expenditures. Ultimately, inaction would result in non-compliance with statute 25.5-5-322, C.R.S. (2017); in addition to lessened comradery between the pharmacist community and the Department.

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

   None.

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

   None.

8.800 PHARMACEUTICALS

8.800.1 DEFINITIONS

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

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

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

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

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

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

G. Drug Class means a group composed of drugs that all treat a particular disease, symptom or indication.

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

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

J. Fiscal agent means a contractor that supports and operates the pharmacy benefit management system on behalf of the Medical Assistance Program.

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

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

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

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

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

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

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

R. Medical Assistance Program shall have the meaning defined in Section 25.5-1-103(5), C.R.S. (2016).

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

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

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

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

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

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

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

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

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

BB. Preferred Drug means a drug that is designated preferred by the Medical Director pursuant to 10 CCR 2505-10, Section 8.800.16.B, that is payable by the Medical Assistance Program without first obtaining a prior authorization unless otherwise required to protect the health and safety of specific members.

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

DD. Prescriber means a healthcare professional who, as licensed by Colorado state law, may prescribe and authorize the use of medicine or treatment to a member. Prescribers must be enrolled in the Medical Assistance Program to receive reimbursement.

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

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

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

~~GG.~~HH. 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.

~~HH.~~II. 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.

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

~~JJ.~~KK. 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 Prescriber, whether in-state or out-of-state, that submits claims for reimbursement must be enrolled in the Medical Assistance program in accordance with 8.040.1 and 8.013.1. The Department may deny a provider application, and the Department may terminate or not renew a provider agreement in accordance with 10 C.C.R. 2505-10, Sections 8.076, 8.125, and 8.130.

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

8.800.3 MAIL ORDER

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

8.800.4 DRUG BENEFITS

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

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

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

2. Agents when used to promote fertility;

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

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

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

6. Non-prescription Drugs;

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

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

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

1. Spirituous liquors of any kind;

2. Dietary needs or food supplements;

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

4. Medical supplies;

5. Drugs classified by the FDA as "investigational" or "experimental"; except for the following:

   a. Stiripentol may be covered if the coverage has been ordered by the member's physician, has been deemed medically necessary by the Department and has been authorized for the specific member's use by the U.S. Food & Drug Administration.

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

7. Medicare Part D Drugs for Part D eligible 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 are the only OTC drugs that are regular benefits without restrictions.

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

1. Without limiting the foregoing, restrictions may be placed on drugs for which it has been deemed necessary to address instances of fraud or abuse, potential for, and history of, drug diversion and other illegal utilization, overutilization, other inappropriate utilization or the availability of more cost-effective comparable alternatives.

8.800.4.F. 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 members.

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

1. Only a brand name drug is manufactured.

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

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

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

a. Mental Illness;

b. Cancer;

c. Epilepsy; or

d. Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome.

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

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

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

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

8.800.5 DRUGS ADMINISTERED OR PROVIDED IN PHYSICIAN OFFICES OR CLINICS

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

8.800.5.B. Dispensing Prescribers whose offices or sites of practice are located within 25 miles from the nearest participating pharmacy shall not be reimbursed for drugs or services that are dispensed from their offices.

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 member's physician, any other health care provider who has authority under Colorado law to prescribe the medication being requested or any long-term-care pharmacy or infusion pharmacy that fills prescriptions on behalf of the member and is acting as the agent of the prescriber. The prior authorization request shall be made to the Fiscal Agent. The prescriber shall provide any information requested by the Fiscal Agent including, but not limited to, the following:

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

2. Name of the drug(s) requested;

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

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

8.800.7.B. When the prior authorization request is received, it shall be reviewed to determine if the request is complete. If it is complete, the requesting provider shall be notified of the approval or denial of the prior authorization request via telephone and/or facsimile at the time the request is made, if possible, but in no case later than 24 hours after the request is made. 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 member for proper treatment. The pharmacist may call the prior authorization help desk to receive override approval. Prescriptions dispensed under the override approval are eligible for reimbursement.

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

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

8.800.8 LIMIT REQUIREMENTS

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

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

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

8.800.9 DRUG UTILIZATION REVIEW

8.800.9.A. Prospective Drug Utilization Review

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

    a. Over-utilization or under-utilization;

    b. Therapeutic duplication;

    c. Drug-disease contraindications;

    d. Drug-drug interactions;

    e. Incorrect drug dosage or duration of drug treatment;

    f. Drug-allergy interactions; and

    g. Clinical abuse/misuse.

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

8.800.9.B. Member Counseling

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

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

    a. The name and description of the drug;

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

    c. Intended use of the drug and expected action;

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

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

    f. Techniques for self-monitoring drug therapy;

    g. Proper storage;

    h. Prescription refill information; and

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

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

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

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

8.800.9.C. Retrospective Drug Utilization Review

1. The Department shall periodically review claims data in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists and members 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 Title 42 of the Code of Federal Regulations, Section 456.716(d)(2015). Title 42 of the Code of Federal Regulations, Section 456.716(d)(2015) are hereby incorporated by reference into this rule. Such incorporation, however, excludes later amendments to or editions of the referenced material. This statute is available for public inspection at the Department of Health Care Policy and Financing, 1570 Grant Street, Denver, CO 80203. Pursuant to C.R.S. §24-4-103(12.5)(V)(b), the agency shall provide certified copies of the material incorporated at cost upon request or shall provide the requestor with information on how to obtain a certified copy of the material incorporated by reference from the agency of the United States, this state, another state, or the organization or association originally issuing the code, standard, guideline or rule.

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

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

   b. A summary of the interventions used;

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

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

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

8.800.10 BILLING PROCEDURES

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

8.800.10.B. Each claim must identify the member, ~~prescribing physician~~ Prescriber, 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 member information from the member or his/her apparent agent for each new prescription:

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

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

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

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

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

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

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

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

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

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

      ii) Micro-fine printed security message generated by a computer, electronic medical records system or other electronic means. The message may serve as a signature line or border. This must be printed in 0.5 font or

smaller and readable when viewed at 5x magnification or greater and illegible when copied.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

i) Inpatient hospital services;

ii) Hospice services;

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

iv) Physician services;

v) Outpatient hospital services;

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

vii) Other laboratory and x-ray services; or

viii) Renal dialysis.

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

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

8.800.11.E. Prescription tracking and claim reversals

1. The pharmacy shall keep:

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

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

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

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

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

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

8.800.12 BASIS FOR REIMBURSEMENT

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

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

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

   a. A pharmacist licensed in the state of Colorado may prescribe the over-the-counter (OTC) medications listed on the Department's Pharmacist OTC Prescriptive Authority List which shall be posted on the Department's website.

   b. A pharmacist prescribing and dispensing over-the-counter medications shall comply with the rules set forth by the Colorado State Board of Pharmacy.

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 members except for OAP State Only clients shall be reimbursed the lesser of:

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

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

Covered drugs for the OAP State Only Program shall be reimbursed according to 10 C.C.R. 2505-10, Section 8.941.9.

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 to the Department or designated vendor as indicated on the Average Acquisition Cost Inquiry Worksheet. The Department shall have five (5) days to provide an inquiry response to the pharmacy. If the AAC rate requires revision, the Department shall then have 5 additional days to update the AAC rate.

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

8.800.13.F. Any pharmacy, except a Mail Order Pharmacy, that is the only pharmacy within a twenty mile radius may submit a letter to the Department requesting the designation as a 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.

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 Prescribers who dispense medications that are reimbursed as a pharmacy benefit pursuant to 8.800 shall 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. (2016), or a licensed health care provider for the purpose of dispensing the medication to another person.

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

8.800.16 PREFERRED DRUG LIST

8.800.16.A. ESTABLISHING THE PREFERRED DRUG LIST

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

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

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

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

        i) Drug safety;

        ii) Drug efficacy;

        iii) The recommendations of the P&T Committee;

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

v) Cost-effectiveness; and

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

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

3. After the Medical Director has designated a reviewed drug as Preferred or Non-preferred and designates prior authorization criteria to protect the health and safety of members, the Department shall refer that drug to the DUR Board for recommendations on prior authorization criteria.

4. After the DUR Board meets, the Medical Director shall review the recommendations of the P&T Committee, the DUR Board and the Department and determine the efficacy, safety and appropriate prior authorization criteria for Preferred and Non-preferred Drugs to ensure the health and safety of members.

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

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

8.800.16.B. NEW DRUGS

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

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

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

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 members.

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

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

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

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

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

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

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

8.800.16.D. AUTHORITY OF THE EXECUTIVE DIRECTOR

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

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

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

8.800.17 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 member representatives;

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

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

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

vi) Four physicians from any other medical specialty.

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

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

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

Committee members constitutes a quorum for the transaction of business at any P&T Committee meeting.

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

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

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

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

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

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

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

a. The clinically appropriate prescribing of covered outpatient drugs;

b. The clinically appropriate dispensing of outpatient drugs;

c. Drug use review, evaluation and intervention;

d. Medical quality assurance; or

e. The treatment of Medical Assistance Program members.

8.800.17.B. CONFLICT OF INTEREST

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

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

8.800.17.C. DUTIES

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

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

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

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

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

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

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

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

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

8.800.17.D. NOTICE/OPEN MEETINGS

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

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

8.800.18 PRESCRIPTION DRUG CONSUMER INFORMATION AND TECHNICAL ASSISTANCE PROGRAM

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

8.800.18.B. REQUIREMENTS FOR PARTICIPATION IN THE PROGRAM

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

2. Pharmacists shall:

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

b. Maintain liability insurance; and

c. Complete an application; and

d. Enter into a contract with the Department; and

e. Meet one of the following qualifications:

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

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

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

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

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

8.800.18.C. SERVICES

1. Pharmacists participating in the program shall:

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

b. Collect and review member drug histories.

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

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

e. Provide the member with information regarding:

i) The prudent use of prescription drugs.

ii) How to avoid dangerous drug interactions.

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

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

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

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

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

DO NOT PUBLISH THIS PAGE

Title of Rule: Revisions to MAGI-Medicaid concerning Income Verification for those receiving Continuous Coverage at sections 8.100.3.G and 8.100.4.G
Rule Number: MSB 18-06-12-A
Division / Contact / Phone: Health Information Office / Ana Bordallo / 303-866-3558

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 18-06-12-A, Revisions to MAGI-Medicaid concerning Income Verification for those receiving Continuous Coverage at sections 8.100.3.G and 8.100.4.G
3. This action is an adoption of: an amendment
4. Rule sections affected in this action (if existing rule, also give Code of Regulations number and page numbers affected):

   Sections(s) 8.100.3.Q and 8.100.4.G, Colorado Department of Health Care Policy and Financing, Staff Manual Volume 8, Medical Assistance (10 CCR 2505-10).
5. Does this action involve any temporary or emergency rule(s)? No
   If yes, state effective date:
   Is rule to be made permanent? (If yes, please attach notice of hearing). Yes

PUBLICATION INSTRUCTIONS*

Replace the current text at 8.100.3.Q with the proposed text beginning at 8.100.3.Q through the end of 8.100.3.Q. Replace the current text at 8.100.4.G with the proposed text beginning at 8.100.4.G through the end of 8.100.4.G.7. This rule is effective October 31, 2018.

*to be completed by MSB Board Coordinator

DO NOT PUBLISH THIS PAGE

Title of Rule: Revisions to MAGI-Medicaid concerning Income Verification for those receiving Continuous Coverage at sections 8.100.3.G and 8.100.4.G
Rule Number: MSB 18-06-12-A
Division / Contact / Phone: Health Information Office / Ana Bordallo / 303-866-3558

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 rule change is to add clarification for members receiving continuous coverage within a child or a pregnant category, whose income is not reasonably compatible based on the self-reported income and the electronic income verified. When the income is not reasonably compatible and it's the first income discrepancy, if the discrepancy is not resolved within the reasonable opportunity period(ROP) of 90 days, their benefits will be terminated.

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:

   Code of Federal Regulation §435.952.(c)(2)

4. State Authority for the Rule:

   25.5-1-301 through 25.5-1-303, C.R.S. (2017);

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REGULATORY ANALYSIS

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

   The classes of persons who will be affected by this proposed rule clarification are members enrolled in a MAGI Medicaid category receiving continuous coverage who is a child or pregnant women. The benefits of this rule change will provide clear guidance to the populations listed, who are receiving benefits and whose benefits may be impacted if they fail to respond to the discrepancy notice.

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 will provide clarification for those members whose income is not reasonably compatible and it's the first income discrepancy, if the discrepancy is not resolved within the reasonable opportunity period (ROP) of 90 days, their benefits will be terminated.

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 are no costs to the Department as this is only adding clarification to the Department's current rules to align with current policy.

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

   Because this rule change already reflects current practice, and the Department is just providing clarification, there will be no difference between the rule change and inaction.

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

   There is no other less costly method to update this rule change.

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

   There are no alternatives methods for the proposed rule that were considered.

8.100.3.Q. Continuous Eligibility (CE) for Medical Assistance programs

1. Continuous eligibility applies to children under age 19, who through an eligibility determination, reassessment or redetermination, are found eligible for a Medical Assistance program. The continuous eligibility period may last for up to 12 months.

    a. The continuous eligibility period applies without regard to changes in income or other factors that would otherwise cause the child to be ineligible.

        i) A 14-day no fault period shall begin on the date the child is determined eligible for Medical Assistance. During the 14-day period, any changes to income or other factors made to the child's case during the 14-day no fault period may change his or her eligibility for Medical Assistance.

    b. Exception: A child's continuous eligibility period will end effective the earliest possible month if any of the following occur:

        i) Child is deceased

        ii) Becomes an inmate of a public institution

        iii) The child is no longer part of the Medical Assistance required household

        iv) Is no longer a Colorado resident

        v) Is unable to be located based on evidence or reasonable assumption

        vi) Requests to be withdrawn from continuous eligibility

        vii) Fails to provide documentation during a reasonable opportunity period as specified in section 8.100.3.H.9

        viii) Fails to provide a reasonable explanation or paper documentation when self-attested income is not reasonably compatible ~~to comply in resolving an income discrepancy~~with income information from an electronic data source, by the end of the 90-day reasonable opportunity period. ~~as outlined in section 8.100.4.C.2~~This exception only applies the first-time income is verified following an initial eligibility determination or an annual redetermination.

2. The continuous eligibility period will begin on the first day of the month the application is received or from the date all criteria is met. Continuous eligibility is applicable to children enrolled in the following Medical Assistance programs:

    a. MAGI-Medical Assistance, program as specified in section 8.100.4.G.2

    b. SSI Mandatory, as specified in section 8.100.6.C

        i.) When a child is no longer eligible for SSI Mandatory they will be categorized as eligible within the MAGI-Child category for the remainder of the eligibility period.

    c. Long- Term Care services

i.) When a child is no longer eligible for Long-Term Care services they will be categorized as eligible within the MAGI- Child category for the remainder of the eligibility period.

d. Medicaid Buy-In program specified in section 8.100.6.Q

i) Exception: Enrollment will be discontinued if there is a failure to pay premiums

e. Pickle

f. Disabled Adult Child DAC)

3. Children, under the age of 19, no longer enrolled in Foster Care Medicaid will be eligible for the MAGI-Medical Assistance program. The continuous eligibility period will begin the month the child is no longer enrolled in Foster Care Medicaid as long as they meet one of the following conditions:

a. Begin living with other Relatives

b. Are reunited with Parents

c. Have received guardianship

8.100.4.G. MAGI Covered Groups

1. For MAGI Medical Assistance, any person who is determined to be eligible for Medical Assistance based on MAGI at any time during a calendar month shall be eligible for benefits during the entire month.

2. Children applying for Medical Assistance whose total household income does not exceed 133% of the federal poverty level (MAGI-equivalent) shall be determined financially eligible for Medical Assistance. Refer to the MAGI-Medicaid income guidelines chart available on the Department's website.

a. Children are eligible for Children's MAGI Medical Assistance through the end of the month in which they turn 19 years old. After turning 19, the individual may be eligible for a different Medical Assistance category.

3. Parents and Caretaker Relatives applying for Medical Assistance whose total household income does not exceed 60% of the federal poverty level (MAGI-equivalent) shall be determined financially eligible for Medical Assistance. Parents or Caretaker Relatives eligible for this category shall have a dependent child in the household.

a. A dependent child is considered to be living in the home of the parent or caretaker relative as long as the parent or specified relative exercises responsibility for the care and control of the child even if:

i) The child is under the jurisdiction of the court (for example, receiving probation services);

ii) Legal custody is held by an agency that does not have physical possession of the child;

iii) The child is in regular attendance at a school away from home;

iv) Either the child or the relative is away from the home to receive medical treatment;

v) Either the child or the relative is temporarily absent from the home;

vi) The child is in voluntary foster care placement for a period not expected to exceed three months. Should the foster care plan change within the three months and the placement become court ordered, the child is no longer considered to be living in the home as of the time the foster care plan is changed.

4. Adults applying for Medical Assistance whose total household income does not exceed 133% of the federal poverty level shall be determined financially eligible for Medical Assistance. This category includes adults who are parents or caretaker relatives of dependent children whose income exceeds the income threshold to qualify for the Parents and Caretaker Relatives MAGI category and who meet all other eligibility criteria.

   a. A dependent child living in the household of a parent or caretaker relative shall have minimum essential coverage, in order for the parent or caretaker relative to be eligible for Medical Assistance under this category. Refer to section 8.100.4.G.3.a on who is considered a dependent child.

5. Pregnant Women whose household income does not exceed 185% of the federal poverty level (MAGI-equivalent) are eligible for the Pregnant Women MAGI Medical Assistance program. Medical Assistance shall be provided to a pregnant woman for a period beginning with the date of application for Medical Assistance through the last day of the month following 60 days from the date the pregnancy ends. Once eligibility has been approved, Medical Assistance coverage will be provided regardless of changes in the woman's financial circumstances once the income verification requirements are met. ~~.~~

   a. A pregnant women's eligibility period will end effective the earliest possible month, if the following occurs:

      i) Fails to provide a reasonable explanation or paper documentation when self-attested income is not reasonably compatible with income information from an electronic data source, by the end of the 90 day reasonable opportunity period. This exception only applies the first-time income is verified following an initial eligibility determination or an annual redetermination.

6. A lawfully admitted non-citizen who is pregnant and who has been in the United States for less than five years is eligible for Medical Assistance if she meets all of the other eligibility requirements specified at 8.100.4.G.5 and fits into one of the immigration categories listed in 8.100.3.G.1.g.iii.1-5 and 8.100.3.G.1.g.vi.1-15. This population is referenced as Legal Immigrant Prenatal.

7. A child whose mother is receiving Medical Assistance at the time of the child's birth is continuously eligible for one year. This population is referred to as "Eligible Needy Newborn". This coverage also applies in instances where the mother received Medical Assistance to cover the

child's birth through retroactive Medical Assistance. The child is not required to live with the mother receiving Medical Assistance to qualify as an Eligible Needy Newborn.

a. To receive Medical Assistance under this category, the birth must be reported verbally or in writing to the County Department of Human Services or eligibility site. Information provided shall include the baby's name, date of birth, and mother's name or Medical Assistance number. A newborn can be reported at any time by any person. Once reported, a newborn meeting the above criteria shall be added to the mother's Medical Assistance case, or his or her own case if the newborn does not reside with the mother, according to timelines defined by the Department. If adopted, the newborn's agent does not need to file an application or provide a Social Security Number or proof of application for a Social Security Number for the newborn