

1 CABINET FOR HEALTH AND FAMILY SERVICES

2 Department for Medicaid Services

3 Division of Administration and Financial Management

4 (Amended After Comments)

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 and clinical appropriateness of a covered benefit or service and shall ensure the right of  
18 a recipient to appeal a 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  
(Amended After Comments)

REVIEWED:

\_\_\_\_\_  
Date

\_\_\_\_\_  
Glenn Jennings, 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

## 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. The amended after comments regulation clarifies that appeals provisions apply to clinical appropriateness determinations and clarifies that the medical necessity definition is distinct from the clinically appropriate definition.
  - (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. The amended after comments regulation is necessary to clarify appeals policy as well as the medical necessity definition.
  - (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. The amended after comments regulation conforms to the content of authorization statutes by clarifying appeals policy as well as the medical necessity definition.
  - (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. The amended after comments regulation assists in the effective administration of the statutes by clarifying appeals policy as well as the medical necessity definition.

- (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 analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:
  - (a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: The amendment to this administrative regulation establishes the use of criteria by the Department for Medicaid Services to determine the clinical appropriateness of any given care. The criteria will be utilized to determine whether a given service or benefit will be covered by the Medicaid program. The amended after comments regulation clarifies that appeals provisions apply to clinical appropriateness determinations and clarifies that the medical necessity definition is distinct from the clinically appropriate definition. Care provided by regulated entities must meet the criteria established in the regulation in order to be covered by the Department for Medicaid Services.
  - (b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (c): No costs are required of regulated entities for compliance with this amendment.
  - (c) As a result of compliance, what benefits will accrue to the entities identified in question (3): The amendment to this administrative regulation establishes the use of criteria by the Department for Medicaid Services to determine the clinical appropriateness of any given care.
- (5) Provide an estimate of how much it will cost to implement this administrative regulation:
  - (a) Initially: The Department for Medicaid Services (DMS) anticipates a one (1) percent reduction in expenditures for any given procedure for which the clinically appropriate criteria is the prior authorization tool.
  - (b) On a continuing basis: DMS anticipates a one (1) percent reduction in expenditures for any given procedure for which the clinically appropriate criteria is the prior authorization tool.
- (6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The sources of funding 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.

## FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Reg NO: 907 KAR 3:130

Contact Person: Stuart Owen  
(564-6204)

1. Does this administrative regulation relate to any program, service, or requirements of a state or local government (including cities, counties, fire departments or school districts)?

Yes  X  No

If yes, complete 2-4.

2. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This administrative regulation and amended after comments regulation will affect Medicaid providers.
3. Identify each state or federal regulation that requires or authorizes the action taken by the administrative regulation. Pursuant to 42 USC 1396a et. seq., the Commonwealth of Kentucky has exercised the option to establish a Medicaid Program for indigent Kentuckians. Having elected to offer Medicaid coverage, the state must comply with federal requirements contained in 42 USC 1396 et. seq.
4. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.
  - (a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This amendment will not generate any additional revenue for state or local governments during the first year of implementation.
  - (b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This amendment will not generate any additional revenue for state or local governments during subsequent years of implementation.
  - (c) How much will it cost to administer this program for the first year? The Department for Medicaid Services (DMS) anticipates a one (1) percent reduction in expenditures for any given procedure for which the clinically appropriate criteria is the prior authorization tool.
  - (d) How much will it cost to administer this program for subsequent years? DMS anticipates a one (1) percent reduction in expenditures for any given procedure for which the clinically appropriate criteria is the prior authorization tool.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): \_\_\_\_\_

Expenditures (+/-): \_\_\_\_\_

Other Explanation: