

1 CABINET FOR HEALTH AND FAMILY SERVICES

2 Department for Medicaid Services

3 Division of Administration and Financial Management

4 (Amendment)

5 907 KAR 3:130. Medical Necessity and Clinically Appropriate Determination Basis.

6 RELATES TO: KRS 205.520; 42 CFR 440.230; 441 Subpart B, and 42 USC 1396d

7 (r)

8 STATUTORY AUTHORITY: KRS 194A.030, 194A.050, 205.560, and 42

9 USC 1396a, b, d[, ~~EO 2004-726~~]

10 NECESSITY, FUNCTION, AND CONFORMITY: [~~EO 2004-726, effective July 9,~~

11 ~~2004, reorganized the Cabinet for Health Services and placed the Department for~~

12 ~~Medicaid Services and the Medicaid Program under the Cabinet for Health and Family~~

13 ~~Services.] The Cabinet for Health and Family Services, Department for Medicaid~~

14 Services, has responsibility to administer the Medicaid Program. KRS 205.520(3)

15 authorizes the cabinet, by administrative regulation, to comply with any requirement that

16 may be imposed or opportunity presented by federal law for the provision of medical

17 assistance to Kentucky's indigent citizenry. This administrative regulation establishes

18 the basis for the determination of the medical necessity and clinical appropriateness of

19 benefits and services for which payment shall be made by the Medicaid program behalf

20 of both the categorically and the medically needy.

21 Section 1. Definitions.

1 (1) "Clinically appropriate" means appropriate pursuant to nationally-recognized
2 clinical criteria for which the department has contracted.

3 (2) "Covered benefit" or "covered service" means a health care service or item for
4 which the department shall reimburse in accordance with state and federal regulations.

5 (3) [(2)] "Department" means the Department for Medicaid Services or its designated
6 agent.

7 (4) [(3)] "Medically necessary" or "medical necessity" means a covered benefit is:

8 (a) Reasonable and required to identify, diagnose, treat, correct, cure, palliate, or
9 prevent a disease, illness, injury, disability, or other medical condition, including
10 pregnancy;

11 (b) Clinically appropriate in terms of the service, amount, scope, and duration based
12 on generally accepted standards of good medical practice;

13 (c) Provided for medical reasons rather than primarily for the convenience of the
14 individual, the individual's caregiver, or the health care provider, or for cosmetic
15 reasons;

16 (d) Provided in the most appropriate location, with regard to generally accepted
17 standards of good medical practice, where the service may, for practical purposes, be
18 be safely and effectively provided;

19 (e) Needed, if used in reference to an emergency medical service, to evaluate or
20 stabilize an emergency medical condition that is found to exist using the prudent
21 layperson standard;

22 (f) Provided in accordance with Early and Periodic Screening, Diagnosis, and
23 Treatment (EPSDT) requirements established in 42 USC 1396d(r) and 42 CFR

1 (g) Provided in accordance with 42 CFR 440.230.

2 (5) [~~(4)~~] "Prudent layperson standard" means the standard for determining the
3 existence of an emergency medical condition whereby a prudent layperson who
4 possesses an average knowledge of health and medicine determines that a medical
5 condition manifests itself by acute symptoms of sufficient severity (including severe
6 pain) such that the person could reasonably expect the absence of immediate medical
7 attention to result in placing the health of the individual (or with respect to a pregnant
8 woman, the health of the woman or her unborn child) in serious jeopardy, serious
9 impairment to bodily functions, or serious dysfunction of any bodily organ or part.

10 Section 2. Medical Necessity Determination.

11 (1) The determination of whether a covered benefit or service is medically necessary
12 shall be:

13 (a) Based on an individualized assessment of the recipient's medical needs; and

14 (b) Comply with the definition of medically necessary established in Section 1(3) of
15 this administrative regulation.

16 (2) The department shall have the final authority to determine the medical necessity
17 of a covered benefit or service and shall ensure the right of a recipient to appeal a
18 negative action in accordance with 907 KAR 1:563.

19 Section 3. Criteria to Establish Clinical Appropriateness.

20 (1) The department shall utilize criteria to determine if a given Medicaid service or
21 benefit is clinically appropriate.

22 (2) The criteria referenced in subsection (1) of this Section shall be nationally-
23 recognized clinical criteria for which the department has contracted.

907 KAR 3:130

REVIEWED:

Date

J. Thomas Badgett, MD, PhD, Acting Commissioner
Department for Medicaid Services

Date

Mike Burnside, Undersecretary
Administrative and Fiscal Affairs

APPROVED:

Date

Mark D. Birdwhistell, Secretary
Cabinet for Health and Family Services

907 KAR 3:130

A public hearing on this administrative regulation shall, if requested, be held on August 21, 2006 at 9:00 a.m. in the Health Services Auditorium, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky. Individuals interested in attending this hearing shall notify this agency in writing by August 14, 2006, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. The hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to attend the public hearing, you may submit written comments on the proposed administrative regulation. You may submit written comments regarding this proposed administrative regulation until close of business August 31, 2006. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to:

CONTACT PERSON: Jill Brown, Office of Legal Services, 275 East Main Street 5 W-B, Frankfort, KY 40601, Phone: 502-564-7905, Fax: 502-564-7573.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Administrative Regulation #: 907 KAR 3:130

Cabinet for Health and Family Services

Department for Medicaid Services

Agency Contact Person: Stuart Owen or Stephanie Brammer-Barnes (502-564-6204)

- (1) Provide a brief summary of:
 - (a) What this administrative regulation does: This administrative regulation establishes medical necessity and clinical appropriateness for Medicaid coverage authorization purposes.
 - (b) The necessity of this administrative regulation: This administrative regulation is necessary to establish medical necessity and clinical appropriateness for Medicaid coverage authorization purposes.
 - (c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of the authorizing statutes by establishing medical necessity and clinical appropriateness for Medicaid coverage authorization purposes.
 - (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation will assist in the effective administration of the authorizing statutes by establishing medical necessity and clinical appropriateness for Medicaid coverage authorization purposes.

- (2) If this is an amendment to an existing administrative regulation, provide a brief summary of:
 - (a) How the amendment will change this existing administrative regulation: This amendment establishes the use of criteria to determine clinically appropriateness of any given Medicaid service or benefit for an individual.
 - (b) The necessity of the amendment to this administrative regulation: This amendment is necessary to establish the use of criteria to determine clinically appropriateness of any given Medicaid service or benefit for an individual.
 - (c) How the amendment conforms to the content of the authorizing statutes: This amendment conforms to the content of authorizing statutes by establishing the use of criteria to determine clinically appropriateness of any given Medicaid service or benefit for an individual.
 - (d) How the amendment will assist in the effective administration of the statutes: The amendment will assist in the effective administration of the authorizing statutes by establishing the use of criteria to determine clinically appropriateness of any given Medicaid service or benefit for an individual.

- (3) List the type and number of individuals, businesses, organizations, or state and local government affected by this administrative regulation: This amendment affects all Medicaid providers.

- (4) Provide an assessment of how the above group or groups will be impacted by either the implementation of this administrative regulation, if new, or by the change if it is an amendment: This amendment establishes the use of criteria to determine clinical appropriateness of any given Medicaid service or benefit for an individual. Providers will be affected in that this criteria will determine if the department will cover any given Medicaid service or benefit.
- (5) Provide an estimate of how much it will cost to implement this administrative regulation:
 - (a) Initially: The Department for Medicaid Services (DMS) is unable to determine a precise aggregate fiscal impact of the use of the criteria to determine clinical appropriateness for multiple programs; however, it anticipates a savings of at least \$2.5 million (\$1.7 million federal funds; \$0.8 million state funds) annually.
 - (b) On a continuing basis: DMS is unable to determine a precise aggregate fiscal impact of the use of the criteria to determine clinical appropriateness for multiple programs; however, it anticipates a savings of at least \$2.5 million (\$1.7 million federal funds; \$0.8 million state funds) annually.
- (6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The sources of revenue to be used for implementation and enforcement of this administrative regulation are federal funds authorized under the Social Security Act, Title XIX and matching funds of general fund appropriations.
- (7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: The current fiscal year budget will not need to be adjusted to provide funds for implementing this administrative regulation.
- (8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation does not establish or increase any fees.
- (9) Tiering: Is tiering applied? (Explain why tiering was or was not used)

Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all those individuals or entities regulated by it. Disparate treatment of any person or entity subject to this administrative regulation could raise questions of arbitrary action on the part of the agency. The “equal protection” and “due process” clauses of the Fourteenth Amendment of the U.S. Constitution may be implicated as well as Sections 2 and 3 of the Kentucky Constitution.