

Title of Rule: Revision to the Medical Assistance Health Program Services and Supports Division Rule Concerning Dialysis Treatment Centers Section 8.310
Rule Number: MSB 14-07-28-C
Division / Contact / Phone: HPBO / Ana Lucaci / x6163

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 is updating this rule to include content from the Dialysis Services Benefit Coverage Standard. Specifically, the rule will define the amount, scope and duration of the 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:

3. Federal authority for the Rule, if any:

42 U.S.C. § 1396d(a)(8)

4. State Authority for the Rule:

25.5-1-301 through 25.5-1-303, C.R.S. (2013);
§ 25.5-5-301, C.R.S.

Initial Review **10/10/2014**
Proposed Effective Date **12/30/2014**

Final Adoption **11/14/2014**
Emergency Adoption

DOCUMENT #02

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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.

This rule will impact clients and providers of Dialysis services.

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

Clearly defined and updated rules will improve client access to appropriate, high quality, cost-effective and evidence-based services while improving the health outcomes of Medicaid clients. Established criteria within rule will provide guidance to clients and providers regarding benefit coverage.

For example, this rule will help ensure that appropriately diagnosed clients are receiving the allowed services, such as hemodialysis or peritoneal dialysis in a dialysis treatment center. The rule also clarifies responsibilities that dialysis centers carry when clients are performing in-center self-dialysis and home-dialysis: provide appropriate course of training by qualified personnel, necessary supplies, and equipment for dialysis services. In the case of home-dialysis, the dialysis center is also responsible for the delivery, installation, and maintenance of the equipment.

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 does not have any costs to the Department or any other agency as a result of its implementation and enforcement.

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

Clearly defined and updated rules increase client access to appropriate services and allow the Department to administer benefits in compliance with federal and state regulations, as well as clinical best practices and quality standards. Defining this benefit in rule will educate clients about their benefits and provide better guidance to service providers. The cost of inaction could result in decreased access to services, poor quality of care, and/or lack of compliance with state and federal guidance.

All of the above translates into cost savings for the state.

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In FY [13-14] estimated benefit utilization and associated costs (estimated due to lack of Quarter 4 data) were as follows:

1. [1,408] people accessed this benefit;
 2. Total expenditures were [\$10,150,667.95];
and
 3. Per capita expenditure averaged [\$7,209.28]
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 this rule. The department must appropriately define amount, scope and duration of this benefit in order to responsibly manage it.
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. The Department also documents its benefit coverage policies in written coverage standards. The benefit coverage policies must be written into rule to have the force of law.

1 **8.310—DIALYSIS TREATMENT CENTERS**
2

3 **8.310.1 Dialysis Treatment Center Benefit Coverage Standard Incorporated by Reference**
4

5 All Dialysis Treatment Centers enrolled in the Colorado Medicaid program shall be in compliance
6 with the Colorado Medicaid Dialysis Treatment Center Benefit Coverage Standard (approved May
7 1, 2012) which is hereby incorporated by reference. The incorporation of the Dialysis Treatment
8 Center Benefit Coverage Standard excludes later amendments to, or editions of, the referenced
9 material.

10
11 The Benefit Coverage Standard is available from Colorado Medicaid's Benefits Collaborative
12 Web site at Colorado.gov/hcpf. Click "Boards & Committees," and click "Benefits Collaborative,"
13 and click "Approved Benefit Coverage Standards." Pursuant to § 24-4-103 (12.5), C.R.S., the
14 Department maintains copies of this incorporated text in its entirety, available for public inspection
15 during regular business hours at: Colorado Department of Health Care Policy and Financing,
16 1570 Grant Street, Denver, CO 80203. Certified copies of incorporated materials are provided at
17 cost upon request.

18
19 **8.310 DIALYSIS TREATMENT CENTERS**

20 **8.310.1 Definitions**

21 Acute Kidney Injury (AKI) is the sudden loss of kidney function, the ability of the kidneys to
22 remove waste and excess fluid. AKI is typically a condition in which kidney function can be
23 expected to recover after a short period of time with treatment (i.e. pharmaceuticals or dialysis).
24 However, AKI can progress to a complete recovery of kidney function, development of Chronic
25 Kidney Disease (CKD) or End Stage Renal Disease (ESRD).

26 Chronic Kidney Disease (CKD) is the slow loss of kidney function over time until the kidneys
27 reach ESRD.

28 Dialysis is the process of cleaning the blood when the kidneys have failed and are no longer
29 filtering the blood to remove waste and excess fluid. Kidney failure can stem from AKI or CKD.
30 Dialysis includes both peritoneal dialysis and hemodialysis.

31 End Stage Renal Disease (ESRD) is defined as irreversible and permanent damage to the
32 kidneys that requires either a regular course of dialysis treatment or kidney transplantation to
33 maintain life.

34 Provider means a Dialysis Treatment Center that is hospital-affiliated or independent of a
35 licensed hospital, and licensed by the Colorado Department of Public Health and Environment to
36 provide outpatient dialysis services or training for home or self-dialysis.

1 Home Dialysis Training is a program that trains Clients to perform dialysis in the client's home
2 with little or no professional assistance, and trains other individuals to assist clients in performing
3 home dialysis.

4 Self-Dialysis Training is a program that trains Clients to perform self-dialysis in the treatment
5 facility with little or no professional assistance, and trains other individuals to assist Clients in
6 performing self-dialysis.

7 **8.310.2. Eligibility**

8 **8.310.2.A. Client Eligibility**

9 1. Any Colorado Medicaid Client diagnosed with CKD, AKI or ESRD, which requires
10 dialysis treatments to restore kidney function or maintain life shall be eligible.

11 **8.310.2.B. Provider Eligibility**

- 12 1. To provide services, a Dialysis Treatment Center must be:
- 13 a. Enrolled in the Colorado Medical Assistance Program;
 - 14 b. Certified by the Centers for Medicare and Medicaid Services (CMS) to
15 participate in the Medicare program as a dialysis treatment center;
 - 16 c. Certified by the Colorado Department of Public Health and Environment

17 **8.310.2.C. Prior Authorization**

18 1. Prior Authorization is not required for services listed at Section 8.310.3.B.

19 **8.310.3. General Services**

20 **8.310.3.A. Provider Requirements**

- 21 1. The Provider must utilize the most cost efficient method of dialysis treatment
22 appropriate for each client, as assessed through an evaluation for peritoneal
23 dialysis based upon an individual medical diagnosis and condition.
- 24 2. The Provider Facility must develop and implement a written, individualized
25 comprehensive plan of care for each patient, which must include:
 - 26 a. The services necessary to address the patient's needs;
 - 27 b. The comprehensive assessment and changes in the patient's condition;

- 1 c. Measurable and expected outcomes, and estimated timetables to
2 achieve these outcomes;
- 3 d. The outcomes specified in the patient plan of care must be consistent
4 with current evidence-based professionally-accepted clinical practice
5 standards; and
- 6 e. The plan of care must represent the selection of a suitable treatment
7 modality (e.g., dialysis or transplantation) and dialysis setting (e.g.,
8 home, self-care) for each patient (42 CFR 405, 410, 413, 414, 488 and
9 494).

10 **8.310.3.B. Covered Dialysis Services**

11 The following are covered services under the Colorado Medicaid Dialysis Center
12 Program:

13 1. In-Center Dialysis

- 14 a. Dialysis treatments completed by facility staff, and all necessary
15 equipment and supplies.
- 16 b. In-Center dialysis is a benefit when the client meets one of the following
17 conditions:
 - 18 i) The client requires dialysis treatments prior to completing home
19 dialysis training;
 - 20 ii) Training to perform self-treatment in the home environment is
21 contraindicated;
 - 22 iii) The client is otherwise not a proper candidate for self-treatment
23 in a home environment;
 - 24 iv) The home environment of the eligible client contraindicates self-
25 treatment; or
 - 26 v) The eligible client is awaiting a kidney transplant.
- 27 c. Self-dialysis may be performed within the facility with limited professional
28 assistance, if the client has completed an appropriate course of training.
 - 29 i) The benefit includes training of the client by qualified personnel.

30 2. Home Dialysis

- 1 a. To be eligible for home dialysis a client or client's caregiver must receive
2 appropriate training to perform dialysis at home.
- 3 b. The benefit includes training by qualified personnel, necessary supplies,
4 and equipment for dialysis services.
- 5 c. The Benefit includes delivery, installation, and maintenance of equipment
6 for home dialysis
- 7 3. The following are included in the Dialysis Center reimbursement and should not
8 be billed separately:
 - 9 a. Costs associated with home dialysis other than necessary delivery,
10 equipment, installation, maintenance, supplies, or training.
 - 11 b. Blood and blood products.
 - 12 c. Additional staff time or personnel costs.
 - 13 d. Routine Laboratory Services
 - 14 i) All laboratory services considered routine for dialysis treatment,
15 and performed by a dialysis treatment facility, are included as
16 part of the dialysis treatment reimbursement.
 - 17 ii) A Provider performing routine laboratory services must be a
18 certified clinical laboratory.
 - 19 e. Routine Pharmaceuticals for Dialysis Treatment
 - 20 i) All pharmaceuticals considered routine for dialysis treatment,
21 and dispensed by a dialysis treatment facility, are included as
22 part of the dialysis treatment reimbursement.
 - 23 ii) Pharmaceuticals not dispensed by the dialysis provider are billed
24 by and reimbursed to the dispensing pharmacy.

25 **8.310.3.C. Non-Covered Services**

26 The following are non-covered services under the Colorado Medicaid Dialysis Center
27 benefit:

- 28 1. Personal care items such as slippers or toothbrushes.

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