

THIS PAGE IS NOT FOR PUBLICATION

Title of Rule: Tamper-Resistant Prescription Drug Pads
Rule Number: MSB 07-11-27-A
Division / Contact / Phone: Client Services / Cathy Traugott / 303-866-2468

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 07-11-27-A, Tamper-Resistant Prescription Drug Pads
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) 8.837, 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:
Is rule to be made permanent? (If yes, please attach notice of hearing). Yes

PUBLICATION INSTRUCTIONS*

Please replace the current text in **§8.837 PRESCRIPTION REQUIREMENTS** with the attached new text through the end of §8.837.3.D.

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STATEMENT OF BASIS AND PURPOSE

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

The purpose of this rule is to implement 42 U.S.C. Section 1396b(i)(23) which requires prescriptions for covered outpatient drugs to be written on a tamper-resistant pad for pharmacies to receive reimbursement.

2. An emergency rule-making is imperatively necessary

☒ to comply with state or federal regulation and/or

☐ for the preservation of public health, safety and welfare.

Explain:

Federal law requires that states not make payment for amounts expended for medical assistance for covered outpatient drugs unless the prescription is executed on a tamper-resistant pad.

3. Federal authority for the Rule, if any:

42 U.S.C. Section 1396b(i)(23)

4. State Authority for the Rule:

25.5-1-301 through 25.5-1-303, C.R.S. (2007);
25.5-5-202, C.R.S. (2007)

Initial Review

Proposed Effective Date

04/01/2008

Final Adoption

Emergency Adoption

02/08/2008

DOCUMENT #01

THIS PAGE IS NOT FOR PUBLICATION

Title of Rule: Tamper-Resistant Prescription Drug Pads
Rule Number: MSB 07-11-27-A
Division / Contact / Phone: Client Services / Cathy Traugott / 303-866-2468

REGULATORY ANALYSIS

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

Pharmacies and prescribers enrolled as Medicaid providers will be affected by the proposed rule.

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

Prescribers will be required to write prescriptions for covered outpatient drugs on tamper-resistant pads. The cost of these pads will be borne by the prescribers, though in some cases prescribers may already utilize pads that comply with the rule. Also, prescribers may send prescriptions electronically (via the internet), by fax or by telephone to eliminate the need for tamper resistant prescriptions entirely. Given these variables, the Department does not have data to quantify the economic impact of this rule on prescribers.

Pharmacies will be required to accept written prescriptions for Medicaid clients on tamper resistant pads only. Pharmacies may incur administrative costs in order to assure compliance with this requirement but the Department does not have data to quantify the costs.

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 implementation costs and expects that existing Department staff is sufficient to enforce the proposed rule.

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

Inaction is not an option because the program is required by the Social Security Act.

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

N/A

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

N/A

8.837 PRESCRIPTION REQUIREMENTS

8.837.1 REIMBURSEMENT

8.837.1.A. Reimbursement shall be made for prescribed drugs provided to eligible recipients when the following conditions are met:

1. ~~A.~~—The item dispensed is a covered prescription drug by a participating company, a compounded prescription as described in 10 C.C.R. 2505-10, Section 8.832, or has been prior authorized;
2. ~~B.~~—The person prescribing the item is authorized to do so by appropriate Colorado statutes;
3. ~~C.~~—The prescription is dispensed in accordance with applicable federal and state laws, rules, and regulations;
4. ~~D.~~—The prescription is dispensed in accordance with the law, rules, and regulations governing the Colorado Medical Assistance Program; and
5. The prescription is written on a tamper-resistant prescription drug pad or is excluded from the tamper-resistant prescription drug pad requirements set forth in 10 C.C.R. 2505-10, Section 8.837.2.

8.837.2 TAMPER-RESISTANT PRESCRIPTION DRUG PADS

8.837.2.A. Tamper-resistant prescription drug pads are written prescription pads used for Medicaid outpatient drugs, including over-the-counter drugs, that prevent unauthorized copying of a completed or blank form, erasure of information written on the prescription by the prescriber, or the use of counterfeit prescription forms.

8.837.2.B. To be considered tamper-resistant, a prescription pad must contain one of the following characteristics by April 1, 2008. By October 1, 2008, the pad must contain all three features.

1. One or more industry recognized features designed to prevent unauthorized copying of completed or blank prescription form.
2. One or more industry recognized features designed to prevent the erasure or modification of information written on the pad by the prescriber.
3. One or more industry recognized features designed to prevent the use of counterfeit forms.

8.837.2.C. The use of tamper-resistant prescription pads is not required when:

1. Prescriptions are transmitted from the prescriber to the pharmacy electronically; or
2. Prescriptions are sent by facsimile to the pharmacy; or
3. Prescriptions are called in by the prescriber; or
4. A Medicaid managed care entity pays for the prescription.

8.837.2.D. The use of tamper-resistant prescription drug pads does not apply to drugs that are provided as part of the following:

1. Inpatient hospital services.
2. Hospice services.

3. Dental services (except when a State Plan authorizes direct reimbursement to the dispensing dentist).
4. Physician services.
5. Outpatient hospital services.
6. Nursing facilities and intermediate care facilities for the mentally retarded.
7. Other laboratory and x-ray services.
8. Renal dialysis.

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

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

8.837.3 RECORD RETENTION

RECORD RETENTION

8.837.3.A. .01—Participating pharmacy providers must maintain the original copy of all prescriptions for which payment from the Medical Assistance Program is requested. The original prescription shall be a hard copy either written by the prescriber or reduced to writing when received by the pharmacist by telephone or other electronic means. Information required by the Colorado State Board of Pharmacy shall be recorded on each prescription but must include, name of patient, name of drug, quantity ordered, directions, name of prescribing practitioner, date written and date filled, and initials of pharmacist filling the prescription or responsible for its contents.

8.837.3.B. .02—In addition, if a substitution for a prescribed brand name drug is made or the prescription is written generically, the name and manufacturer of the drug dispensed shall be recorded on the face of the prescription. A copy of a label which is created to accompany the drug will not suffice as the prescription.

8.837.2.C. Any refill prescription records shall be maintained in accordance with Colorado State Board of Pharmacy requirements and contain the same information as required above.

8.837.3.D. Such files and records shall be maintained in an orderly manner and shall promptly be available for inspection by authorized personnel of the Colorado State Department of Health Care Policy and Financing, the U. S. Department of Health and Human Services, and the Colorado Medicaid Fraud Control Unit.

THIS PAGE IS NOT FOR PUBLICATION

Title of Rule: Modification to Quals for the CICP Rural Hospital Payment

Rule Number: MSB 07-12-20-A

Division / Contact / Phone: Safety Net Financing/Cindy Arcuri/X3996

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 07-12-20-A, Modification to Qualifications for the Colorado Indigent Care Rural Hospital Payment
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) 8.903.C.15, 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*

Please replace the existing text at §8.903.C.15 through 8.903.C.15.c. with the attached new text. Please note the heading that is included is for clarification only and not intended to be published in the middle of the rule.

THIS PAGE IS NOT FOR PUBLICATION

Title of Rule: Modification to Quals for the CICP Rural Hospital Payment
Rule Number: MSB 07-12-20-A
Division / Contact / Phone: Safety Net Financing/Cindy Arcuri/X3996

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).

Colorado Revised Statutes, Section 25.5-3-107(4)(a)(I) (2007) directs the Rural Hospital Payment to be "distributed to rural hospitals of 60 beds or less." The Department's rule for this payment, at Section 8.903.C.15.a, states that in order to qualify for this payment, rural hospitals must have 60 or fewer licensed beds. This proposed rule strikes the qualifying word "licensed" and adds "staffed acute care" in order to conform the rule to legislative intent.

2. An emergency rule-making is imperatively necessary

☐ to comply with state or federal regulation and/or

☐ for the preservation of public health, safety and welfare.

Explain:

3. Federal authority for the Rule, if any:

4. State Authority for the Rule:

25.5-1-301 through 25.5-1-303, C.R.S. (2007);
and 25.5-3-207(4)(a), C.R.S. (2007).

Initial Review **02/08/2008**

Proposed Effective Date **04/30/2008**

Final Adoption

03/14/2008

Emergency Adoption

DOCUMENT #06

THIS PAGE IS NOT FOR PUBLICATION

Title of Rule: Modification to Quals for the CICP Rural Hospital Payment
Rule Number: MSB 07-12-20-A
Division / Contact / Phone: Safety Net Financing/Cindy Arcuri/X3996

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 amendment modifies the qualifications for the Rural Hospital payment in order to match these qualifications to the legislative intent. Based on this modification, four additional hospitals will qualify for a Rural Hospital payment from the available funding.

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

This proposed rule will provide available funding, in the form of a Rural Hospital payment, to four additional hospitals that would not have qualified for this funding based on the qualifications in the previous rule. This funding will provide a partial reimbursement to these four providers for their uncompensated costs associated with providing discounted health care through the Colorado Indigent Care Program to the underinsured and uninsured.

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

There are no measurable costs to the Department or to any other agency regarding the implementation and enforcement of the proposed amendment.

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

The costs of inaction are twofold: noncompliance with legislative intent, and four rural hospitals will not receive a Rural Hospital payment.

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. The rule must be amended to ensure conformance with legislative intent.

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.

Alternative methods were not considered.

8.903 PROVISIONS APPLICABLE TO QUALIFIED HEALTH CARE PROVIDERS

C. Distribution of Available Funds to Providers

15. Rural Hospital Payment. This payment is an allocation of the Supplemental Tobacco Litigation Settlement Moneys Account and is available to qualified Rural Hospital providers. [Eff. 10/30/07]

- a. A Rural Hospital provider shall meet the following requirements to qualify for the payment: (1) participate in the Colorado Indigent Care Program; (2) reside outside the boundaries of a federally designated metropolitan statistical area; and (3) have 60 or fewer ~~licensed~~staffed acute care beds. [Eff. 10/30/07]
- b. Fifty percent of the moneys appropriated to the Supplemental Tobacco Litigation Settlement Moneys Account each fiscal year plus any corresponding available federal financial participation shall be allocated to qualified Rural Hospital providers on a quarterly basis. [Eff. 10/30/07]
- c. The Rural Hospital payment to a qualified provider shall be calculated as the individual provider's Weighted Medically Indigent Costs relative to the sum of total Weighted Medically Indigent Costs for all qualified hospital providers multiplied by the allocation available to Rural Hospital providers. Weighted Medically Indigent Costs shall be as defined in Section 8.903.C.10 and the allocation available to Rural Hospital providers shall be as specified in Section 8.903.C.15.b. [Eff. 10/30/07]