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Title of Rule: Revision to the Medical Assistance Act Rule concerning Doula Services
Rule Number: MSB 24-04-05-A
Division / Contact / Phone: Policy Development and Implementation / Erica Schaler / 3195

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 24-04-05-A, Revision to the Medical Assistance Act Rule concerning Doula Services
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) 8.734, Colorado Department of Health Care Policy and Financing, Staff Manual Volume 8, Medical Assistance (10 CCR 2505-10).
5. Does this action involve any temporary or emergency rule(s)? Yes
If yes, state effective date: 7/1/2024
Is rule to be made permanent? (If yes, please attach notice of hearing). Yes

PUBLICATION INSTRUCTIONS*

Insert the newly proposed text beginning at 8.734 through to the end of 8.734.6.A.1.
This rule is effective July 1, 2024.

*to be completed by MSB Board Coordinator

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Rule Number: MSB 24-04-05-A
Division / Contact / Phone: Policy Development and Implementation / Erica Schaler / 3195

STATEMENT OF BASIS AND PURPOSE

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

The Department of Health Care Policy and Financing (Department) intends to provide coverage for doula services for Medicaid-enrolled pregnant persons effective July 1, 2024. These changes will increase access to care for all pregnant persons throughout the perinatal period to improve birth-related outcomes.

- 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:

Pursuant to C.R.S. 25.5-4-506(6), the Department of Health Care Policy and Financing is required to have completed a robust stakeholder engagement process to create a Doula benefit for pregnant and postpartum people to improve health outcomes of pregnant and postpartum people who face a disproportionately greater risk of poor birth outcomes. After a lengthy stakeholder engagement process that was necessary to comply with statute, the Department has designed this benefit to comply with this legislative mandate and must present this rule as an emergency rule to meet the July 1, 2024 deadline.

- 3. Federal authority for the Rule, if any:

42 C.F.R. 440.130(c)

- 4. State Authority for the Rule:

C.R.S. Section 25.5-4-506(6)

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

Initial Review

Proposed Effective Date

07/01/24

Final Adoption

Emergency Adoption

07/12/24

05/10/24

DOCUMENT #12

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Title of Rule: Revision to the Medical Assistance Act Rule concerning Doula Services
Rule Number: MSB 24-04-05-A
Division / Contact / Phone: Policy Development and Implementation / Erica Schaler / 3195

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 persons who will be affected by the proposed rule are Medicaid members who are pregnant or in the postpartum period. This rule will increase access to care and improve birth outcomes by providing physical and emotional support during pregnancy, labor and delivery, and after giving birth. Doula providers will bear the cost of training to become eligible as a provider and the Department will absorb the cost of service operations. Additionally, the Department, in compliance with statute, is developing a scholarship program for Doula training to assist Doula's in becoming enrolled providers.

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 impact of the proposed rule is an increase in access to care for pregnant and postpartum persons and improve birth outcomes for these populations. These populations will receive more support during the prenatal period, labor and delivery, and postpartum period.

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

This rule will cost the Department to implement and operate the Doula Services benefit. This rule has been reviewed by budget and is being funded through an approved 2023 budget request. This will not cost the state additional funding beyond the Colorado 2023 Long Bill. As a result of improved birth outcomes, the hope is to increase state revenue by decreasing the number of infants needing intensive medical care.

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

The benefits of the proposed rule outweigh the costs as improved birth outcomes reduce costs to the state long-term as fewer infants and postpartum persons will

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require intensive medical care and will receive increased support throughout all perinatal stages. There is no benefit to inaction.

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

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

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

There are no alternative methods for achieving the purpose of the proposed rule as this rule is drafted to meet the requirements of a legislative mandate.

8.734 DOULA SERVICES

8.734.1 DEFINITIONS

8.734.1.A. “Doula” means a trained birth companion who provides personal, nonmedical support to pregnant and postpartum people and their families prior to childbirth, during labor and delivery, and during the postpartum period.

8.734.2 PURPOSE

8.734.2.A. Doula services will be used to provide support for pregnant and postpartum people throughout the perinatal period, which may improve birth-related outcomes. Pursuant to 42 C.F.R. Section 440.130(c), Doula services are provided as preventive services in order to promote the physical and mental health of the member during the perinatal period.

8.734.3 MEMBER ELIGIBILITY

8.734.3.A. To be eligible for Doula services, a Colorado Medicaid member must be pregnant, in the postpartum period, or had a pregnancy end within the previous 12 months

8.734.4 PROVIDER ELIGIBILITY

8.734.4.A Registered Medicaid providers who provide Doula services must be at least 18 years of age. Doulas must:

8.734.4.B Complete Doula training, which must include core competencies and a minimum number of services hours. Doula providers must have received training from a HCPF approved training program. HCPF approved Doula training can be found on the HCPF billing site (LINK); or

8.734.4.C Has attested to one of the experience pathways listed on the billing site; and

8.734.4.D Completed CPR Training; and

8.734.4.E Signed a doula Code of Conduct, which can be found on the HCPF billing site (LINK)

8.734.5 COVERED SERVICES

8.734.5.A Doulas will provide services for birthing people during pregnancy, childbirth and the postpartum period. Service components include:

1. Perinatal support services, including pre- and postnatal care;
2. Labor support;

8.734.6 NON-COVERED SERVICES

8.734.6.A The following services are not covered:

1. Doula services do not include diagnosis of medical conditions, provision of medical advice, or any type of clinical assessment, exam, or procedure

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Title of Rule: Revision to the Medical Assistance Act concerning the Coverage of
FDA-Approved Imported Drugs, Section 8.800.4.B.

Rule Number: MSB 24-04-11-A

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: MSB 24-04-11-A, Revision to the Medical Assistance Act concerning
the Coverage of FDA-Approved Imported Drugs, Section 8.800.4.B.

3. This action is an adoption of: N/A

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

Sections(s) 8.800.4, Colorado Department of Health Care Policy and Financing, Staff
Manual Volume 8, Medical Assistance (10 CCR 2505-10).

5. Does this action involve any temporary or emergency rule(s)? Yes
If yes, state effective date: 05/10/24
Is rule to be made permanent? (If yes, please attach notice of hearing). Yes

PUBLICATION INSTRUCTIONS*

Replace the current text at 8.800.4 with the proposed text beginning at 8.800.4.A
through the end of 8.800.4.B.1.e. This rule is effective May 10, 2024.

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Title of Rule: Revision to the Medical Assistance Act concerning the Coverage of FDA-Approved Imported Drugs, Section 8.800.4.B.

Rule Number: MSB 24-04-11-A

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).

The purpose of this proposed rule change is to allow the Department the authority to cover FDA-approved imported drugs and other selected prescribed drugs that are not covered outpatient drugs. This would help members to maintain access to critical drugs that have become unavailable in the United States in addition to allowing the Department to cover a broader number of prescribed products for members. Therefore, the Department is seeking an amendment to 10 C.C.R. 2505-10, Section 8.800.4.B, to include selected prescribed drugs that are not covered outpatient drug as a covered benefit.

- 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:

There are ongoing and emerging drug shortages in the United States, affecting member access to critical drugs. The FDA has exercised enforcement discretion for temporary importation and use of select drugs to mitigate the effects of these drug shortages. An emergency rule change is required to allow the Department the authority to cover the FDA-approved imported drugs. There is a public health emergency related to the surge and increased numbers of syphilis and congenital syphilis cases occurring in Colorado. This rule would allow coverage of the imported Extencilline product during the nationwide Bicillin Shortage, in addition to covering imported Tiglutik, which is used to treat ALS.

- 3. Federal authority for the Rule, if any:

The Department is submitting SPA 24-0015 in conjunction with this rule change, which would allow the State federal authority to cover select prescribed drugs that are not covered outpatient drugs. The requested effective date of the State Plan Amendment is April 11, 2024.

- 4. State Authority for the Rule:

Initial Review

Proposed Effective Date

05/10/24

Final Adoption

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07/12/24

05/10/24

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Section 25.5-1-303, C.R.S. (2023)

Initial Review
Proposed Effective Date

05/10/24

Final Adoption
Emergency Adoption

07/12/24
05/10/24

DOCUMENT #13

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Act concerning the Coverage of
FDA-Approved Imported Drugs, Section 8.800.4.B.

Rule Number: MSB 24-04-11-A

Division / Contact / Phone: Pharmacy Office / Korri Conilogue / 303-866-6398

REGULATORY ANALYSIS

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

Medicaid members who require drugs that are affected by shortages in the US and members who require other prescribed drugs that are not covered outpatient drugs will benefit from expanded coverage. The proposed rule would result in no additional cost to Medicaid members. The Department will bear the cost of the additional coverage.

2. 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 for coverage of these prescribed products will help to mitigate the possible negative health consequences of not having access to a medically necessary prescribed product. Quantitatively there is no impact.

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 annual aggregate increase in prescribed drug expenditures (including state funds and federal funds) is \$39,091 (state share \$11,336; federal share \$27,755) in FFY 2024 and \$40,851 (state share \$11,846; federal share \$29,004) in FFY 2025.

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

The cost of inaction is that members who are affected by drug shortages and who require medically necessary prescribed products that are not covered outpatient drugs would go without treatment. There are no benefits of inaction.

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

There is not a less costly or less intrusive method.

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

There are no alternatives.

8.800 PHARMACEUTICALS

8.800.4 DRUG BENEFITS

8.800.4.A. Only those drugs designated by companies participating in the federally approved Medical Assistance Program drug rebate program and not otherwise excluded according to these rules are regular drug benefits. Notwithstanding the foregoing, drugs not covered by rebate agreements may be reimbursed if the Department has made a determination that the availability of the drug is essential, such drug has been given an "A" rating by the U. S. Food and Drug Administration (FDA), and a prior authorization has been approved. Prescribed drugs not covered by rebate agreements may also be reimbursed if approved for importation by the FDA when medically necessary for drug shortages, if approved by the FDA under emergency use authorization, if available over-the-counter (OTC), or if non-traditional prescribed products such as insect repellent. Reimbursement of any drugs that are regular drug benefits may be restricted as set forth in these rules.

8.800.4.B. Pursuant to 42 U.S.C. 1396r-8 (d)(2), certain drugs or classes of drugs may be excluded from coverage or may be subject to restrictions.

1. The following are covered with restrictions:

- a. Agents when used for weight gain;
- b. Agents when used for the symptomatic relief of cough and colds;
- c. Prescription vitamin and mineral products, except prenatal vitamins and fluoride, for documented deficiency; ~~and~~
- d. Non-prescription Drugs; and
- e. Selected prescribed drugs that are not covered outpatient drugs. Such prescribed drugs may include ~~over-the-counter (OTC)~~ nutritional supplements, drugs approved by the ~~Food and Drug Administration (FDA)~~ under emergency use authorization (EUA), FDA-approved imported drugs, and non-traditional prescribed products such as insect repellent.

2. The following are excluded from coverage:

- a. Agents when used for anorexia or weight loss;
- b. Agents when used to promote fertility;
- c. Covered outpatient drugs that the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee; and
- d. Agents used for the treatment of sexual or erectile dysfunction unless such agents are used to treat a condition, other than a sexual or erectile dysfunction, for which the agents have been approved by the FDA.

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Title of Rule: Revision to the Medical Assistance Act Rule concerning Physician Oversight, Section 8.200.2.D.a
Rule Number: MSB 24-04-18-B
Division / Contact / Phone: Policy Development and Implementation / Erica Schaler / 3195

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 24-04-18-B, Revision to the Medical Assistance Act Rule concerning Physician Oversight
3. This action is an adoption of: an amendment
4. Rule sections affected in this action (if existing rule, also give Code of Regulations number and page numbers affected):
Sections(s) 8.200.2.D.a, Colorado Department of Health Care Policy and Financing, Staff Manual Volume 8, Medical Assistance (10 CCR 2505-10).
5. Does this action involve any temporary or emergency rule(s)? Yes
If yes, state effective date: July 1, 2024
Is rule to be made permanent? (If yes, please attach notice of hearing). Yes

PUBLICATION INSTRUCTIONS*

Replace the current text at 8.200.2.D with the proposed text beginning at 8.200.2.D.1 through the end of 8.200.2.D.1.d. This rule is effective July 1, 2024.

*to be completed by MSB Board Coordinator

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Title of Rule: Revision to the Medical Assistance Act Rule concerning Physician Oversight, Section 8.200.2.D.a

Rule Number: MSB 24-04-18-B

Division / Contact / Phone: Policy Development and Implementation / Erica Schaler / 3195

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).

Pursuant to C.R.S. 25.5-4-506, provide doula benefit for Medicaid-enrolled pregnant persons effective July 1, 2024. In order to implement the doula benefit, this proposed amendment removes doulas from the rule requiring all providers who are not provided oversight by the Colorado Department of Regulatory Agencies (DORA), practice under the direct supervision of a physician. In order for doulas to be effective, they must provide community-based care. If physician oversight is required, it destroys the integrity of the community-based aspect of this important service.

- 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:

Pursuant to C.R.S. 25.5-4-506, the Department of Health Care Policy and Financing is required to create a Doula benefit for pregnant and postpartum people to improve health outcomes of pregnant and postpartum people who face a disproportionately greater risk of poor birth outcomes.

After a lengthy stakeholder engagement process, the Department has designed this benefit to comply with this legislative mandate and must present this rule, in order to implement the doula benefit, as an emergency rule to meet the July 1, 2024 deadline.

- 3. Federal authority for the Rule, if any:

42 CFR 440

- 4. State Authority for the Rule:

C.R.S. Section 25.5-4-506;

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

Initial Review

Proposed Effective Date

07/01/24

Final Adoption

Emergency Adoption

07/12/24

05/10/24

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Title of Rule: Revision to the Medical Assistance Act Rule concerning Physician Oversight, Section 8.200.2.D.a
Rule Number: MSB 24-04-18-B
Division / Contact / Phone: Policy Development and Implementation / Erica Schaler / 3195

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 persons who will be affected by the proposed rule are Medicaid members who are pregnant or in the postpartum period and Doula providers. This rule will increase access to care and improve birth outcomes by providing physical and emotional support during pregnancy, labor and delivery, and after giving birth. Doulas will be able to provide services within a community setting aligning with the purpose of Doula services. There are no associated costs with the proposed rule.

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

The impact of the proposed rule is an increase in access to care for pregnant persons and postpartum persons and improve birth outcomes for these populations. These populations will receive more support during the prenatal period, labor and delivery, and postpartum period. Doulas will be able to provide care within a community setting without the restriction of requiring physician oversight which would cause delays in service delivery and increase barriers to access for pregnant Medicaid members.

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

This rule is budget neutral to implement. However, the Department anticipates an increase in state revenues by decreasing the number of infants needing intensive medical care.

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

The benefits of the proposed rule outweigh the costs. Excluding doulas from the rule that requires providers who are not regulated by DORA to practice under direct physician supervision will increase access to care for pregnant Medicaid members

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and allow for doulas to practice in community settings. There are no benefits to inaction and in fact, inaction would prevent implementation of the doula benefit.

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

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

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

There are no alternative methods for achieving the purpose of the proposed rule as this rule is drafted to meet the requirements of a legislative mandate.

8.200 PHYSICIAN SERVICES

8.200.2 Providers

[SECTIONS 8.200.2.A-.C and .E ARE UNAFFECTED BY THIS RULE CHANGE]

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

1. With the exception of the non-physician providers described in Sections 8.200.2.A. through 8.200.2.C. and 8.200.2.D.1.a., a non-physician provider may provide covered goods and services only under the Direct Supervision of an enrolled provider who has the authority to supervise those services, according to the Colorado Department of Regulatory Agencies rules. If Colorado Department of Regulatory Agencies rules do not designate who has the authority to supervise, the non-physician provider must provide services under the Direct Supervision of an enrolled physician, with exception of doulas.
 - a. Registered Nurses (RNs) are authorized to provide delegated medical services within their scope of practice as described in the Colorado Department of Regulatory Agencies rules under General Supervision.
 - b. Non-physician providers are authorized to provide Health Education Services under General Supervision of a provider who has the authority to supervise them in accordance with Colorado Department of Regulatory Agencies rules.
 - c. Physical therapy assistants, occupational therapy assistants, and speech language pathology clinical fellows are authorized to provide services within their scope of practice, and under the General Supervision of an enrolled provider who has the authority to supervise them, in accordance with Colorado Department of Regulatory Agencies rules.
 - d. Speech language pathology assistants are authorized to provide services within their scope of practice only under the Direct Supervision of a licensed speech language pathologist who has the authority to supervise them, in accordance with Colorado Department of Regulatory Agencies rules.