DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Act Rule concerning The HB23-1183 Implementation, Section 8.800.A and 8.800.7
Rule Number: MSB 23-04-25-C
Division / Contact / Phone: Pharmacy Office / Korri Conilogue / 303-866-6398

SECRETARY OF STATE

RULES ACTION SUMMARY AND FILING INSTRUCTIONS

SUMMARY OF ACTION ON RULE(S)

1. Department / Agency Name: Health Care Policy and Financing / Medical Services Board

2. Title of Rule: Revision to the Medical Assistance Act Rule concerning the HB23-1183 Implementation, Section 8.800.A and 8.800.7.

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.A and 8.800.7, 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 8.800.1 with the proposed text beginning at 8.800.A through the end of 8.800.A. Replace the current text at 8.800.7 with the proposed text beginning at 8.800.7 through the end of 8.800.7.F.3. This rule is effective April 30, 2024.

*to be completed by MSB Board Coordinator

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Act Rule concerning The HB23-1183 Implementation, Section 8.800.A and 8.800.7
Rule Number: MSB 23-04-25-C
Division / Contact / Phone: Pharmacy Office / Korri Conilogue / 303-866-6398

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).

HB23-1183 requires the Department to review and determine if an exception to step therapy is granted if the prescribing provider submits a prior authorization request with justification and supporting clinical documentation for treatment of a serious or complex medical condition. Therefore, the Department recommends rule revisions at 10 CCR 2505-10, Section 8.800.A, to define "Serious or Complex Medical Condition" and "Step Therapy". In addition, the Department recommends rule revisions at Section 8.800.7, to describe the exception to step therapy process for drugs used to treat a Serious or Complex Medical Condition pursuant to HB23-1183.

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:

   Sections 25.5-1-301-303, and 25.5-4-428 C.R.S. (2023).

Initial Review **02/09/24** Final Adoption **03/30/24**
Proposed Effective Date **04/30/24** Emergency Adoption

DOCUMENT #

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Title of Rule: Revision to the Medical Assistance Act Rule concerning The HB23-1183 Implementation, Section 8.800.A and 8.800.7
Rule Number: MSB 23-04-25-C
Division / Contact / Phone: Pharmacy Office / Korri Conilogue / 303-866-6398

REGULATORY ANALYSIS

5. 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.

   8.800.A: Medicaid members with a serious or complex medical condition will benefit from this proposed rule because there will be a clear definition of what a "serious or complex medical condition" is and what "step therapy" means.

   8.800.7.F: Medicaid members with a serious or complex medical condition will benefit from this proposed rule because there will be a published process in alignment with HB23-1183 for obtaining a step therapy exception for serious or complex medical conditions.

   The proposed rule would result in no additional costs to Medicaid members, though the Department anticipates a marginal increase in drug costs.

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

   Qualitatively, allowing exceptions to step therapy for the treatment of serious or complex medical conditions may improve health outcomes for members. Quantitatively, there may be an increase in step therapy exception requests for members with serious or complex medical conditions.

7. 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.

   Due to the expanded definition of a serious or complex medical condition, the Department anticipates a marginal increase in drug expenditures.

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

   The cost of inaction is that the Department would not be compliant with HB23-1183. There are no benefits of inaction.

DO NOT PUBLISH THIS PAGE

The cost of this action is a marginal increase in the Department's drug expenditures. The benefit of this action is set forth in response to 6, above.

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

   N/A- this is implementation of legislation.

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

    N/A- this is implementation of legislation.

8.800 PHARMACEUTICALS

8.800.A1 DEFINITIONS

1. A. 340B Pharmacy means any pharmacy that participates in the Federal Public Health Service Act section's 340B Drug Pricing Program as described in Title 42 of the United States Code, Section 256b (2020)42 U.S.C. § 256b (2023), which . Title 42 of the United States Code, Section 256b (2020) 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 Street303 E. 17th Avenue, Denver, CO 80203. Pursuant to C.R.S. § 24-4-103(12.5)(a)(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.

2. B. Average Acquisition Cost (AAC) means the average acquisition cost for like drugs grouped by Generic Sequence Number (GSN). For GSNs with both generic and brand drugs, the Department shall determine two separate AAC rates for the GSN. 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.

3. C. Clotting Factor Maximum Allowable Cost (CFMAC) means the rate for a clotting factor drug for which no Average Acquisition Cost (AAC) rate is established. The CFMAC rate is determined based on available acquisition cost data and publicly available data unique to each clotting factor drug.

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

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

6. F. 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.

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

8. H. Drug Class means drugs that are grouped together due to a common mechanism of action, or to treat a particular disease, symptom, or indication.

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

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

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

12. L. Federal Upper Limit (FUL) means the upper limit for multiple source drugs as set by the Centers for Medicare and Medicaid Services pursuant to Title 42 of the Code of Federal Regulations,42 C.F.R. § Part 447.512-447.5156 (20203), which. Title 42 of the Code of Federal

~~Regulations, Part 447.512-447.516 (2020)~~ 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~~303 E. 17th Avenue, Denver, CO 80203. Pursuant to C.R.S. § 24-4-103(12.5)(a)(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.

13. ~~M.~~ Generic Sequence Number (GSN) means a standard number to group together drugs that have the same ingredients, route of administration, drug strength, and dosage form.

14. ~~N.~~ Good Cause for purposes of terminating the appointment of any P&T Committee member 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.

15. ~~O.~~ 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.

16. ~~P.~~ 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.

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

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

19. ~~S.~~ Maximum Allowable Cost (MAC) means the rate for a covered drug ~~which does not possess~~for which no Average Acquisition Cost (AAC) nor National Average Drug Acquisition Cost (NADAC) rates apply. This rate is calculated using an adjustment of the national pricing benchmark Wholesale Acquisition Cost (WAC).

20. ~~T.~~ Medical Assistance Program ~~shall have the meaning~~is a program of Medical Assistance as defined in ~~Section~~ § 25.5-1-103(5), C.R.S. (202~~0~~3).

21. ~~U.~~ 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 Section 8.754.

22. ~~V.~~ Medical Director means the physician or physicians who are employed by the Department to provide medical direction. ~~advise the Department.~~

23. ~~W.~~ 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, as codified at 42 U.S.C. § 1395w-101, et seq.

24. ~~X.~~ Medicare Part D Drugs means drugs defined at ~~Title 42 of the United States Code,~~42 U.S.C. ~~§ Section~~ 1395w-102(e) (202~~0~~3) and ~~Title~~ 42 ~~of the Code of Federal Regulations, Section~~C.F.R. § 423.100 (202~~0~~3), which~~. Title 42 of the United States Code, Section 1395w-102(e) (2020) and Title 42 of the Code of Federal Regulations, Section 423.100 (2020)~~ 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~~303 E. 17th Avenue, Denver, CO 80203. Pursuant to C.R.S. § 24-4-103(12.5)(a)(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.

25. ~~Y.~~ National Average Drug Acquisition Cost (NADAC) is a Centers for Medicare and Medicaid Services published rate which represents the national average of the drug acquisition costs submitted by retail community pharmacies.

26. ~~Z.~~ Non-preferred Drug means a drug that is designated as non-preferred by the Medical Director pursuant to Section 8.800.16.A and which requires prior- authorization to be payable by the Medical Assistance Program.

27. ~~AA.~~ Old Age Pension Health Care Program and Old Age Pension Health Care Supplemental Program (OAP State Only) means the program established pursuant to § 25.5-2-101 to provide necessary medical care for clients that qualify for Old Age Pension but do not qualify for the Medical Assistance Program ~~under~~ pursuant to Title XIX of the Social Security Act and Colorado statutes.

28. ~~BB.~~ 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.

29. ~~CC.~~ Part D eligible individual has the same meaning as defined in Section 8.1000.1.

30. ~~DD.~~ 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 Section 8.800.17.

31. ~~EE.~~ Preferred Drug means a drug that is designated preferred by the Medical Director pursuant to Section 8.800.16.A, 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.

32. ~~FF.~~ 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 that is applicable only to fee-for-service and primary care physician Medical Assistance Program members.

33. ~~GG.~~ Prescriber means a healthcare professional ~~who, as~~ licensed ~~by~~ pursuant to Colorado state law~~,~~ who 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.

34. ~~HH.~~ Provider Bulletin means a document published and distributed by the Department program and policy staff to communicate information to providers related to the ~~Department~~Medical Assistance Program.

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

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

37. ~~KK.~~ Serious Mental Illness means the following psychiatric illnesses: bipolar disorders (hypomanic, manic, depressive, and mixed), depression in childhood and adolescence, major depressive disorders (single episode or recurrent), obsessive-compulsive disorders (single or recurrent), paranoid and other psychotic disorders, schizoaffective disorders (bipolar or depressive), and schizophrenia.

38. Serious ~~or complex illness O~~or Complex Medical Condition is defined as one of the following medical conditions: S~~s~~erious M~~m~~ental I~~i~~llness, cancer, epilepsy, multiple sclerosis, or HIV/AIDS, or a condition requiring medical treatment to avoid death, hospitalization, or a worsening or advancing of disease progression resulting in significant harm or disability.

~~37.~~39. Step Therapy means a protocol that requires a member to use a prescription drug or sequence of prescription drugs, other than the drug that the member's Prescriber recommends for the member's treatment~~.~~, before the Department provides coverage for the recommended prescription drug.

~~38.~~40. ~~LL.~~ 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.

~~39.~~41. ~~MM.~~ 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.

~~40.~~42. ~~NN.~~ Usual and Customary Charge means the reimbursement amount the provider charges the general public to pay for a drug.

~~41.~~43. ~~OO.~~ 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.

8.800.7 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 72 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. PRIOR AUTHORIZATION FOR NEW DRUGS

1. If a new drug entity, including new generic drugs and new drug product dosage forms of existing drug entities, is approved by the FDA and is in a Drug Class already subject to prior authorization, the new drug entity may be subject to prior authorization without any comment period.

   a. If it is a new drug entity that is subject to the PDL, the prior authorization criteria for that new drug entity shall remain in effect until the applicable Drug Class is reviewed by the Drug Utilization Review (DUR) Board.

   b. If it is a new drug entity that is not subject to the PDL, the prior authorization criteria shall remain in effect until the new drug entity is reviewed by the DUR Board, which shall be completed within six months.

2. If a new drug entity, including new generic drugs and new drug product dosage forms of existing drug entities, is approved by the FDA and is not in a Drug Class already subject to prior authorization, the new drug entity may be subject to prior authorization and will be reviewed by the DUR board within six months.

3. The Department shall conduct preliminary coverage reviews for a new drug entity indicated for the treatment of Serious Mental Illness within 90 days of FDA approval.

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, Appendix P or PDL. Notification in the Provider Bulletin, Appendix P or PDL shall satisfy any notification requirements of any such changes. The Appendix P and PDL documents ~~can~~ may be accessed on the Department's website at www.colorado.gov/hcpf.

8.800.7.F The Department shall review a request and determine if an exception to Step Therapy is granted if the Prescriber submits a prior authorization request with justification and supporting clinical documentation for the treatment of a Serious or Complex Medical Condition that meets the criteria set forth in § 25.5-4-428. ~~which states one of the following:~~

~~1. The Prescriber attests that the required prescription drug is contraindicated, or will likely cause intolerable side effects, a significant drug-drug interaction, or an allergic reaction to the member;~~

2. The required prescription drug lacks efficacy based on the known clinical characteristics of the member and the known characteristics of the prescription regimen;

3. The member has tried the required the prescription drug, and the use of the prescription drug by the member was discontinued due to intolerable side effects, a significant drug-drug interaction, or an allergic reaction; or

4. The member is stable on a prescription drug selected by the Prescriber for the medical condition.

DO NOT PUBLISH THIS PAGE

Title of Rule: New High Utilizer Supplemental Payment, NF Parolees Supplemental Payment, Post Eligibility Treatment of Income (PETI) Dental Benefit Removal, Sections 8.443 & 8.482.
Rule Number: MSB 23-11-03-A
Division / Contact / Phone: OCL, Christine Bates, 303-866-5419

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 23-11-03-A, New High Utilizer Supplemental Payment, NF Parolees Supplemental Payment, Post Eligibility Treatment of Income (PETI) Dental Benefit Removal, Sections 8.443 & 8.482.

3. This action is an adoption of: 2 New Rule Sections, 1 Rule Section Amendment

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

   Sections(s) 8.443.23 page 146, 8.443.24 page 147, 8.482.33 page 161, 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 8.401 with the proposed text beginning at 8.401.18 through the end of 8.401.42. Replace the current text at 8.440 with the proposed text beginning at 8.440.13 through the end of 8.440.13. Replace the current text at 8.443 with the proposed text beginning with 8.443.23 through the end of 8.443.24. Replace the current text at 8.482 with the proposed text beginning at 8.482.33 through the end of 8.482.33.D.4.d. This rule is effective April 30, 2024.

*to be completed by MSB Board Coordinator

DO NOT PUBLISH THIS PAGE

Title of Rule: New High Utilizer Supplemental Payment, NF Parolees Supplemental Payment, Post Eligibility Treatment of Income (PETI) Dental Benefit Removal, Sections 8.443 & 8.482.
Rule Number: MSB 23-11-03-A
Division / Contact / Phone: OCL, Christine Bates, 303-866-5419

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).

   Section 8.443.23 is being added due to House Bill (HB) 23-1228 allowing for a new supplemental payment for nursing facilities with 75% or higher Medicaid population or the facility is the only nursing facility in the county. This is referred to as the "High Medicaid Utilizer Supplemental Payment". The purpose is to support the financial stability of these facilities.

   Section 8.443.24 is being added due to SB 22-196 allowing the Department of Health Care Policy & Financing (HCPF) and the Department of Corrections (DOC) to work together to support individuals who have been paroled and are in need of nursing facility services. The nursing facilities will receive a supplemental payment to provide additional support services beyond what is typically expected to be provided for these individuals. This is referred to as "Nursing Facility Parolees Supplemental Payment".

   Section 8.482.33 is being amended to take out dental services as a benefit of the Post Eligibility Treatment of Income (PETI) program due to Senate Bill (SB) 23-214 that removed adult dental Medicaid State Plan benefit limits.

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:

DO NOT PUBLISH THIS PAGE

Sections 25.5-1-301 through 25.5-1-303, C.R.S. (2023)

Title of Rule: New High Utilizer Supplemental Payment, NF Parolees Supplemental Payment, Post Eligibility Treatment of Income (PETI) Dental Benefit Removal, Sections 8.443 & 8.482.
Rule Number: MSB 23-11-03-A
Division / Contact / Phone: OCL, Christine Bates, 303-866-5419

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 payments are aimed at improving access to care for Medicaid members. The Parolee payment directly incentivizes the provision of medical care for individuals who currently struggle to access nursing facility services. The High Medicaid Utilizer Supplemental Payment seeks to better compensate facilities that serve the highest number of Medicaid members and/or are located in areas that have no other nursing facility providers. Nursing facility residents will be losing a negligible amount of benefits from the PETI program changes.

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 High Medicaid Utilizer Supplemental Payment will equal $20 million in total costs per state fiscal year. The supplemental payment will be used to increase Medicaid reimbursement to approximately 50 nursing facilities providing care to the greatest number of Medicaid patients.

   DOC has estimated there are 10 individuals currently who need to be released from DOC custody to a nursing facility with the Nursing Facility Parolees Supplemental Payment.

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 cost for the High Medicaid Utilizer Supplemental Payment is approximately $10 million per state fiscal year.

   The cost for the Nursing Facility Parolees Supplemental Payment is estimated to cost $474,500 in FY 2024.

There is no budgetary impact to the dental benefit being removed from the PETI. There are very few claims being submitted.

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

   If HCPF does not act, HCPF will not be following the intent of the stated statutes.

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

   There are no less costly methods for achieving the intent of these statutes.

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

   N/A

8.401.18 PRE-ADMISSION SCREENING AND ANNUAL RESIDENT REVIEW (PASRR) AND SPECIALIZED SERVICES FOR INDIVIDUALS WITH MENTAL ILLNESS OR INDIVIDUALS WITH AN INTELLECTUAL OR DEVELOPMENTAL DISABILITY

.182 Definitions

A. Serious Mental Illness

1. ~~A major mental disorder~~ Serious mental illness (SMI) is defined as:~~-~~ a mental, behavioral, or emotional disorder resulting in serious functional impairment, which substantially interferes with or limits one or more major life activities.~~A primary diagnosis of schizophrenic, paranoid, major affective, schizoaffective disorders or other psychosis. The burden of mental illnesses is particularly concentrated among those who experience disability due to SMI.~~

2. For the purposes of the PASRR program, a person is considered to have serious mental illness if they meet the diagnosis, level of impairment and recent treatment criteria found at 42 C.F.R. § 483.102.

~~2~~3. An individual is considered to not have serious mental illness if they have:

a. a primary diagnosis of dementia (including Alzheimer's disease or a related disorder); or

b. a non-primary diagnosis of dementia (including Alzheimer's disease or a related disorder) without a primary diagnosis of serious mental illness, or intellectual or developmental disability or a related condition.

8.401.20 LEVEL II PASRR EVALUATION

.201 The purpose of the Level II evaluation is to determine whether:

A. Each individual with mental illness or intellectual or developmental disability requires the level of services provided by a nursing facility.

B. An individual has a ~~major~~ serious mental illness or is individuals with an intellectual or developmental disability.

C. The individual requires a Specialized Services program for the mental illness or intellectual or developmental disability.

.203 An individual meets the requirements of a Depression Diversion Screen.

A. A Depression Diversion Screen shall be applied under the following conditions:

1. Depression is the only Level I positive finding (i.e. a depression diagnosis is the only Yes checked on the Level I screen); and

2. The URC or the PASRR Level II Contractor for that geographic area shall make the determination of need for a Depression Diversion Screen.

B. The nursing facilities are not authorized to apply the Depression Diversion Screen.

C. When a ~~non-major~~ serious mental illness depression is validated as the only Level I positive finding through the Depression Diversion Screen, a complete Level II referral and evaluation is not required unless the individual's condition changes.

.206 PASRR Findings from Level II Evaluations

A. PASRR Level II findings shall include the following documentation:

1. The individual's current functional level must be addressed;

2. The presence of diagnosis, numerical test scores, quotients, developmental levels, etc. shall be descriptive; and

3. The findings shall be made available to the family or designated representatives of the nursing facility resident, the parent of the minor individual or the legal guardian of the individual.

B. PASRR Findings from the Level II Evaluations shall be used by the URC in making determinations whether an individual with mental illness or intellectual or developmental disability is appropriate or inappropriate for nursing facility care, and

C. The individual shall be referred back to the URC for a determination of the need for long-term care services if at any time it is found that the individual is not mentally ill or individuals with an intellectual or developmental disability, or has a primary diagnosis of dementia or Alzheimer's disease or related disorders or a non-primary diagnosis of dementia (including Alzheimer's disease or a related disorder) without a primary diagnosis of serious mental illness, or intellectual or developmental disability or a related condition.

8.401.21 SPECIALIZED SERVICES FOR INDIVIDUALS WITH MENTAL ILLNESS OR INDIVIDUALS WITH AN INTELLECTUAL OR DEVELOPMENTAL DISABILITY

.213 Specialized services shall have the following characteristics:

A. The specialized services and treatment plan must be developed and supervised by an interdisciplinary team which includes a physician, a qualified mental health professional and other professionals, as appropriate.

B. Specific therapies, treatments and mental health interventions and activities, health services and other related services shall be prescribed for the treatment of individuals with mental illness who are experiencing an episode of ~~severe~~ serious mental illness which necessitates supervision by trained mental health personnel.

8.401.4 GUIDELINES FOR INSTITUTIONS FOR MENTAL DISEASES (IMD's)

.42 CRITERIA USED FOR DETERMINATION OF IMD STATUS

The primary criteria for the determination of the IMD status of an institution is that more than fifty percent (50%) of all patients in the facility have primary diagnoses of ~~major~~ serious mental illness as determined by the Level II Pre-Admission Screening and Resident Review (PASRR) process which is verified by the Utilization Review Contractor.

8.440 NURSING FACILITY BENEFITS

13. "Class I nursing facility provider" means a private for-profit or not-for-profit nursing facility provider or a facility provider operated by the state of Colorado, a county, a city and county, or special district that provides general skilled nursing facility care to residents who require twenty-four-hour nursing care and services due to their ages, infirmity, or health care conditions, including residents who are behaviorally challenged by virtue of ~~severe~~ serious mental illness or dementia. Swing bed facilities are not included as Class I nursing facility providers.

8.443 NURSING FACILITY REIMBURSEMENT

8.443.23 SUPPLEMENTAL PAYMENT FOR DISPROPORTIONATELY HIGH MEDICAID UTILIZATION OR GEOGRAPHICALLY CRITICAL TO ENSURING ACCESS TO CARE

The Department shall pay a supplemental payment to Class 1 nursing facilities~~facility providers with e~~ither with disproportionately high Medicaid utilization or ~~a facility~~ that are~~is~~ geographically critical to ensuring access to care for Colorado residents.

1. Annually, based on the previous calendar year, the Department shall calculate the percentage of Medicaid patient days to total patient days for each facility participating in the Medicaid program to determine qualification for the high Medicaid utilization payment.

2. The Medicaid utilization shall be calculated by dividing Medicaid patient days by total patient days from the previous calendar year, and exempting days with no payor source or paid by the ~~veterans administration.~~Veterans Health Administration.

    a. Medicaid patient days shall be determined from the MMIS for the calendar year prior to the state fiscal year. Total patient days shall be determined from the nursing facility provider for the calendar year ending prior to the state fiscal year.

3. Facilities will qualify for a tiered payment based on the following factors:

    a. Tier 1: Having a Medicaid utilization of 85% of greater based on the above calculation.

    b. Tier 2: Having a Medicaid utilization of 75% to 84.99% based on the above calculation~~,~~ or being the only Medicaid nursing home provider in the county.

4. Tier 1 facilities will be paid a $10/Medicaid day supplemental payment. Tier 2 facilities will be paid a $5/Medicaid day supplemental payment. Both payments will be calculated Section 8.443.23.1.-2. and paid annually with the following proration:

    a. For the non-state administered nursing facility providers, the amount shall be divided by twelve and reimbursed monthly via ACH transaction or check.

    b. For state administered nursing facility providers the amount shall be divided by four and reimbursed quarterly via intergovernmental transfer.

5. The payment will only be made if there is available federal financial participation under the Upper Payment Limit (UPL). For the purposes of UPL limitations, this payment will be prioritized after all provider fee related supplemental payments but prior to all other nursing facility supplemental payments.

8.443.24 NURSING FACILITY PAROLEES SUPPLEMENTAL MEDICAID PAYMENT

The Department shall make a supplemental Medicaid payment to Class 1 nursing facilities that admit residents directly from the Colorado Department of Corrections (DOC) who are released on parole, or due to compassionate care or medical release.

1. Eligible population includes individuals discharged from the DOC whose medical, behavioral, or social needs are beyond the scope of what is provided in a typical nursing facility setting, which limits their access to care options under the standard nursing home reimbursement rate. The payment for each individual shall be prior authorized, as described in section 3 below, for tiered reimbursement, based on their needs.

    a. Tiered reimbursement add-ons include:

        i. Tier I add-on for individuals who require one or more of the following:

            1) Enhanced staff training/education cost,

            2) Psychosocial supports,

            3) Community readjustment and reintegration supports/resources,

            4) A secure unit or neighborhood,

            5) Specialty intervention,

            6) Medically complex needs,

            7) Personal needs items,

            8) Psychiatry,

            9) Guardianship needs, and

            10) Sex offender treatment (if needed).

        ii. Tier II add-on for individuals who meet Tier I criteria and additionally meet one or more of the following criteria:

1) 1:1 behavioral health support,

2) High behavioral health needs that require a private room,

3) Higher acuity needs, and

4) 4. High-cost medication or specialty equipment needs.

2. Quarterly, the Department shall complete a count of Medicaid patient days for the eligible population. Medicaid-covered patient days shall be pulled from the MMIS. The supplemental payment shall be calculated by multiplying the actual dates of care provided to the eligible population by the applicable per-diem rate. Per-diem rates for Tier I and Tier II individuals shall be published in the Colorado Medicaid Provider Bulletin found on the Department's website at: www.Colorado.gov/hcpf/bulletins. The payment may be adjusted, subject to the following limitations:

   a. The per diem rate shall not exceed fifty percent (50%) of the statewide average MMIS per diem reimbursement rate,

   b. Payments shall be withheld or reduced subject to available UPL reimbursement, and

   c. Payments may be adjusted to account for data corrections in previous payments.

3. The DOC will have a licensed physician review each eligible individual being discharged from parole to verify each individual meets the criteria as outlined in Section 1 above. The licensed physician will document the services needed and submit a prior authorization form to the Department for approval. Both the Department and DOC administration will approve the prior authorization of each individual being discharged from parole prior to the Department authorizing payment to a nursing facility.

8.482.33 Nursing Facility Post Eligibility Treatment of Income – Incurred Medical Expenses (PETI-IME)

Effective April 8, 1988, with respect to the post-eligibility treatment of income of individuals who are institutionalized there shall be taken into account amounts for incurred expenses for medical or remedial care that are not subject to payment by Colorado Medicaid or third party insurance, including health insurance premiums, deductibles or co-insurance; ~~dental care;~~ hearing aids, supplies, and care; corrective lenses, eye care, and supplies; and other incurred expenses for medical or remedial care that are not subject to payment by a third party.

A. All PETI-IME expenses shall be prior authorized by the Department or its designee. The purpose of the prior authorization process is to verify the medical necessity of the services or supplies, to validate that the requested expense is not a benefit of the Medicaid program, and to determine if the expenses requested are a duplication of expenses previously prior authorized.

B. Prior Authorization Request Process:

For allowable PETI-IME expenses costs shall be prior authorized by the Department or its designee. The process is as follows:

1. Prior authorization requests must be submitted to the Department as prescribed by the State through the Provider Web Portal. In addition to the information requested on the web portal form, the following attachments must be included:

    a. For All PETI-IME requests: The medical necessity form legibly signed by the physician (and the physician name legibly written) and resident or resident representative.

    b. For All PETI-IME requests: An itemized invoice with codes and fees for the service or supply being requested.

    c. Additionally, for hearing aids: a current audiogram test less than one year old.

    d. Additionally, for medical health Insurance: premium statement to identify the type of plan, monthly fee and copy of health Insurance card (front and back).

    ~~e. Additionally, for Dental: Medicaid denial of coverage, verification dental benefit has been exhausted.~~

2 Prior authorizations will be certified by the Department based on the following criteria:

    a. The request is not a benefit of the Medicaid program.

    b. The cost of the request does not exceed the basic Medicaid rate for such services or supply.

    c. The special medical service or supply is medically necessary, approved and signed by a physician.

3. The Department or its designee shall review and approve/deny the Prior Authorization Request within fifteen working days of receipt. The Provider Web Portal shall reflect the status of the request.

4. Upon receipt of the approved Prior Authorization Request (PAR), the nursing facility shall submit the PETI-IME reimbursement on the following month's Medicaid billing or on the nursing facility's next billing cycle.

    a. PETI-IME PAR requests must be submitted within the timely filing period of 365 days from the date of service.

    b. For approved PETI-IME PARs requested prior to services rendered, the Department has the discretion to close the PAR if reimbursement is not requested within 12 months from the date of Department approval.

C. Private health insurance premiums, deductibles, or co-insurance as defined by state law.

1. Monthly premium payment paid by the resident for private health insurance.

    a. If premium payments exceed the patient payment amount for one month, a monthly average is calculated by dividing the total premium by the number of

months of coverage. The resulting amount is to be applied as a monthly PETI-IME expense for each month of coverage until spent.

2. Medical health insurance premiums will be allowed for the resident only. This does not include prescription drug, vision, dental or life insurance.

3. Private Health insurance premiums, deductibles, and coinsurance must be reviewed by the Department or its designee yearly for final approval.

   a. If duplicate coverage has been purchased, only the cost of the least expensive policy will be allowed. Premiums, deductibles and co-insurances which the Department or its designee determine to be too expensive in relation to coverage purchased shall not be allowed.

   b. Upon approval, private medical health insurance premiums are billable for 12 months.

D. The allowable expenses for special medical services are subject to the following criteria:

1. General Instructions (applies to all special medical services).

   a. If the resident does not make a patient payment; then no PETI-IME will be allowed. The resident must be Medicaid ~~enrolled~~ approved and not in pending status for any PETI-IME service request to be approved.

   b. Costs will be allowed only if they are not a benefit of the Medicaid program, or not a benefit of other insurance coverage the resident may have.

   c. All allowable costs must be for items that are medically necessary as described in Section 8.076.1.8, and medical necessity must be documented by the attending physician. The physician statement must be current, within one year of the authorization.

   d. The resident or resident representative must agree to the purchase of the service/equipment and related charge, with signed authorization in the resident's record.

   e. Nursing facilities or providers are not permitted to assess a surcharge or handling fee to the resident's income.

   f. The allowable costs for services and supplies may not exceed the basic Medicaid rate.

   g. In the case of damage or loss of supplies, replacement items may be requested with relevant signed documentation. If the damage or loss is due to negligence on the part of the nursing facility, the nursing facility is responsible for the cost of replacement.

   h. Costs will not be allowed if the equipment, supplies or services are for cosmetic reasons only.

      i. Monthly PETI-IME payments may not exceed the monthly patient payment. Approval for reimbursement shall only be allowed if the provider agrees to accept installment payments.

j. For special medical services/supplies provided but not yet paid for, the encumbrance agreement and monthly payment schedule must be documented in the resident's record, as well as receipts of payment.

~~2. Dental Care Instructions~~

~~In 2013, the state legislature passed Senate Bill 242 which authorized the Department to create a new limited dental benefit in Medicaid for adults age 21 and over. Once the benefit has been exhausted, then a PETI-IME request may be submitted to the Department for approval for the additional services.~~

~~a. Documentation showing the allowed benefit has been exhausted for the current year shall be attached to the prior authorization request.~~

~~b. The signed medical necessity form and itemized invoice shall be attached to the prior authorization request.~~3.2. Hearing Aid Instructions

a. All referrals for hearing aids must be authorized by the attending physician, and must include an evaluation for suitability and specifications of the appropriate appliance performed by a licensed audiologist.

b. Purchase of new hearing aids to replace pre-existing hearing aids must include documentation of necessity of replacement of the pre-existing hearing aid. New hearing aids are a benefit after five (5) years with appropriate documentation.

c. Documentation attached to the prior authorization request should include the signed medical necessity form, itemized invoice with codes and fees and current (within one (1) year) audiogram.

~~4.~~3. Corrective Lenses Instructions

PETI-IME expenses for corrective lenses will be limited to services not covered under Section 8.203 Vision Services. Corrective lenses are limited to one (1) pair per twenty-four (24) month period under Section 8.203.4.B. For a change in vision within twenty-four (24) months, an eye exam is required to show the change in vision.

a. The evaluation of the need for corrective eyeglasses (lenses) must be a part of a comprehensive general visual examination conducted by a licensed ophthalmologist or optometrist.

b. The medical necessity for prescribed corrective lenses should not be based on the determination of the refractive state of the visual system alone, but should be identified by the current procedural terminology in the Physician Current Procedures Terminology (CPT) Code as established by the American Medical Association.

i. Documentation attached to the prior authorization request should include the signed medical necessity form and itemized invoice.

~~5.~~4. All documentation of the incurred expenses must be available in the client's financial and medical record for audit purposes by the Department or its designee. Lack of documentation shall cause the PETI-IME to be disallowed and shall be considered an overpayment subject to recovery by the Department. Documentation shall include:

a. Printed copy of approved PAR.

b. Copy of all attachments to the PAR.

c. Yearly nursing facility tracking activity log that includes the ~~dental,~~ vision and PETI-IME reimbursement activity. Specifically:

1) Member number and name receiving the service;

2) Type of service requested;

3) Date service was requested by the member;

4) Date PAR was added to Provider Web Portal:

5) Date PAR was approved by the Department;

6) Date facility received payment from Medicaid for service;

7) Date service provider was paid by the facility;

8) Date service was rendered to the member;

9) When/if the member's personal needs funds were used;

10) When applicable, documentation that the member's personal needs account was reimbursed;

11) Documentation that the member was still at the facility when the service was rendered;

d. All documentation shall be retained for six years and is subject to audit by the Department or its designee.

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Rule concerning the Program of All-Inclusive Care for the Elderly (PACE), Section 8.497
Rule Number: MSB 22-08-02-A
Division / Contact / Phone: Benefits & Services Division / Zack Gibbons / 303-866-5100

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 22-08-02-A, Revision to the Medical Assistance Rule concerning the Program of All-Inclusive Care for the Elderly (PACE), Section 8.497

3. This action is an adoption of: Senate Bill 22-203

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

   Sections(s) 8.497, 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 8.497 with the proposed text beginning at 8.497 through the end of 8.497.14.F.3.c. This rule is effective April 30, 2024.

*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).

   PACE provides comprehensive health services for individuals age 55 and older who meet nursing facility levels of care and are able to live in a community setting without jeopardizing their health or safety. A PACE organization is responsible for providing care that meets the needs of each participant across all care settings, 24 hours a day, every day of the year. Services must be furnished in at least the PACE center, the home, and inpatient facilities, up to and including admission to an acute care or long-term care facility when the PACE program can no longer support the participant safely in the community. The PACE center includes a primary care clinic and areas for therapeutic recreation, restorative therapies, socialization, personal care, and dining, and serves as the focal point for coordination and provision of most PACE services. There are currently five PACE organizations operating in Colorado with a total of 12 PACE centers across the state. The areas served include zip codes in: Aurora, Colorado Springs, Delta, Denver, Grand Junction, Lafayette, Lakewood, Loveland, Montrose, and Thornton.

   Historically, the Department has held PACE organizations accountable to the federal rules for PACE through individual contracts with each organization and has not had a comprehensive set of Colorado state specific regulations. The Centers for Medicare and Medicaid Services (CMS) took the lead in conducting audits of PACE organizations in coordination with the Department. In recent years, CMS has changed their audit schedule, creating an opportunity for the Department to initiate its own auditing process. Because of this, Senate Bill 22-203 was adopted in order for the Department to implement a state-specific regulatory set in Colorado. The ultimate purpose of this rule change is for the Department to establish minimum regulatory standards and rules for the PACE program in order to sufficiently ensure the health, safety, and welfare of PACE participants.

   The following is a brief summary of key points covered in the rule:

   - Incorporation of the federal rule set by reference throughout to avoid conflict with the federal rule.
   - Department-specific application requirements for an entity seeking to become a PACE organization in Colorado, or an existing PACE organization seeking to expand its service area.

Initial Review	**02/09/24**	Final Adoption	**03/08/24**
Proposed Effective Date	**04/30/24**	Emergency Adoption	

DOCUMENT #

- Violations for which the Department may impose sanctions, along with authority to suspend new participant enrollment of, and suspend payment to, PACE organizations.
- Training requirements of PACE staff members.
- Minimum standards of transportation services, including maintenance of vehicles and qualifications of drivers.
- Allowable use of telehealth for provision of services delivered under PACE.

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 C.F.R. §460.190

4. State Authority for the Rule: Senate Bill 22-203

   Sections 25.5-5-412, C.R.S.

Sections 25.5-1-301 through 25.5-1-303, C.R.S. (2023)

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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 proposed regulation will positively affect adults aged 55 and older who reside in a PACE service area and who need the level of care required under the State Medicaid plan for coverage of nursing facility services, making them eligible to enroll in a PACE program. There is no cost of this rule to PACE participants or PACE organizations operating in Colorado. The benefit to these participants is the provision to the Department of formal oversight and compliance enforcement of PACE organizations operating in Colorado, to ensure the highest possible quality level of care provided to PACE participants.

   The Department and the Colorado Department of Public Health and Environment (CDPHE) may incur some additional costs to implement oversight activities, including onsite inspections. However, the projected additional costs are already accounted for in the budgets of both agencies.

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

   These proposed regulations will improve participant outcomes by holding PACE organizations accountable to these regulations which have been developed and designed to ensure the health, safety, and welfare of PACE participants.

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 does not anticipate any costs to be incurred by PACE organizations as PACE organizations are currently required to adhere to a large majority of these rules under Center for Medicare and Medicaid Services federal regulations, the PACE contract, and the PACE program agreement.

   The Fiscal Note for SB22-203 did not appropriate funding for oversight activities. The appropriation for the development of the rules was allocated through American Rescue Plan Act (ARPA) dollars. The Department will still need to work with

stakeholders and CDPHE for the next phase of this project, which is to determine who the survey agency will be and whether there will be licensure through CDPHE or certification through HCPF. A budget request will be submitted at that time to request funding for survey oversight activities.

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

   Inaction will result in the lack of formal regulatory oversight authority by the Department and the ability to ensure the health, safety, and well-being of PACE participants. It will also place the Department out of compliance with its obligations under Senate Bill22-203, codified at C.R.S. § 25.5-5-412.

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

   There are no less costly or less intrusive methods for achieving the purpose of the proposed rule, which is to ensure the health, safety, and welfare of PACE participants.

6. At present, PACE organizations are required to adhere to the terms and provisions outlined in their contract. However, based on existing concerns with service delivery in the PACE program, the Colorado legislature determined that additional oversight was required to ensure adequate service delivery and passed Senate Bill 22-203 as a result. 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 were no other options considered by the Department as this rule has been developed specifically based on the requirements laid out in Senate Bill 22-203.

8.497 PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

8.497.1 ~~ENROLLMENT BROKER~~ STATUTORY AUTHORITY AND APPLICABILITY

8.497.1.A. ~~PACE organizations shall be allowed to contract with the Department's enrollment broker to include information on PACE in materials the enrollment broker provides to clients.~~ The statutory authority for these rules is set forth in § 25.5-5-412, C.R.S.

8.497.1.B. ~~PACE organizations shall be responsible for all costs associated with the marketing of PACE through the enrollment broker.~~ A PACE organization, as defined herein, must comply with all applicable federal, state, and local statutes, regulations, and laws including but not limited to the following:

1. Code of Federal Regulations (CFR), Title 42 – Public Health, Chapter IV – Centers for Medicare & Medicaid Services, Department of Health and Human Services, Subchapter E Programs of All-Inclusive Care for the Elderly (PACE), Part 460 – Programs of All-Inclusive Care for the Elderly (PACE). This will be referred to in this regulation as 42 CFR 460.

2. Section 25.5-5-412, C.R.S.

8.497.1.C. ~~[Expired 05/15/2016 per House Bill 16-1257]~~ A PACE organization must have an agreement with the CMS and the Department, as defined herein, for the operation of a PACE program.

8.497.2 ~~ENROLLMENT~~ SCOPE AND PURPOSE

8.497.2.A. ~~An eligible person, as defined by 25.5-5-412 (7)(b) C.R.S., who is enrolled in a managed care organization, the Accountable Care Collaborative program or other risk-bearing entity may elect to disenroll and enroll in and receive services through a PACE organization. The effective date of an eligible person's disenrollment shall be no later than the first day of the second month following the month in which the eligible person files the request.~~ The purpose of these rules is to implement § 25.5-5-412, C.R.S. which require the Department to establish, administer, and enforce minimum regulatory standards and rules for the PACE program, including for contracted entities of the PACE program, to ensure the health, safety and welfare of PACE participants.

8.497.2.B. ~~[Expired 05/15/2016 per House Bill 16-1257]~~ Scope and purpose.

1. General. This regulation sets forth the following:

   a. The requirements that an entity must meet to be approved as a PACE organization that operates a PACE program under Medicaid in the State of Colorado;

   b. Marketing requirements for PACE organizations;

   c. Requirements for ensuring fiscal soundness of PACE organizations;

   d. Procedures for sanctions, enforcement actions, and terminations;

   e. How individuals may qualify to enroll in a PACE program;

   f. Reimbursement for PACE services;

g. Provisions for State monitoring of PACE programs;

h. General PACE organization requirements and PACE services;

i. Requirements to collect data, maintain records and report information, including encounter data; and

j. Requirements for PACE quality improvement monitoring.

2. Program purpose. PACE provides, prepaid, capitated, comprehensive health care services designed to meet the following objectives:

a. Enhance the quality of life and autonomy for older adults who require the level of care provided in a nursing facility;

b. Maximize dignity of, and respect for, older adults;

c. Enable older adults to live in the community as long as medically and socially feasible; and

d. Preserve and support the older adult's family unit.

8.497.3 DEFINITIONS

As used in this regulation, unless the context indicates otherwise, the following definitions apply:

A. CMS means Centers for Medicare and Medicaid Services.

B. Dementia diseases and related disabilities means a condition where mental ability declines and is severe enough to interfere with an individual's ability to perform everyday tasks. Dementia diseases and related disabilities include Alzheimer's disease, mixed dementia, Lewy Body Dementia, vascular dementia, frontotemporal dementia, and other types of dementia.

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

D. Designated Representative means a representative who is designated by the participant to act on the participant's behalf.

E. Medicaid participant means an individual determined eligible for Medicaid who is enrolled in a PACE program.

F. PACE means the programs of all-inclusive care for the elderly.

G. PACE center is a facility which includes a primary care clinic, and areas for therapeutic recreation, restorative therapies, socialization, personal care, and dining, and which serves as the focal point for coordination and provision of most PACE services.

H. PACE contract means the contract between the Department and a PACE organization.

I. PACE organization means an entity that has in effect a PACE program agreement to operate a PACE program under this regulation.

J. PACE program means a program of all-inclusive care for the elderly that is operated by an approved PACE organization and that provides comprehensive healthcare services to PACE enrollees in accordance with a PACE program agreement.

K. PACE program agreement means an agreement between a PACE organization, CMS, and the Department.

L. Participant means an individual who is enrolled in a PACE program.

M. Service, as used in this regulation, means all services that could be required under Section 8.497.8.B., including items and drugs.

N. State administering agency means the Department.

O. Survey Agency means either the Colorado Department of Public Health and Environment or any contractor the Department engages to conduct onsite inspections of a PACE center.

P. Subcontractor means a third party contracted with a PACE organization to aid in performance of the PACE contract work.

Q. Telehealth means a mode of delivery of health care services through HIPAA-compliant telecommunications systems, including information, electronic, and communication technologies, remote monitoring technologies and store-and-forward transfers, to facilitate the assessment, diagnosis, consultation, treatment, education, care management, or self-management of a covered person's health care while the covered person is located at an originating site and the provider is located at a distant site.

R. The Act means the Social Security Act.

S. Trial period means the first 3 contract years in which a PACE organization operates under a PACE program agreement, including any contract year during which the entity operated under a PACE demonstration waiver program.

8.497.4 PACE ORGANIZATION APPLICATION AND WAIVER PROCESS

8.497.4.A. This section sets forth the application procedures and the process by which a PACE organization may request a waiver of certain regulatory requirements, pursuant to 42 CFR § 460.10.

8.497.4.B. Application requirements.

1. The application requirements for PACE organizations shall be in accordance with 42 CFR § 460.12.

2. Letter of intent. Prior to submission of an application. Any individual authorized to act for an entity seeking to become a PACE organization or a PACE organization that seeks to expand its service area and/or add a PACE center site must notify the Department by submitting a letter of intent in the form and manner specified by the Department at least 90 calendar days before the anticipated application date.

3. Department-specific application requirements. An entity’s application to the Department to become a PACE organization or to expand its service area and/or add a PACE center must contain information to demonstrate financial and operational stability. This includes, but is not limited to:

a. Financial assets;

b. Additional owners and/or financially invested organizations;

c. Risk reserve;

d. Reinsurance; and

e. Staff recruitment and retention program.

4. The Department may allow more than one PACE organization per zip code.

8.497.4.C. Department evaluation of applications. The Department evaluates an application in accordance with the requirements of 42 CFR § 460.18 and based on the following information.

1. Information contained in the application;

2. Information obtained by the Department or a Survey Agency through on-site visits or any other means;

3. Department and/or state of Colorado budgetary considerations and constraints; and

4. Financial and operational stability of the applicant.

8.497.4.D. Notice of the Department's determination will be conducted in accordance with 42 CFR § 460.20.

8.497.4.E. Submission and evaluation of waiver requests. A PACE organization, or an entity submitting an application to become a PACE organization, must submit its waiver request in accordance with 42 CFR § 460.26.

8.497.4.F. Notice of the Department's determination on waiver requests will be conducted in accordance with 42 CFR § 460.28.

8.497.5 PACE PROGRAM AGREEMENT

8.497.5.A. A PACE program agreement must meet the requirements set forth at 42 CFR § 460.30.

8.497.5.B. Content and terms of PACE program agreement.

1. The PACE program agreement must include:

a. All content required by 42 CFR § 460.32.

b. The criteria used to determine if an individual's health or safety would be jeopardized by living in a community setting at the time of enrollment.

8.497.5.C. The duration of the PACE program agreement shall be in accordance with 42 CFR § 460.34.

8.497.5.D. The PACE organization must comply with all requirements of the PACE program agreement. If the PACE program agreement is amended or modified in any way, the amendment or modification must be automatically incorporated herein as of the effective date of the amendment or modification, and the PACE organization must comply with all requirements of the amendment or modification as of that date.

8.497.6 SANCTIONS, ENFORCEMENT ACTIONS, AND TERMINATION

8.497.6.A. Violations for which the Department may impose sanctions.

1. In addition to other remedies authorized by law or contract, the Department may impose any of the sanctions specified in Section 8.497.6.B., if the Department or a Survey Agency determines that a PACE organization commits any of the violations specified in 42 CFR § 460.40(a) or the following violations:

   a. Makes payment to or employs or contracts with any individual or organization that has a criminal conviction as defined in 42 § CFR 460.68(a); or

   b. Makes payment to individuals and entities excluded by the Office of Inspector General or included on the preclusion list as pursuant to 42 § CFR 460.86.

2. If the Department or a Survey Agency makes a determination that could lead to termination of a PACE program agreement under Section 8.497.6.C., the Department may impose any of the sanctions specified in Section 8.497.6.B. If the Department determines that the circumstances in Section 8.497.6.C.2.a. exist, the Department does not have to determine that the circumstances in Section 8.497.6.C.2.b. exist prior to imposing an enrollment and/or payment suspension.

8.497.6.B. Suspension of enrollment or payment by the Department.

1. Enrollment Suspension. If a PACE organization commits one or more violations specified in 42 CFR § 460.40(a), the Department may suspend enrollments or place a limit on enrollments after the date the Department notifies the organization of the violation.

2. Payment Suspension. If a PACE organization commits one or more violations specified in 42 CFR § 460.40(a), for participants enrolled after the date the Department notifies the PACE organization of the violation, the Department may suspend Medicaid payment to the PACE organization.

3. Term of suspension. A suspension or denial of payment remains in effect until the Department is satisfied that the following conditions are met:

   a. The PACE organization has corrected the cause of the violation; and

   b. The violation is not likely to recur.

4. Restrictions and Conditions. The Department may impose restrictions or conditions on a PACE organization, which may include at least one of the following:

   a. Retaining a consultant to monitor the effectiveness of corrective measures for a specific period determined by the Department;

   b. Monitoring the effectiveness of corrective measures by the Department for a specific period; or

   c. Requiring additional training for personnel, owners, or operators of the PACE organization.

5. Notification and Plan Requirements.

a. If the Department imposes any restriction or condition that is not the result of a serious and immediate threat to the health, safety, or welfare of a PACE participant, the Department shall notify the PACE organization of the restriction or condition in writing.

b. If the Department imposes any restriction or condition that is the result of a serious and immediate threat to the health, safety, or welfare of a PACE participant, the Department shall notify the PACE organization of the restriction or condition in writing, by telephone, or in person during an on-site visit.

i. The PACE organization must remedy the circumstances creating the harm or likelihood of harm immediately upon receiving notice of the restriction or condition.

c. If the Department provides notice of a restriction or condition by telephone or in person, the Department shall send written confirmation of the restriction or condition to the PACE organization.

d. A PACE organization must complete corrective action as specified in Section 8.497.13.C.1.

8.497.6.C. Termination of a PACE program agreement. The Department may terminate a PACE program agreement for cause, pursuant to 42 CFR § 460.50.

8.497.6.D. Transitional care during termination. The PACE organization must meet the transitional care requirements set forth in 42 CFR § 460.52.

8.497.6.E. Termination procedures.

1. Except as provided in Section 8.497.6.E.2., if the Department terminates a PACE program agreement with a PACE organization, it will furnish the PACE organization with a reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies that were the basis of the Department's determination that cause exists for termination:

2. The Department may terminate a PACE program agreement and PACE contact without invoking the procedures in Section 8.497.6.E.1. if the Department determines that a delay in termination, resulting from compliance with these procedures before termination, would pose an imminent and serious risk to the health of participants enrolled with the organization..

8.497.7 PACE ADMINISTRATIVE REQUIREMENTS

8.497.7.A. PACE organizational structure. The PACE organizational structure must comply with the requirements set forth in 42 CFR § 460.60.

8.497.7.B. Governing body. The governing body of the PACE organization must comply with the requirements set forth in 42 CFR § 460.62

8.497.7.C. Compliance oversight requirements.– The PACE organization must adopt and implement compliance oversight requirements in accordance with 42 CFR § 460.63.

8.497.7.D. Personnel qualifications for staff with direct participant contact. The PACE organization must comply with the personnel qualifications set forth in 42 CFR § 460.64.

8.497.7.E. Training.

1. The PACE organization must provide training to maintain and improve the skills and knowledge of each staff member with respect to the individual's specific duties that results in their continued ability to demonstrate the skills necessary for the performance of the position.

2. In addition to the general qualification requirements specified in 42 CFR § 460.66, all PACE organization personnel having direct participant contact must complete the following trainings annually. Newly hired personnel must complete the training before working independently:

a. Mandatory reporting of adult mistreatment. Staff members must complete training that includes reporting requirements as specified in C.R.S. § 18-6.5-108;

b. The service determination process as specified in Section 8.497.9.G; and

c. Dementia diseases and related disabilities. The training must be culturally competent and include at least the following content:

i. Dementia disease and related disabilities.

ii. Person-centered care.

iii. Care planning.

iv. Activities of daily living.

v. Dementia-related behaviors and communication.

3. All orientation, training, competency, and personnel action documentation must be retained in the personnel files.

8.497.7.F. Program integrity. The PACE organization must comply with the program integrity requirements set forth in 42 CFR § 460.68.

8.497.7.G. Contracted services. The PACE organization must comply with the contracted service requirements set forth in 42 CFR § 460.70.

8.497.7.H. Oversight of direct participant care. The PACE organization must oversee direct participant care in accordance with the requirements set forth in 42 CFR § 460.71.

8.497.7.I. Physical environment. The PACE center must meet the physical environment requirements set forth in 42 CFR § 460.72.

8.497.7.J. Infection control. The PACE organization must comply with the infection control requirements set forth in 42 CFR § 460.74.

8.497.7.K Transportation services.

1. Safety, accessibility, and equipment. A PACE organization's transportation services must be safe, in good working order, accessible, and equipped to meet the needs of the participant population and meet the transportation services requirements set forth in 42 CFR § 460.76.

2. Maintenance of vehicles.

a. If the PACE organization owns, rents, or leases transportation vehicles, it must maintain these vehicles in accordance with the manufacturer's recommendations.

b. If a contractor provides transportation services, the PACE organization must ensure that the vehicles are maintained in accordance with the manufacturer's recommendations.

c. Safety inspections must include the inspection of items as described in Rules Regulating Transportation by Motor Vehicle, 4 CCR 723-6; § 6103 and § 6104.

3. Drivers.

a. PACE organizations must ensure that each driver meets the following requirements:

i. Drivers must be 18 years of age or older;

ii. Have at least one year of driving experience;

iii. Possess a valid Colorado driver's license.

iv. Provide a copy of their current Colorado motor driving vehicle record, with the previous seven years of driving history; and

v. Complete a Colorado or National-based criminal history record check.

b. Drivers must be disqualified from serving as drivers for any program participants for any of the following reasons:

i. A conviction of substance abuse occurring within the seven (7) years preceding the date the criminal history record check is completed;

ii. A conviction in Colorado, at any time, of any Class 1 or 2 felony under Title 18, C.R.S.;

iii. A conviction in Colorado, within seven (7) years preceding the date the criminal history record check is completed, of a crime of violence, as defined in C.R.S. § 18-1.3-406(2);

iv. A conviction in Colorado, within four (4) years preceding the date the criminal history record check is completed, of any Class 4 felony under Title 18, Articles 2, 3, 3.5, 4, 5, 6, 6.5, 8, 9, 12, or 15, C.R.S.;

v. A conviction of an offense in any other state that is comparable to any offense listed in subparagraphs (f)(II)(A) through (D) within the same time periods as listed in subparagraphs (f)(II)(A) through (D) of Rules Regulating Transportation by Motor Vehicle, 4 C.C.R. 723-6; § 6114;

vi. A conviction in Colorado, at any time, of a felony or misdemeanor unlawful sexual offense against a child, as defined in § 18-3-411, C.R.S., or of a comparable offense in any other state or in the United States at any time;

vii. A conviction in Colorado within two (2) years preceding the date the criminal history record check is completed of driving under the influence, as described in § 42-4-1301(1)(f), C.R.S. or driving with excessive alcoholic content, as described in §42-4-1301(1)(g), C.R.S;

viii. A conviction within two (2) years preceding the date the criminal history record check is completed of an offense comparable to those included in subparagraph (f)(III)(B), 4 C.C.R. 723-6; § 6114 in any other state in the United States; and

ix. For purposes of 4 C.C.R. 723-6; § 6114(f)(IV), a deferred judgment and sentence pursuant to § 18-1.3-102, C.R.S., shall be deemed to be a conviction during the period of the deferred judgment and sentence.

8.497.7.L. Dietary services. The PACE organization must comply with the dietary services requirements set forth in 42 CFR § 460.78.

8.497.7.M. Fiscal Soundness. The PACE organization must comply with the fiscal soundness requirements set forth in 42 CFR § 460.80.

8.497.7.N. Marketing.

1. The PACE organization must comply with the marketing requirements set forth in 42 CFR § 460.82.

2. Marketing information must be free of material inaccuracies, misleading information, or misrepresentations on all platforms.

3. The Department retains the right to disapprove previously approved marketing materials if they are subsequently found to be inaccurate, altered, or otherwise non-compliant.

8.497.7.O. Emergency preparedness. The PACE organization must comply with all applicable federal, state, and local emergency preparedness requirements and must establish and maintain an emergency preparedness program that meets the requirements set forth in 42 CFR § 460.84.

8.497.8 PACE SERVICES

8.497.8.A. Pursuant to 42 CFR § 460.90, if an eligible Medicaid participant elects to enroll in a PACE program:

1. Medicare and Medicaid benefit limitations and conditions relating to amount, duration, scope of services, deductibles, copayments, coinsurance, or other cost-sharing do not apply.

2. The participant, while enrolled in a PACE program, must receive Medicare and Medicaid benefits solely through the PACE organization.

8.497.8.B. Required services. The PACE organization must comply with the requirements set forth in 42 CFR § 460.92.

8.497.8.C. Excluded services. The services set forth in 42 CFR § 460.96 are excluded from coverage under PACE.

8.497.8.D. Service delivery.

1. Access to services. The PACE organization is responsible for providing care that meets the needs of each participant across all care settings, 24 hours a day, every day of the year, and must establish and implement a written plan to ensure that care is appropriately furnished.

2. Provision of services.

a. The PACE organization must provide services in accordance with 42 CFR § 460.98(b).

b. The PACE organization must visit each participant in-person or via telehealth across all care settings as often as the participant's condition requires, but no less than once each calendar month.

i. If a participant does not receive a visit during a calendar month, the PACE organization must notify the Department, in writing, within 15 calendar days of the following calendar month. The notice must explain the reason(s) why the participant did not receive a visit.

ii. For the purposes of this requirement, a visit must be provided directly by PACE staff or a contracted specialist. The delivery of items or medications and services routinely provided by a contracted residential care provider are not considered a visit.

iii. If the PACE organization provides these visits via telehealth, the PACE organization must ensure the telehealth delivery option meets the following requirements:

1) Participants must have an informed choice between in-person and telehealth services;

2) The use of the telehealth delivery option will not prohibit or discourage the use of in-person services;

3) Telehealth will not be used for the provider's convenience; and

~~1)~~4) Telehealth must be provided using technology compliant with Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy, Security and Breach Notification Rules.

iv. The telehealth permissions in this section do not apply to the in-person assessment and reassessment requirements as described in 8.497.8.G.

3. Minimum services furnished at each PACE center. At a minimum, the PACE organization must provide the services set forth in 42 CFR § 460.98(c) at each PACE center.

4. PACE center operation. The PACE organization must operate its center(s) in accordance with 42 CFR § 460.98(d).

a. Services at the PACE center must be provided consistent with any applicable standards of practice for that service, and, when applicable, by staff with the requisite qualifications to perform the service.

5. Center attendance. The frequency of a participant's attendance at a center is determined by the interdisciplinary team, based on the needs and preferences of each participant.

8.497.8.E. Emergency care. The PACE organization must comply with the emergency care requirements set forth in 42 CFR § 460.100.

8.497.8.F. Interdisciplinary team. The PACE organization must comply with the interdisciplinary team requirements set forth in 42 CFR § 460.102.

8.497.8.G. Participant assessment.

1. The PACE organization must comply with the assessment and plan of care requirements set forth in 42 CFR § 460.104.

2. Unscheduled reassessments. In addition to the requirements set forth in 42 CFR § 460.104(d), as it relates to a participant being discharged from a hospital, the appropriate members of the interdisciplinary team, as identified by the interdisciplinary team, must conduct an in-person assessment within 72 hours of a participant's hospital discharge for a participant who was admitted for 24 hours or more.

8.497.8.H. Plan of care.

1. The PACE organization must comply with the plan of care requirements set forth in 42 CFR § 460.106.

2. Residential care provider involvement in plan of care. For participants receiving residential care, the PACE organization must include residential care providers in the evaluation of the plan of care and share the plan of care with residential care providers.

8.497.9 PARTICIPANT RIGHTS

8.497.9.A. Bill of rights. The PACE organization must comply with the requirements set forth in 42 CFR § 460.110.

8.497.9.B. Specific rights to which a participant is entitled. The PACE organization must comply with the requirements set forth in 42 CFR § 460.112.

1. Information disclosure. In addition to the requirements set forth in 42 CFR § 460.112(b), the participant has the following rights:

a. To receive a list of the employees of the PACE organization who furnish direct care to the participant upon enrollment and upon request. At a minimum, the list must include each discipline of the interdisciplinary team as set forth in 42 CFR § 460.102(b).

b. To have an equal opportunity to receive meaningful communication and to participate fully in discussions involving the PACE program, services, activities, eligibility, enrollment and other benefit information, in the language preferred by the participant.

8.497.9.C. Restraints. The PACE organization must comply with the requirements set forth in 42 CFR § 460.114.

8.497.9.D. Explanation of rights. The PACE organization must comply with the requirements set forth in 42 CFR § 460.116 and must display the contact information for the Colorado PACE Ombudsman in a prominent place in the PACE center.

8.497.9.E. Violation of rights. The PACE organization must have established documented procedures to respond to and rectify a violation of a participant's rights.

8.497.9.F. Grievance process. The PACE organization must comply with the requirements set forth in 42 CFR § 460.120.

8.497.9.G. Service determination process.

1. The PACE organization must comply with the requirements set forth in 42 CFR § 460.121.

2. PACE organization decisions to reduce or terminate services. If the PACE organization terminates or reduces a service, without the participant requesting the termination or reduction, the PACE organization must provide written notice to the participant of the right to file a service determination request to continue the service.

8.497.9.H. PACE organization's appeals process.

1. The PACE organization must comply with the requirements set forth in 42 CFR § 460.122.

2. A PACE participant must exhaust the internal appeals process described in this part prior to requesting a State Fair Hearing as described in Section 8.497.9.I. and 10 CCR 2505-10 8.057.

8.497.9.I. Additional Appeal Rights Under Medicare or Medicaid.

1. A PACE organization must comply with the requirements set forth in 42 CFR § 460.124.

2. Medicaid participants have the right to a state fair hearing under Section 8.057. Appeals must be filed within 60 calendar days of the date of the notice of adverse action.

8.497.10 QUALITY IMPROVEMENT

8.497.10.A. Quality improvement program and plan. A PACE organization must establish, implement, maintain, and evaluate an effective data-driven quality improvement program and plan, pursuant to 42 CFR § 460.130 and 460.132, that contains all requirements set forth in 42 CFR § 460.134.

8.497.10.B. Internal quality improvement activities. A PACE organization must comply with the requirements set forth in 42 CFR § 460.136.

8.497.10.C. Committees with community input. A PACE organization must comply with the requirements set forth in 42 CFR § 460.138.

1. Minimum program requirements.– A PACE organization's quality improvement program must include, but is not limited to, the use of objective measures to demonstrate improved performance with regard to the following:

8.497.11 PARTICIPANT ENROLLMENT AND DISENROLLMENT

8.497.11.A. Eligibility to enroll in a PACE program. A PACE organization must comply with the requirements set forth in 42 CFR § 460.150.

8.497.11.B. Enrollment process.

1. A PACE organization must comply with the requirements set forth in 42 CFR § 460.152.

2. Additional intake process requirements.

a. At least one member of an interdisciplinary team must assess the individual in the individual's place of residence prior to enrollment. This assessment must be completed by a Registered Nurse, Physical Therapist, Occupational Therapist, Home Care Coordinator, or appropriate members of an interdisciplinary team as appointed by an interdisciplinary team.

b. The appropriate members of an interdisciplinary team, as identified by an interdisciplinary team, must review and discuss each potential participant and decide to approve or deny the individual's enrollment based on that review.

8.497.11.C. Enrollment agreement. If the potential participant meets the eligibility requirements and wants to enroll, he or she must sign an enrollment agreement which contains, at a minimum, the information required by 42 CFR § 460.154.

8.497.11.D. Other enrollment procedures. The PACE organization must comply with the requirements set forth in 42 CFR § 460.156.

8.497.11.E. Effective date of enrollment. A participant's enrollment in the program is effective on the first day of the calendar month following the date the PACE organization receives the signed enrollment agreement.

8.497.11.F. Continuation of enrollment.

1. The PACE organization must comply with the requirements set forth in 42 CFR § 460.160.

2. In addition to the waiver of annual requirement regulations set forth in 42 CFR § 460.160(b)(1), a participant who continues to meet nursing facility level of care during their first annual recertification, is permanently waived from the annual recertification requirement.

3. In addition to the deemed continued eligibility regulations set forth in 42 CFR § 460.160(b)(2), the following apply:

a. If the PACE organization believes the participant would be expected to meet the nursing facility level of care within the next 6 months, the organization must submit a request for deemed continued eligibility in the form and manner specified by the Department.

b. The Department will notify the PACE organization of the Department's decision in writing within 15 calendar days upon receipt of all requested information.

c. If the Department determines the participant does not qualify for deemed continuous eligibility, the PACE organization must follow involuntary disenrollment procedures as described in Section 8.497.11.H., unless the participant chooses to voluntarily disenroll.

8.497.11.G. Voluntary disenrollment. The PACE organization must comply with the voluntary disenrollment requirements set forth in 42 CFR § 460.162.

8.497.11.H. Involuntary disenrollment.

1. The PACE organization must comply with the involuntary disenrollment requirements set forth in 42 CFR § 460.164.

2. In addition to the reasons for involuntary disenrollment regulations set forth in 42 CFR § 460.164(b), the following applies for involuntary disenrollment:

a. As it relates to 42 CFR § 460.164(b)(1) and 460.164(b)(2), the PACE organization must provide written notice to the participant, designated representative, or both explaining the amount due.

b. A participant may be involuntarily disenrolled if the participant engages in noncompliant behavior, as described in 42 CFR § 460.164(e).

3. Involuntary disenrollment request requirements.

a. A PACE organization must submit an involuntary disenrollment request to the Department in a timely manner and in the form and manner specified by the Department.

b. Before an involuntary disenrollment is effective, the Department must review it and determine in a timely manner that the PACE organization has adequately documented acceptable grounds for disenrollment.

8.497.11.I. Disenrollment responsibilities. The PACE organization must comply with the disenrollment responsibilities requirements set forth in 42 CFR § 460.166.

8.497.11.J. Reinstatement in Medicaid programs. The PACE organization must comply with the reinstatement in other Medicaid program requirements set forth in 42 CFR § 460.168.

8.497.11.K. Reinstatement in PACE. The PACE organization must comply with the reinstatement in PACE requirements set forth in 42 CFR § 460.170.

8.497.11.L. Documentation of disenrollment. The PACE organization must comply with the documentation of disenrollment requirements set forth in 42 CFR § 460.172.

8.497.12 PAYMENT

8.497.12.A. Medicaid payment.

1. The PACE organization shall receive Medicaid payments in accordance with 42 CFR § 460.182.

2. The Department may also recover, at the Department's discretion, payments made to the PACE organization in error for any reason, including, but not limited to, overpayments, improper payments, and excess funds received by the PACE organization by deduction from subsequent payments as specified in the PACE contract, deduction from any payment due under any other contracts, grants or agreements between Colorado and the PACE organization, or by any other appropriate method for collecting debts owed to the Department.

3. Payment Reconciliations. A PACE organization must adhere to the terms related to the participant-specific amount reconciliation, participant-specific reconciliation payments, and annual reconciliation as specified in the PACE contract.

8.497.12.B. Post-eligibility treatment of income.

1. The Department may provide for post-eligibility treatment of income for PACE participants as set forth in Sections 8.482.33 and 8.485.80.

2. Post-eligibility treatment of income is applied, as specified in 42 CFR § 460.184(b).

8.497.12.C. PACE premiums. The PACE organization must comply with the PACE premiums requirements set forth in 42 CFR § 460.186.

8.497.13 STATE MONITORING

8.497.13.A. Monitoring during trial period. During the trial period, the Department conducts comprehensive annual reviews of the operation of a PACE organization, in accordance with the requirements and scope set forth in 42 CFR § 460.190.

8.497.13.B. Ongoing monitoring after trial period. At the conclusion of the trial period, the Department continues to conduct review of a PACE organization, as appropriate, in accordance with the requirements set forth in 42 CFR § 460.192.

8.497.13.C. Corrective action. The PACE organization must comply with the requirements set forth in 42 CFR § 460.194. In addition, as it relates to a corrective action plan, a PACE organization must:

1. Submit an acceptable corrective action plan in the form, manner and timeframe specified by the Department, when corrective action is deemed necessary by the Department. An acceptable plan must include but is not limited to:

a. The corrective action the PACE organization will take on behalf of the participants affected by the deficient practice;

b. How the PACE organization will identify other participants who could be affected by the same deficient practice;

c. The measures or systemic changes the PACE organization has or will implement to ensure the deficient practice will not recur, including the responsible staff;

d. How the PACE organization will monitor the corrective action to ensure the deficient practice is corrected and the solution is sustained, including the responsible staff; and

e. The date each plan was or will be completed.

8.497.13.D. Disclosure of review results. The PACE organization must comply with the requirements set forth in 42 CFR § 460.196.

8.497.14 DATA COLLECTION, RECORD MAINTENANCE, AND REPORTING

8.497.14.A. Maintenance of records and reporting of data. The PACE organization must collect data, maintain records, and submit reports as required by the Department and in accordance with 42 CFR § 460.200.

8.497.14.B. Participant health outcomes data. The PACE organization must comply with the requirements set forth in 42 CFR § 460.202.

8.497.14.C. Financial recordkeeping and reporting requirements. The PACE organization must comply with the requirements set forth in 42 CFR § 460.204.

8.497.14.D. Financial statements.

1. The PACE organization must comply with the financial statement reporting requirements set forth in 42 CFR § 460.208.

2. Annual financial report. A PACE organization must submit the financial data as specified in the PACE contract.

8.497.14.E. Medical records.

1. A PACE organization must maintain a single, comprehensive medical record for each participant in accordance with the requirement set forth in 42 CFR § 460.210.

2. Additional content of medical records. In addition to the medical record content requirements set forth in 42 CFR § 460.210(b), the PACE organization must document whether a service or visit was provided in person or via telehealth.

8.497.14.F. Encounter data submission requirements.

1. Encounter data submission report. A PACE organization must submit encounter data, as directed by the Department, directly to the Department or its designee.

a. The PACE organization must use the Healthcare Common Procedure Coding System (HCPCS), ICD-10 Procedure Coding System (ICD-10 PCS), and Current Procedural Terminology (CPT) for provided services in each submission of encounter data.

b. A PACE organization must prepare and submit all pharmacy and non-pharmacy encounter data monthly, as specified by the Department, to the Department through its Fiscal Agent. Unless otherwise directed by the Department, encounter data must not be submitted to the Department, or its designated Fiscal Agent, more than 30 days from the final day of the previous month.

i. Submissions must be comprised of encounter records or adjustments to previously submitted records from provider encounter or claim records of any contracted or directly provided services rendered to the participant in the current or any prior months.

ii. Submission of encounter records of services rendered from all providers, including PACE organizations and their respective subcontractors, must have a valid, enrolled National Provider Identifier (NPI) with the Department. Subcontractors who submit encounter records to the Department must be enrolled and approved through the Department.

1) If a PACE organization's encounter is not established in the HCPCS, ICD-10 PCS, or CPT, the PACE organization must document the encounter and submit an Encounter Data Submission Report to the Department for review and for coding

consideration through a process defined by the Department in collaboration with the PACE organization.

2. Encounter data submission to the Pharmacy Benefit Management (PBM) vendor. A PACE organization must ensure pharmacy encounters are submitted to the PACE organization's PBM vendor.

   a. If a business need is identified by the Department, or non-compliance is identified, the Department or the Department's PBM vendor will notify the PACE organization 90 days in advance of any requirement changes that are deemed necessary to ensure compliance, as set forth in the Colorado Pharmacy Benefit Management System Batch Pharmacy Encounters Companion Guide, unless there are unforeseen circumstances that require immediate system changes, in which case the PACE organization will be notified as soon as possible.

3. Annual signed encounter data certification. The PACE organization must submit an Annual Signed Encounter Data Certification to show that the encounter data submitted through the designated Fiscal Agent is accurate to the best of the PACE organization's information, knowledge and belief.

   a. The encounter data submission must comply with the format prescribed by the Department or its designated Fiscal Agent. The encounter data submission must include:

      i. The name and provider ID of any ordering, referring, prescribing, or attending provider and information on the rendering, operating, or other professional.

         1) Generic provider IDs shall be used only when specific Provider IDs remain unknown after reasonable inquiry.

         2) NPI numbers of providers not enrolled in Medicaid must be reported.

         3) If the NPI is not available, the PACE organization must report the tax payer ID.

      ii. The PACE organization must require subcontractors and non-contracting providers to provide encounter data to the PACE organization.

   b. The PACE organization must obtain an Annual Signed Encounter Data Certification from either the Chief Executive Officer or the Chief Financial Officer, or an individual who has delegated authority to sign for, and who reports directly to, the Chief Executive Officer or Chief Financial Officer.

   c. The PACE organization must provide an Annual Signed Encounter Data Certification to the Department or its designees covering all of the submissions for the preceding year of Encounter Data as specified in the PACE contract.

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Rule concerning Non-Emergent Medical Transportation, Sections 8.014 & 8.125
Rule Number: MSB 24-01-29-A
Division / Contact / Phone: Fraud, Waste, and Abuse Division / Sarah Geduldig/ 2341

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 24-01-29-A, Revision to the Medical Assistance Rule concerning Non-Emergent Medical Transportation, Sections 8.014 & 8.125

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) OP Pages, 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 8.014 with the proposed text beginning at 8.104.1 through the end of 8.014.8. Replace the current text at 8.125 with the proposed text beginning at 8.125.1 through the end of 8.125.15.F. This rule is effective April 30, 2024.

*to be completed by MSB Board Coordinator

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Rule concerning Non-Emergent Medical Transportation, Sections 8.014 & 8.125
Rule Number: MSB 24-01-29-A
Division / Contact / Phone: Fraud, Waste, and Abuse Division / Sarah Geduldig/ 2341

STATEMENT OF BASIS AND PURPOSE

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

   This rule change is occurring because there has been an increase in suspected fraud within the Non-Emergent Medical Transportation (NEMT) benefit. This has resulted in a CMS approved temporary moratorium of newly enrolling NEMT providers for at least six (6) months. While this Moratorium is in place, the Department is working on statutes, rules, regulations and guidance to address concerns and issues that were discovered through reviewing the suspected fraud scheme. This proposed emergency rule is being put in place in order to clarify the Department's expectations of NEMT providers, reduce the risk of suspected fraud, and protect the health, safety, and welfare of our members. To do this, the proposed revisions include changes to the screening and credentialing of NEMT providers, clarifying the obligations of drivers compared to the state designated entity, and removing outdated language related to licensing requirements by the public Utilities Commission (PUC).

   1. 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:

   2. Federal authority for the Rule, if

      any: 42 CFR 455.450(e)

   3. State Authority for the Rule:

      Sections 25.5-1-301 through 25.5-1-303, C.R.S. (2023);
      Section 25.5-1-802(1), C.R.S.

Initial Review
Proposed Effective Date

Final Adoption
Emergency Adoption

DOCUMENT #04

DO NOT PUBLISH THIS PAGE

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Rule Number: MSB 24-01-29-A
Division / Contact / Phone: Fraud, Waste, and Abuse Division / Sarah Geduldig/ 2341

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.

   Providers will be impacted by the proposed rule change because under federal regulation upon enrollment or reenrollment any provider type that was subject to a moratorium in the last six months must be screened at a high-risk level, which includes requiring a fingerprint-based background check. Providers will be responsible for bearing the cost of this. Providers will also be required to take part in credentialing requirements of their drivers and vehicles, though these costs will be the responsibility of the Department.

   Members will benefit from ensuring proper screening and credentialing of providers, drivers, and vehicles used in NEMT which will increase member safety and improve members' experience of NEMT. It will also protect members from being contacted by competing transportation providers and having their member status exploited for profit.

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

   Providers may be impacted by the increased screening and credentialing requirements for the owners and the drivers, including background checks and vehicle safety inspections. However, the need to protect members' safety outweighs the associated cost and inconvenience to providers of these requirements.

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 increased screening and credentialing requirements will increase costs to the Department; however these costs were included in a supplemental budget request presented to the JBC and were approved in December 2023. This rule will not result in increased costs to any other agency.

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

Denver metro area providers will not experience additional costs because they have historically been required to perform this credentialing. However, providers outside the metro area who will now be required to perform credentialing will experience increased costs. The Department will also experience increased costs of administering these requirements. (See number 3, above.) Inaction would avoid increase costs but would result in a failure to alleviate potential risks to the health, safety, and welfare of our members.

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

   The Department determined there were no other less costly or less intrusive methods to clarify HCPF's expectations of providers, protect member safety and reduce suspected fraud. Proper screening and credentialing of providers, drivers, and vehicles used in NEMT is the best method identified to achieve the purpose of the 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.

   Moving NEMT providers from the moderate categorical risk level to the high risk level, as necessitated by the increased fraud activity in the benefit, implicate federal regulations that require providers to conduct additional screening measures. Failure to place NEMT providers in the higher categorical risk level would fail to address the increase in fraud activity. Under the moderate categorical risk level, providers were not required to perform screening measure robust enough to avoid risks to member safety. To change the risk level associated with NEMT providers, a rule-making is necessary.

8.014 NON-EMERGENT MEDICAL TRANSPORTATION

8.014.1. DEFINITIONS

8.014.1.A. Access means the ability to make use of.

8.014.1.B. Air Ambulance means a Fixed-Wing or Rotor-Wing Air Ambulance equipped with medically necessary supplies to provide Emergency Medical Transportation.

8.014.1.C. Ambulatory Vehicle means a passenger-carrying vehicle available for those clients able to walk and who do not rely on wheelchairs or other mobility devices, during boarding or transportation, which would necessitate a vehicle with a lift or other accommodations.

8.014.1.D. Ancillary Services mean services incurred indirectly when a client authorized to receive NEMT also requires the assistance of an Escort or financial assistance for meals or lodging.

8.014.1.E. At-Risk Adult means an adult who is unable to make personal or medical determinations, provide necessary self-care, or travel independently.

8.014.1.F. Child means a minor under the age of 18.

8.014.1.G. Day Treatment means facility-based services designed for Children with complex medical needs. Services include educational or day care services when the school or day care system is unable to provide skilled care in a school setting, or when the Child's medical needs put them at risk when around other Children.

8.014.1.H. Emergency Medical Transportation means Ground Ambulance or Air Ambulance transportation under Section 8.018 during which clients who are ill, injured, or otherwise mentally or physically incapacitated receive needed emergency medical services en route.

8.014.1.I. Escort means a person who accompanies an At-Risk Adult or minor client.

8.014.1.J. Fixed-Wing Air Ambulance means a fixed wing aircraft that is certified as a Fixed-Wing Air Ambulance by the Federal Aviation Administration.

8.014.1.K. Ground Ambulance means a ground vehicle, including a water ambulance, equipped with medically necessary supplies to provide Emergency Medical Transportation.

8.014.1.L. Medicaid Client Transport (MCT) Permit means a permit issued by the Colorado Department of Regulatory Agencies Public Utilities Commission (PUC) in accordance with the PUC statute at Section 40-10.1-302, C.R.S.

8.014.1.M. Mode means the method of transportation.

8.014.1.N. Non-Emergent Medical Transportation (NEMT) means transportation to or from medically necessary non-emergency treatment. Non-emergency care may be scheduled or unscheduled. This may include Urgent Care transportation and hospital discharge transportation.

8.014.1.O. Program of All Inclusive Care for the Elderly (PACE) is a capitated rate benefit which provides all-inclusive long-term care to certain individuals as defined in Section 8.497.

8.014.1.P. Rotor-Wing Air Ambulance means a helicopter that is certified as an ambulance by the Federal Aviation Administration.

8.014.1.Q. State Designated Entity (SDE) means the organization responsible for administering NEMT. ~~For the purposes of this rule, the responsible SDE is determined by the client's county of residence.~~

8.014.1.R. Stretcher Van means a vehicle that can legally transport a client in a prone or supine position when the client does not require medical attention en route. This may be by stretcher, board, gurney, or another appropriate device.

8.014.1.S. Taxicab means a motor vehicle operating in Taxicab Service, as defined in 4 CCR 723-6, § 6001(yyy) (2019), which is hereby incorporated by reference.

8.014.1.T. Taxicab Service has the same meaning as defined in 4 CCR 723-6, § 6001(yyy) (2019), which is hereby incorporated by reference.

8.014.1.U. Trip means one-way transportation from the point of origin to the point of destination.

8.014.1.V. Urgent Care means an appointment for a covered medical service with verification from an attending physician or facility that the client must be seen or picked up from a discharged appointment within 48 hours.

8.014.1.W. Wheelchair Vehicle means a motor vehicle designed and used for the non-emergent transportation of individuals with disabilities who use a wheelchair. These vehicles include vans modified for wheelchair Access or wheelchair accessible minivans.

8.014.2. CLIENT ELIGIBILITY AND RESPONSIBILITIES

8.014.2.A. All Colorado Medical Assistance Program clients are eligible for NEMT services unless the client falls within the following eligibility groups on the date of the Trip:

1. Qualified Medicaid Beneficiary (QMB) Only
2. Special Low Income Medicare Beneficiary (SLMB) Only
3. Medicare Qualifying Individual-1 (QI-1) Only
4. Old Age Pension- State Only (OAP-state only)

8.014.2.B. Child Health Plan Plus clients are not eligible for NEMT.

8.014.2.C. PACE clients receive transportation provided by their PACE organization and are not eligible for NEMT.

8.014.2.D. NEMT services may be denied if clients do not observe the following responsibilities:

1. Comply with applicable state, local, and federal laws during transport.
2. Comply with the rules, procedures and policies of the Department, its designees, or the SDE.
3. Obtain authorization from their SDE, if the client lives within the designated SDE area.
4. Clients must not engage in violent or illegal conduct while utilizing NEMT services.
5. Clients must not pose a direct threat to the health or safety of themselves or others, including drivers.

6. Clients must cancel their previously scheduled NEMT Trip if the ride is no longer needed, except in emergency situations or when the client is otherwise unable to cancel.

8.014.3. PROVIDER ELIGIBILITY AND RESPONSIBILITIES

8.014.3.A. Providers must enroll with the Colorado Medical Assistance Program as an NEMT provider.

8.014.3.B. Enrolled NEMT providers must:

1. Meet all provider screening requirements in Section 8.125;

2. Comply with commercial liability insurance requirements and, if applicable, PUC financial responsibility requirements established in the PUC statute at C.R.S. § 40-10.1-107;

3. ~~Refrain from attempting to~~Not directly solicit individual clients known to have already established ~~-~~NEMT service with another provider;

4. Maintain and comply with the following appropriate licensure, or exemption from licensure, requirements:

a. PUC common carrier certificate as a Taxicab;

~~b. PUC MCT Permit as required by the PUC statute at C.R.S. § 40-10.1-302;~~

b~~c~~. Ground Ambulance license as required by Department of Public Health and Environment (CDPHE) rule at 6 CCR 1015-3, Chapter Four;

c~~d~~. Air Ambulance license as required by CDPHE rule at 6 CCR 1015-3, Chapter Five; or

d~~e~~. Exemption from licensure requirements in accordance with PUC statute at C.R.S. § 40-10.1-105.

5. ~~Only P~~provide only NEMT services appropriate to their current licensure(s), within applicable geographic limitations, and in accord with~~Department~~ statutes, rules, and guidance~~, and within the geographic limitations applicable to the licensure~~; and

~~6. Ensure that all vehicles and auxiliary equipment used to transport clients meet federal, state, and local safety inspection and maintenance requirements.~~

6. Ensure vehicles used during the provision of NEMT meet federal, state, and local statutes and regulations~~,~~. Vehicles shall be ~~and are~~ safe and in good working order. To ensure ~~the~~ safety and proper functioning ~~of the vehicles~~, all vehicles must pass a ~~vehicle~~ safety inspection prior to ~~it~~ being used to render services to members.

a. Safety inspections shall include the inspection of items as described in Rule Regulating Transportation by Motor Vehicle, 4 C.C.R. 723-6; § 6104.

b. Vehicles must be inspected on a schedule commensurate with their age:

i. Vehicles manufactured within the last five (5) years: no inspection.

ii. Vehicles manufactured within the last six (6) to ten (10) years: inspected every 24 months.

iii. Vehicles manufactured eleven (11) years or longer: inspected annually.

iv. Vehicles for wheelchair transportation: inspected annually, regardless of the manufacture date of vehicle.

c. The vehicle inspector must be trained to conduct the inspection and be employed by an automotive repair company authorized to do business in Colorado.

d. The vehicle inspector and automative repair company must not be owned or controlled by an individual who also has an ownership or controlling interest in the NEMT provider entity.~~.~~

~~d~~e. Providers must maintain liability insurance with the following automobile liability minimum limits:

~~a~~i. Bodily injury (BI) $300/$600K per person/per accident; and

1) Property damage $50,000.

2) Drivers that utilize their personal vehicle on behalf of a provider agency to provide NMT must maintain the following minimum automobile insurance limits, in addition to the insurance maintained by the provider agency:

3) Bodily injury (BI) $25/$50K per person/per accident; and

4) Property damage $15,000Member Eligibility.

7. ~~Document, maintain~~Create and maintain documentation of, and train staff on, the following policies and procedures:

a. Fraud, waste, and abuse identification and preventions;

b. Compliance with 42 C.F.R. § 403.812, the Health Insurance Portability and Accountability Act (HIPAA);

c. Compliance with vehicle maintenance and safety requirements

8. Ensure that each driver meets the following requirements:

a. Drivers must be 18 years of age or older to render services;

b. Have at least one year of driving experience;

c. Possess a valid Colorado driver's license;

d. Provide a copy of their current Colorado motor driving vehicle record, with the previous seven years of driving history;

e. Complete a Colorado or National-based criminal history record check; and

f. Has received training and obtained certification in CPR and Naloxone administration.

9. Maintain documentation regarding drivers must be maintained by the provider and provided to the Department or its designees on request:

a. Name

b. Valid Driver's License

c. 10 Panel Drug screen prior to hire and annually there after

d. State sex offender check prior to hire and annually there after

e. National sex offender check prior to hire and annually there after

f. Criminal background check without disqualification found below:

i. A conviction of substance abuse occurring within the seven (7) years preceding the date the criminal history record check is completed;

ii. A conviction in the State of Colorado, at any time, of any Class 1 or 2 felony under Title 18, C.R.S.;

iii. A conviction in the State of Colorado, within the seven (7) years preceding the date the criminal history record check is completed, of a crime of violence, as defined in C.R.S. § 18-1.3-406(2);

iv. A conviction in the State of Colorado, within the four (4) years preceding the date the criminal history record check is completed, of any Class 4 felony under Articles 2, 3, 3.5, 4, 5, 6, 6.5, 8, 9, 12, or 15 of Title 18, C.R.S.;

v. A conviction of an offense in any other state that is comparable to any offense listed in subparagraphs (f)(II)(A) through (D) within the same time periods as listed in subparagraphs (f)(II)(A) through (D) of Rules Regulating Transportation by Motor Vehicle, 4 C.C.R. 723-6; § 6114;

vi. A conviction in the State of Colorado, at any time, of a felony or misdemeanor unlawful sexual offense against a child, as defined in § 18-3-411, C.R.S., or of a comparable offense in any other state or in the United States at any time;

vii. A conviction in Colorado within the two (2) years preceding the date the criminal history record check is completed of driving under the influence, as defined in § 42-4-1301(1)(f), C.R.S.; driving with excessive alcoholic content,as described in §42-4-1301(1)(g), C.R.S;

viii. A conviction within the two (2) years preceding the date the criminal history record check is completed of an offense comparable to those included in subparagraph (f)(III)(B), 4 C.C.R. 723-6; § 6114 in any other state or in the United States; and

ix. For purposes of 4 C.C.R. 723-6; § 6114(f)(IV), a deferred judgment and sentence pursuant to § 18-1.3-102, C.R.S., shall be deemed to be a conviction during the period of the deferred judgment and sent.

~~PUC statute at C.R.S. §§ 40-10.1-105, 40-10.1-107 and 40-10.1-302 (2019) and CDPHE rule at 6 CCR 1015-3, Chapters Four and Five (2019), are hereby incorporated by reference.~~

8.014.3.C. NEMT transportation providers must maintain a Trip report for each NEMT Trip provided and must, at a minimum, include:

1. The pick-up address;
2. The destination address;
3. Date and time of the Trip;
4. Client's name or identifier;
5. Confirmation that the driver verified the client's identity;
6. Confirmation by the client, Escort, or medical facility that the Trip occurred;
7. The actual pick-up and drop off time;
8. The driver's name; and
9. Identification of the vehicle in which the Trip was provided.

8.014.3.D. Multiple Loading

1. NEMT providers may not transport more than one client at the same time, unless the additional passenger is an Escort.

8.014.3.E. The Section 8.014.3 requirements do not apply to client reimbursement or bus or rail systems.

8.014.4. COVERED PLACES OF SERVICE

8.014.4.A. NEMT must be provided to the closest provider available qualified to provide the service the client is traveling to receive. The closest provider is defined as a provider within a 25-mile radius of the client's residence, or the nearest provider if one is not practicing within a 25-mile radius of the client's residence.

8.014.4.B Exceptions may be made if a rationale and certification from the member's treating provider as to why the member cannot be treated by the closest provider within 25 miles of the member's residence is provided to and approved by ~~Exceptions may be made by~~ the Department, its designees, or the SDE and one of ~~in~~ the following circumstances applies:

1. If the closest provider is not willing to accept the client, the client may use NEMT to access the next closest qualified provider.
2. If the client has complex medical conditions that restrict the closest medical provider from accepting the patient, the Department, its designees, or the SDE may authorize NEMT to be used to travel to the next closest qualified provider. The treating medical provider must send the Department, its designees, or the SDE written documentation indicating why the client cannot be treated by the closest provider.

3. If a client has moved within the three (3) months preceding an NEMT transport, the client may use NEMT to their established medical provider seen in their previous locale. During these three (3) months, the client and medical provider must transfer care to the closest provider as defined at Section 8.014.4.B. or determine transportation options other than NEMT.

8.014.5. COVERED SERVICES

8.014.5.A. Transportation Modes

1. Covered Modes of transportation include:

    a. Bus and public rail systems

        i. Transit passes may be issued by the SDE when the cumulative cost of bus tickets exceeds the cost of a pass.

    b. Personal vehicle mileage reimbursement

    c. Ambulatory Vehicles

    d. Wheelchair Vehicles

    e. Taxicab Service

    f. Stretcher Van

    g. Ground Ambulance

    h. Air Ambulance

    i. Commercial plane

    j. Train

8.014.5.B. NEMT Services

1. NEMT is a covered service when:

    a. The client does not have Access to other means of transportation, including free transportation;

    b. Transportation is required to obtain a non-emergency service(s) that is medically necessary, as defined in Section 8.076.1.8.; and

    c. The client is receiving a service covered by the Colorado Medical Assistance Program.

2. NEMT services may be covered for clients even if the medical procedure is paid for by an entity other than the Colorado Medical Assistance Program.

3. Non-emergent ambulance service (Ground and Air Ambulance), from the client's pickup point to the treating facility, is covered when:

    a. Transportation by any other means would endanger the client's life; or

b. The client requires basic life support (BLS) or advanced life support (ALS) to maintain life and to be transported safely.

i. BLS includes:

1. Cardiopulmonary resuscitation, without cardiac/hemodynamic monitoring or other invasive techniques;

2. Suctioning en route (not deep suctioning); and

3. Airway control/positioning.

ii. ALS includes ALS Levels 1 and 2 in accordance with 42 CFR § 414.605 (2019), which is hereby incorporated by reference.

1. ALS Level 1 includes the provision of at least one ALS intervention required to be furnished by ALS personnel.

2. ALS Level 2 includes:

a. Administration of at least three medications by intravenous push/bolus or by continuous infusion, excluding crystalloid, hypotonic, isotonic, and hypertonic solutions (Dextrose, Normal Saline, Ringer's Lactate); or

b. The provision of at least one of the following ALS procedures:

i. Manual defibrillation/cardioversion.

ii. Endotracheal intubation.

iii. Central venous line.

iv. Cardiac pacing.

v. Chest decompression.

vi. Surgical airway.

vii. Intraosseous line.

4. NEMT may be provided to an Urgent Care appointment under the following circumstances:

a. A provider is available;

b. The appointment is for a covered medical service with verification from an attending physician that the client must be seen within 48 hours; and

c. The client is transported to an Urgent Care facility, which may include a trauma center if it is the nearest and most appropriate facility.

8.014.5.C. Personal Vehicle Mileage Reimbursement

1. Personal vehicle mileage reimbursement is covered for a privately owned, non-commercial vehicle when used to provide NEMT services in accordance with Section 8.014.5.B and owned by:

    a. A client, a client's relative, or an acquaintance; or

    b. A volunteer or organization with no vested interest in the client.

2. Personal vehicle mileage reimbursement will only be made for the shortest Trip length in miles as determined by an internet-based map, Trip planner, or other Global Positioning System (GPS).

    a. Exceptions can be made by the SDE if the shortest distance is impassable due to:

        i. Severe weather;

        ii. Road closure; or

        iii. Other unforeseen circumstances outside of the client's control that severely limit using the shortest route.

    b. If an exception is made under Section 8.014.5.C.2.a., the SDE must document the reason and pay mileage for the actual route traveled.

3. To be reimbursed for personal vehicle mileage, the client must provide the following information to the SDE within forty-five (45) calendar days of the final leg of the Trip:

    a. Name and address of vehicle owner and driver (if different from owner);

    b. Name of the insurance company and policy number for the vehicle; and

    c. Driver's license number and expiration date.

8.014.5.D. Ancillary Services

1. Escort

    a. The Colorado Medical Assistance Program may cover the cost of transporting one Escort when the client is:

        i. A Child.

            1. An Escort is required to accompany a client if the client is under thirteen (13) years old, unless the Child:

                a. Is traveling to a Day Treatment program (Children are not eligible for NEMT travel to and from school-funded day treatment programs);

                b. The parent or guardian signs a written release;

                c. An adult will be present to receive the Child at the destination and return location; and

d. The Day Treatment program and the parents approve of the NEMT provider used.

2. Clients who are at least thirteen (13) years old, but younger than eighteen (18) years old, may travel without an Escort if:

a. The parent or guardian signs a written release; and an adult will be present to receive the Child at the destination and return location.

ii. An At-Risk Adult unable to make personal or medical determinations, or to provide necessary self-care, as certified in writing by the client's attending Colorado Medical Assistance Program enrolled NEMT provider.

b. The Escort must be physically and cognitively capable of providing the needed services for the client.

i. If a client's primary caregiver has a disability that precludes the caregiver from providing all of the client's needs during transport or extended stay, a second Escort may be covered under Section 8.014.5.D.1.c.ii.

c. The Colorado Medical Assistance Program may cover the cost of transporting a second Escort for the client, if prior authorized under Section 8.014.7. A second Escort will only be approved if:

i. The client has a behavioral or medical condition which may cause the client to be a threat to self or to others if only one Escort is provided; or

ii. The client's primary caregiver Escort has a disability that precludes the caregiver from providing all of the client's needs during transport or extended stay.

2. Meals and Lodging

a. Meals and lodging for in-state treatment may be reimbursed when:

i. Travel cannot be completed in one calendar day; or

ii. The client requires ongoing, continuous treatment and:

1. The cost of meals and lodging is less than or equal to the cost of traveling to and from the treatment facility and the client's residence; or

2. The client's treating medical professional determines that traveling to and from the client's residence would put the client's health at risk.

b. Meals and lodging may be covered for the Escort(s) when the client is a Child or an At-Risk Adult who requires the Escort's continued stay under Section 8.014.5.D.1.

c. Reimbursement will only be made for meals and lodging for which clients and Escorts are actually charged, up to the per diem rate established by the Colorado Medical Assistance Program.

d. Meals and lodging will not be paid or reimbursed when those services are included as part of an inpatient stay.

8.014.6. NON-COVERED NEMT SERVICES AND GENERAL LIMITATIONS

8.014.6.A. The following services are not covered or reimbursable to NEMT providers as part of a NEMT service:

1. Services provided only as a convenience to the client.

2. Charges incurred while client is not in the vehicle, except for lodging and meals in accordance with Section 8.014.5.D.2.

3. Transportation to or from non-covered medical services, including services that do not qualify due to coverage limitations...

4. Waiting time.

5. Cancellations.

6. Transportation which is covered by another entity.

7. Metered taxi services.

8. Charges for additional passengers, including siblings or Children, not receiving a medical service, except when acting as an Escort under Section 8.014.5.D.1.

9. Transportation for nursing facility or group home residents to medical or rehabilitative services required in the facility's program, unless the facility does not have an available vehicle.

10. Transportation to emergency departments to receive emergency services. See Section 8.018 for Emergency Medical Transportation services.

11. Providing Escorts or the Escort's wages.

12. Trips to receive Home and Community Based Services

    a. Non-medical transportation should be utilized if other transportation options are not available to the client.

8.014.6.B. General Limitations

1. The Provider and the SDE are~~is~~ responsible for ensuring that the client utilizes the least costly Mode of transportation available that is suitable to the client's condition. This must be documented and available upon request by the Department, its designees, or the SDE.

8.014.7. AUTHORIZATION

8.014.7.A. If the Provider is rendering services in the SDE area, all~~All~~ NEMT services must be authorized as required by the SDE.

1. Authorization requests submitted more than three months after an NEMT service is rendered will be denied.

2. NEMT services may be denied if proper documentation is not provided to the SDE.

8.014.7.B. If a client requests transportation via Wheelchair Vehicle, Stretcher Van, or ambulance, the SDE must verify the service is medically necessary with the client's medical provider

1. Medical or safety requirements must be the basis for transporting a client in the prone or supine position.

8.014.7.C. Out-of-State NEMT

1. NEMT to receive out of state treatment is permissible only if treatment is not available in the state of Colorado.

2. The following border towns are not considered out of state for the purposes of NEMT prior authorization:

a. Arizona: Flagstaff and Teec Nos Pos.

b. Kansas: Elkhart, Goodland, Johnson, Sharon Springs, St. Francis, Syracuse, Tribune.

c. Nebraska: Benkelman, Cambridge, Chappell, Grant, Imperial, Kimball, Ogallala, and Sidney.

d. New Mexico: Aztec, Chama, Farmington, Raton, and Shiprock.

e. Oklahoma: Boise City.

f. Utah: Monticello and Vernal.

g. Wyoming: Cheyenne and Laramie.

8.014.7.D. Prior Authorization

1. The following services require prior authorization by Colorado Medical Assistance Program:

a. Out-of-state travel, except to the border towns identified at section 8.014.7.C.2.

b. Air travel, both commercial air and Air Ambulance.

c. Train travel via commercial railway.

d. Second Escort.

2. Prior authorization requests require the following information:

a. NEMT prior authorization request form completed by SDE and member's physician and submitted to Colorado Medical Assistance Program according to form instructions.

i. The Colorado Medical Assistance Program will return requests completed by non-physicians and incomplete requests to the SDE.

ii. The Colorado Medical Assistance Program's determination will be communicated to the SDE. If additional information is requested, the SDE must obtain the information and submit to the Colorado Medical Assistance Program. If the request is denied, the SDE must send the client a denial notice.

8.014.8. INCORPORATIONS BY REFERENCE

The incorporation by reference of materials throughout section 8.014 excludes later amendments to, or editions of, the referenced materials. Pursuant to C.R.S. § 24-4-103(12.5), the Department maintains copies of this incorporated text in its entirety, available for public inspection during regular business hours, at: Colorado Department of Health Care Policy and Financing, 1570 Grant Street, Denver, CO 80203. Certified copies of incorporated materials are provided at cost upon request.

8.125 PROVIDER SCREENING

8.125.1 DEFINITIONS.

Managed Care Entity is defined at 42 CFR § 455.101.

Ownership interest is defined at 42 CFR § 455.101.

Person with an ownership or control interest is defined at 42 CFR § 455.101.

Enrollment is defined as the process by which an individual or entity not currently enrolled as a Colorado Medicaid provider submits a provider application, undergoes any applicable screening, pays an application fee, as appropriate for the provider type, and is approved by the Department for participation in the Medicaid program. Entities that have never previously enrolled as Medicaid providers or whose enrollment was previously terminated and are not currently enrolled are required to enroll. The date of enrollment shall be considered the date that is communicated to the provider in communication from the Department or its fiscal agent verifying the provider's enrollment in Medicaid.

Revalidation is defined as the process by which an individual or entity actively enrolled as a Colorado Medicaid provider resubmits a provider application, undergoes a state-defined screening process, pays an application fee, as appropriate for the provider type, and is approved by the Department to continue participation in the Medicaid program.

Disclosing Entity and Other Disclosing Entity are defined at 42 CFR § 455.101.

8.125.2 PROVIDERS DESIGNATED AS LIMITED CATEGORICAL RISK AND NEW PROVIDER TYPES

8.125.2.A. Except as provided for in Section 8.125.2.B, provider types not designated as moderate or high categorical risk at Sections 8.125.3 or 8.125.4 shall be considered limited risk.

8.125.2.B. The risk category for each provider type designated by CMS shall be the risk category for purposes of this rule regardless of whether a provider type may be listed in Sections 8.125.3 or 8.125.4.

8.125.3 PROVIDERS DESIGNATED AS MODERATE CATEGORICAL RISK

8.125.3.A. Emergency Transportation including ambulance service suppliers

1 ~~8.125.3.B. Non-Emergency Medical Transportation~~

8.125.3.B~~C~~. Community Mental Health Center

8.125.3.C~~D~~. Hospice

8.125.3.D~~E~~. Independent Laboratory

8.125.3.E~~F~~. Comprehensive Outpatient Rehabilitation Facility

8.125.3.F~~G~~. Physical Therapists, both individuals and group practices

8.125.3.G~~H~~ X-Ray Facilities

8.125.3.H~~I~~. Revalidating Home Health agencies

8.125.3.~~I~~J. Revalidating Durable Medical equipment suppliers, including revalidating pharmacies that supply Durable Medical Equipment

8.125.3.J~~K~~. Revalidating Personal Care Agencies under the state plan

8.125.3.KL. Providers of the following services for HCBS waiver members:

1. Alternative Care Facility
2. Adult Day Services
3. Assistive Technology, if the provider is revalidating
4. Behavioral Programing
5. Behavioral Therapies
6. Behavioral Health Supports
7. Behavioral Services
8. Care Giver Education
9. Children's Case Management
10. Children's Habilitation Residential Program (CHRP)
11. Community Connector
12. Community Mental Health Services
13. Community Transition Services
14. Complementary and Integrative Health
15. Day Habilitation
16. Day Treatment
17. Expressive Therapy
18. Home Delivered Meals
19. Home Modifications/Adaptations/Accessibility
20. Independent Living Skills Training
21. In-Home Support Services, if the provider is revalidating
22. Intensive Case Management
23. Massage Therapy
24. Mentorship
25. Non-Medical Transportation
26. Palliative/Supportive Care Skilled
27. Peer Mentorship
28. Personal Care/Homemaker Services, if the provider is revalidating
29. Personal Emergency Response System/Medication Reminder/Electronic Monitoring

30. Prevocational Services

31. Professional Services

32. Residential Habilitation Services

33. Respite

34. Specialized Day Rehabilitation Services

35. Specialized Medical Equipment and Supplies, if the provider is revalidating

36. Substance Abuse Counseling

37. Supported Employment

38. Supported Living Program

39. Therapy and Counseling

40. Transitional Living Program

41. Youth Day Services

8.125.3.~~M~~L. Medicare Only Providers

1. Independent Diagnostic Testing Facility

2. Revalidating Medicare Diabetes Prevention Program Supplier

3. Newly enrolling Opioid Treatment Program that has been fully and continuously certified by Substance Abuse and Mental Health Services Administration (SAMHSA) since October 24, 2018.

4. Revalidating Opioid Treatment Program

8.125.4 PROVIDERS DESIGNATED AS HIGH CATEGORICAL RISK

8.125.4.A. Enrolling DME Suppliers

8.125.4.B. Enrolling Home Health Agencies

8.125.4.C. Enrolling Personal Care Agencies providing services under the state plan

8.125.4.D. Enrolling providers of the following services for HCBS waiver members:

1. Assistive Technology

2. Personal Care/Homemaker Services

3 Specialized Medical Equipment and Supplies

4 In-Home Support Services

8.125.4.E. Non-Emergent Medical Transportation

8.125.4.F. Medicare Only Providers

1. Enrolling Medicare Diabetes Prevention Program Supplier

2. Enrolling Opioid Treatment Program that has not been fully and continuously certified by SAMHSA since October 24, 2018.

8.125.4.GF. Enrolling and revalidating providers for which the Department has suspended payments during an investigation of a credible allegation of fraud, for the duration of the suspension of payments.

8.125.4.HG. Enrolling and revalidating providers which have a delinquent debt owed to the State arising out of Medicare, Colorado Medical Assistance or other programs administered by the Department, not including providers which are current under a settlement or repayment agreement with the State.

8.125.4.IH. Providers that were excluded by the HHS Office of Inspector General or had their provider agreement terminated for cause by the Department, its contractors or agents or another State's Medicaid program at any time within the previous 10 years.

8.125.4.JI. Providers applying for enrollment within six (6) months from the time that the Department or CMS lifts a temporary enrollment moratorium on the provider's enrollment type.

8.125.5 PROVIDERS WITH MULTIPLE RISK LEVELS

8.125.5.A Providers shall be screened at the highest applicable risk level for which a provider meets the criteria. Providers shall only pay one application fee per location.

8.125.6 PROVIDERS WITH MULTIPLE LOCATIONS

8.125.6.A. Providers must enroll separately each location from which they provide services. Only claims for services provided at locations that are enrolled are eligible for reimbursement.

8.125.6.B. Each provider site will be screened separately and must pay a separate application fee. Providers shall only pay one application fee per location.

8.125.7 ENROLLMENT AND SCREENING OF PROVIDERS

8.125.7.A. All enrolling and revalidating providers must be screened in accordance with requirements appropriate to their categorical risk level.

8.125.7.B. Notwithstanding any other provision of the Colorado Code of Regulations, providers who provide services to Medicaid members as part of a managed care entity's provider network who would have to enroll in order to participate in fee-for-service Medicaid must enroll with the Department and be screened as Medicaid providers.

8.125.7.C. Nothing in Section 8.125.7.B shall require a provider who provides services to Medicaid members as part of a managed care entity's provider network to participate in fee-for-service Medicaid.

8.125.7.D. All physicians or other professionals who order, prescribe, or refer services or items for Medicaid members, whether as part of fee-for-service Medicaid or as part of a managed care entity's provider network under either the state plan, the Children's Health Insurance Program, or a waiver, must be enrolled in order for claims submitted for those ordered, referred, or prescribed services or items to be reimbursed or accepted for the calculation of managed care rates by the Department.

8.125.7.E. The Department may exempt certain providers from all or part of the screening requirements when certain providers have been screened, approved and enrolled or revalidated:

1. By Medicare within the last 5 years, or

2. By another state's Medicaid program within the last 5 years, provided the Department has determined that the state in which the provider was enrolled or revalidated has screening requirements at least as comprehensive and stringent as those for Colorado Medicaid.

8.125.7.F. The Department may deny a Provider's enrollment or terminate a Provider agreement for failure to comply with screening requirements.

8.125.7.G. The Department may terminate a Provider agreement or deny the Provider's enrollment if CMS or the Department determines that the provider has falsified any information provided on the application or cannot verify the identity of any provider applicant.

8.125.8 NATIONAL PROVIDER IDENTIFIER FOR ORDERING, PRESCRIBING, REFERRING

8.125.8.A. As a condition of reimbursement, any claim submitted for a service or item that was ordered, referred, or prescribed for a Medicaid member must contain the National Provider Identifier (NPI) of the ordering, prescribing or referring physician or other professional.

8.125.9 VERIFICATION OF PROVIDER LICENSES

8.125.9.A. If a provider is required to possess a license or certification in order to provide services or supplies in the State of Colorado, then that provider must be so licensed as a condition of enrollment as a Medicaid provider.

8.125.9.B. Required licenses must be kept current and active without any current limitations throughout the term of the agreement.

8.125.10 REVALIDATION

8.125.10.A. Actively enrolled providers must complete all requirements for revalidation at least every 5 years as established by the Department, or upon request from the Department for an off cycle review.

8.125.10.B. The date of revalidation shall be considered the date that the provider's application was initially approved plus 5 years, or by an off-cycle request from the Department.

8.125.10.C. If a provider fails to comply with any requirement for revalidation by the deadlines established by Sections 8.125.10.A. or 8.125.10.B., the provider agreement may be terminated. In the event that the provider agreement is terminated pursuant to this section, any claims for dates of service submitted after deadlines established by Sections 8.125.10.A. or 8.125.10.B., are not reimbursable beginning on the day after the date indicated by Section 8.125.10.B.

8.125.11 SITE VISITS

8.125.11.A. All providers designated as "moderate" or "high" categorical risks to the Medicaid program must consent to and pass a site visit before they may be enrolled or re-validated as Colorado Medicaid providers. The purpose of the site visit is to verify that the information submitted to the state department is accurate and to determine compliance with federal and state enrollment requirements.

8.125.11.B. All enrolled providers who are designated as "moderate" or "high" categorical risks must consent to and pass an additional site visit after enrollment or revalidation. The purpose of the site visit is to verify that the information submitted to the state department is accurate and to determine compliance with federal and state enrollment requirements. Post-enrollment or post- revalidation site visits may occur anytime during the five-year period after enrollment or revalidation.

8.125.11.C. All providers enrolled in the Colorado Medicaid program must permit CMS, its agents, its designated contractors, the State Attorney General's Medicaid Fraud Control Unit or the Department to conduct unannounced on-site inspections of any and all provider locations

8.125.11.D. All site visits shall verify the following information:

1. Basic Information including business name, address, phone number, on-site contact person, National Provider Identification number and Employer Identification Number, business license, provider type, owner's name(s), and owner's interest in other medical businesses.

2. Location including appropriate signage, utilities that are turned on, the presence of furniture and applicable equipment, and disability access where applicable and where clients are served at the business location.

3. Employees with relevant training, designated employees who are trained to handle Medicaid billing, where applicable, and resources the provider uses to train employees in Medicaid billing where applicable.

4. Appropriate inventory necessary to provide services for specific provider type.

5. Other information as designated by the Department.

8.125.11.E. The Department shall give the provider a report detailing the discrepancies or insufficiencies in the information disclosed by the provider and the criteria the provider failed to meet during the site visit.

8.125.11.F. Providers that are found in full compliance shall be recommended for approval of enrollment or revalidation, subject to other enrollment or revalidation requirements.

8.125.11.G. Providers who meet the vast majority of criteria in 8.125.11.D but have small number of minor discrepancies or insufficiencies shall have 60 days from the date of the issuance of the report in 8.125.11.E to submit documentation to the Department attesting that the provider has corrected the issues identified during the site visit.

1. If the provider submits attestation within the 60 day timeframe and has met requirements, then the provider shall be recommended for enrollment or revalidation, subject to the verification of other enrollment or revalidation requirements.

2. If the provider fails to submit the attestation in 8.125.11.G.1 within the 60 day deadline, the Department may deny the provider's application for enrollment or revalidation.

3. If the provider submits an attestation within 60 days indicating that the provider is not fully compliant with criteria in 8.125.11.D, then the Department may,

   a. For existing providers, suspend the provider, until the provider demonstrates compliance in a subsequent site visit, conducted at the provider's expense; or

   b. For new providers, deny the application and require the provider to restart the enrollment process.

8.125.11.H. When site visits reveal major discrepancies or insufficiencies in the information provided in the enrollment application or a majority of the criteria described in 8.125.11.D are not met, the Department shall allow for an additional site visit for the provider.

1. Additional site visits shall be conducted at the provider's expense.

2. The provider shall have 14 days from the date of the issuance of the report listed in 8.125.11.E above to request an additional site visit.

3. The Department shall deny or terminate enrollment or revalidation of any provider subject to 8.125.11.G who does not request an additional site visit within 14 days.

4. If the Department determines that a provider is not in full compliance upon the additional site visit:

   a. for a revalidating provider, the Department shall immediately suspend the provider until a subsequent site visit demonstrates provider is in compliance.

   b. for an enrolling provider, deny the application and require the provider to restart the enrollment process.

8.125.11.I. The Department shall deny or terminate enrollment or revalidation of any provider who refuses to allow a site visit, unless the Department determines the provider or the provider's staff refused the on-site inspection in error. The provider must provide credible evidence to the Department that it refused the on-site inspection in error within in 7 days of the date of the issuance of the report in 8.125.11.E. Any provider who does not provide credible evidence to the Department that it refused the on-site inspection in error shall be denied or terminated from enrollment or revalidation.

8.125.11.J. The Department shall deny an application or terminate a provider's enrollment when an on-site inspection provides credible evidence that the provider has committed Medicaid fraud.

8.125.11.K. The Department shall refer providers in 8.125.11.J to the State Attorney General.

8.125.12 CRIMINAL BACKGROUND CHECKS AND FINGERPRINTING

8.125.12.A. As a condition of provider enrollment, any person with an ownership or control interest in a provider designated as "high" categorical risk to the Medicaid program, must consent to criminal background checks and submit a set of fingerprints, in a form and manner to be determined by the Department.

8.125.12.B. Any provider, and any person with an ownership or control interest in the provider, must consent to criminal background checks and submit a set of fingerprints, in a form and manner designated by the Department, within 30 days upon request from CMS, the Department, the Department's agents, or the Department's designated contractors.

8.125.13 APPLICATION FEE

8.125.13.A. Except when exempted in Sections 8.125.13.C and 8.125.13.D, enrolling and re- validating providers must submit an application fee or a formal request for a hardship exemption with their application.

8.125.13.B. The amount of the application fee is the amount calculated by CMS in accordance with17 42 CFR § 424.514(d).

8.125.13.C. Application fees shall apply to all providers except:

1. Individual practitioners

2. Providers who have enrolled or re-validated in Medicare and paid an application fee within the last 12 months

3. Providers who have enrolled or re-validated in another State's Medicaid or Children's Health Insurance Program and paid an application fee within the last 12 months provided that the Department has determined that the screening procedures in the state in which the provider is enrolled are at least as comprehensive and stringent as the screening procedures required for enrollment in Colorado Medicaid.

8.125.13.D. The Department may exempt a provider, or group of providers, from paying the applicable application fee, through a hardship exemption request or categorical fee waiver, if:

1. The Department determines that requiring a provider to pay an application fee would negatively impact access to care for Medicaid clients, and

2. The Department receives approval from the Centers for Medicare and Medicaid Services to exempt the application fee.

8.125.13.E. A provider may not be enrolled or revalidated unless the provider has either paid any applicable application fee or obtained an exemption described at Section 8.125.13.D.

8.125.13.F. The application fee is non-refundable, except if submitted with one of the following:

1. A request for hardship exemption described at Section 8.125.13.D, that is subsequently approved;

2. An application that is rejected prior to initiation of screening processes;

3. An application that is subsequently denied as a result of the imposition of a temporary moratorium as described at Section 8.125.14.

8.125.14 TEMPORARY MORATORIA

8.125.14.A. In consultation with CMS and HHS, the Department may impose temporary moratoria on the enrollment of new providers or provider types, or impose numerical caps or other limits on providers that the Department and the Secretary of HHS identify as being a significant potential risk for fraud, waste, or abuse, unless the Department determines that such an action would adversely impact Medicaid members' access to medical assistance.

8.125.14.B. Before imposing any moratoria, caps, or other limits on provider enrollment, the Department shall notify the Secretary of HHS in writing and include all details of the moratoria.

8.125.14.C. The Department shall obtain the Secretary of HHS's concurrence with imposition of the moratoria, caps, or other limits on provider enrollment, before such limits shall take effect.

8.125.15 DISCLOSURES BY MEDICAID PROVIDERS, MANAGED CARE ENTITIES, MEDICARE PROVIDERS AND FISCAL AGENTS

8.125.15.A. All providers, disclosing entities, fiscal agents, and managed care entities must provide the following federally required disclosures to the Department:

1. The name and address of any entity (individual or corporation) with an ownership or control interest in the disclosing entity, fiscal agent, or managed care entity having direct or indirect ownership of 5 percent or more. The address for corporate entities must include, as applicable, primary business address, every business location, and P.O. Box address.

2. For individuals: Date of birth and Social Security number

3. For business entities: Other tax identification number for any entity with an ownership or control interest in the disclosing entity (or fiscal agent or managed care entity) or in any subcontractor in which the disclosing entity (or fiscal agent or managed care entity) has a 5 percent or more interest.

4. Whether the entity (individual or corporation) with an ownership or control interest in the disclosing entity (or fiscal agent or managed care entity) is related to another person with ownership or control interest in the disclosing entity as a spouse, parent, child, or sibling; or whether the entity (individual or corporation) with an ownership or control interest in any subcontractor in which the disclosing entity (or fiscal agent or managed care entity) has a 5 percent or more interest is related to another person with ownership or control interest in the disclosing entity as a spouse, parent, child, or sibling.

5. The name of any other disclosing entity (or fiscal agent or managed care entity) in which an owner of the disclosing entity (or fiscal agent or managed care entity) has an ownership or control interest.

6. The name, address, date of birth, and Social Security Number of any managing employee of the disclosing entity (or fiscal agent or managed care entity).

7. The identity of any person who has an ownership or control interest in the provider, or is an agent or managing employee of the provider who has been convicted of a criminal offense related to that person's involvement in any program under Medicare, Medicaid, Children's Health Insurance Program or the Title XX services since the inception of these programs.

8. Full and complete information about the ownership of any subcontractor with whom the provider has had business transactions totaling more than $25,000 during the 12 month period ending on the date of the request; and any significant business transactions between the provider and any wholly owned supplier, or between the provider and any subcontractor, during the 5-year period ending on the date of the request.

8.125.15.B. Disclosures from any provider or disclosing entity are due at any of the following times:

1. Upon the provider or disclosing entity submitting the provider application.

2. Upon the provider or disclosing entity executing the provider agreement.

3. Upon request of the Department during revalidation.

4. Within 35 days after any change in ownership of the disclosing entity.

8.125.15.C. Disclosures from fiscal agents are due at any of the following times:

1. Upon the fiscal agent submitting its proposal in accordance with the State's procurement process.

2. Upon the fiscal agent executing a contract with the State.

3. Upon renewal or extension of the contract.

4. Within 35 days after any change in ownership of the fiscal agent.

8.125.15.D. Disclosures from managed care entities are due at any of the following times:

1. Upon the managed care entity submitting its proposal in accordance with the State's procurement process.

2. Upon the managed care entity executing a contract with the State.

3. Upon renewal or extension of the contract.

4. Within 35 days after any change in ownership of the managed care entity.

8.125.15.E. The Department will not reimburse any claim from any provider or entity or make any payment to an entity that fails to disclose ownership or control information as required by 42 CFR § 455.104. The Department will not reimburse any claim from any provider or entity or make any payment to an entity that fails to disclose information related to business transactions as required by 42 CFR § 455.105 beginning on the day following the date the information was due and ending on the day before the date on which the information was supplied. Any payment made to a provider or entity that is not reimbursable in accordance with this section shall be considered an overpayment.

8.125.15.F. The Department may terminate the agreement of any provider or entity or deny enrollment of any provider that fails to disclose information when requested or required by 42 CFR § 455.100-106.