Title of Rule: Revision to the Medical Assistance Program Integrity Rule Concerning the Definition of Medical Necessity, Section 8.076.1.8; and EPSDT Rule Concerning the Definition of Medical Necessity, Section 8.280.
Rule Number: MSB 15-12-18-A
Division/Contact/Phone: Health Programs Benefits & Operations Division/Amanda Forsythe/ 303-866-6459

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).

   Section 8.076.1.8. currently defines "medical necessity" for the purposes of the Department's Program Integrity section. The Department proposes revisions to this section of rule in order to create a uniform definition of "medical necessity" to be used across all applicable Medical Assistance program rules. By consistently referencing the Section 8.076.1.8 definition, the Department aims to increase transparency and reduce unnecessary confusion as to the meaning of "medical necessity" as it applies to a particular program or benefit.

   Proposed revisions to Section 8.076.1.8:

   -- Adds "condition" to list previously limited to "illness, injury, or disability".

   -- Adds provision excluding an experimental or investigational good or service from definition of medically necessary.

   -- Changes "generally accepted standards of medical practice" to "professionally recognized standards for health care." This revision aligns the language with federal Medicaid regulations and with other definitions in Section 8.076.

   -- Clarifies that a good or service may not be provided "primarily" for the convenience of the client, caretaker, or provider.

   -- Replaces requirement that a good or service be "cost effective" with requirement that a good or service not be "more costly than other equally effective treatment options".

   -- Adds reference to Section 8.280 for EPSDT-specific medical necessity criteria.

   Proposed revisions to Section 8.280:

   -- Strikes Section 8.280.1 definition of “medical necessity” in its entirety, because it is almost identical to the proposed language for Section 8.076.1.8.

   -- Strikes Section 8.280.4.E in its entirety, because it is comprised almost entirely of language found in the proposed language for Section 8.076.1.8.

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-- Replaces Section 8.280.4.E.1 with a brief explanation that, under EPSDT all §1905(a) services are covered benefits when medically necessary as defined at Section 8.076.1.8.

-- Replaces Section 8.280.4.E.2 with EPSDT-specific "medical necessity" criteria concerning the coverage of program goods or services that will—or are reasonably expected to—assist clients in achieving or maintaining maximum functional capacity in performing ADLs.

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(r) and 42 CFR 440.230(d)

4. State Authority for the Rule:

C.R.S. 25.5-4-401(2) and 25.5-1-301 through 25.5-1-303, C.R.S. (2015);

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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.**

   The proposed rule provides clearer definition language that will benefit clients, providers, and stakeholders. The Department does not anticipate any costs of the proposed rule creating a single uniform definition of medical necessity to be used throughout its program rules.

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 proposed rule may slightly reduce the need for the Department to answer client and provider questions as to the definition of medical necessity applicable to a given program or benefit. It may also slightly reduce the number of claims submitted and/or denied due to confusion regarding medical necessity criteria. Likewise, the increased clarity and transparency provided by the proposed rule may result in fewer and/or more efficient client appeals.

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- or enforcement-related costs to the Department or any other agency as a result of this proposed rule. Likewise, the Department does not anticipate that this proposed rule will have any effect on state revenues.

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

   The probable benefits of the proposed rule include a reduction in unnecessary provider and client confusion regarding the many varying definitions of medical necessity currently scattered throughout the Department's rules. Consistent use of a single uniform definition will increase the efficiency of processes such as PARs and appeals.

The probable costs of inaction are continued confusion as to how medical necessity is defined for one program benefit as compared to another. This would result in continued inefficiencies and a lack of transparency as to the coverage determination process.

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 for achieving the purpose of the proposed rule revision.

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.**

   The Department considered maintaining a separate definition of medical necessity for EPSDT, given the specific federal criteria of that program. This was ultimately rejected in favor of constructing a uniform definition at 8.076 with a citation to the EPSDT Section 8.280, which contains clarifications and criteria specific to EPSDT medical necessity determinations.

8.076 PROGRAM INTEGRITY ~~[Eff. 12/30/2008]~~

8.076.1 DEFINITIONS

8. Medical necessity means that a Medical Assistance program good or service: ~~that will~~

a. Will, or is reasonably expected to prevent, diagnose, cure, correct, reduce, or ameliorate the pain and suffering, or the physical, mental, cognitive, or developmental effects, of an illness, condition, injury, or disability. ~~It~~ This may ~~also~~ include a course of treatment that includes mere observation or no treatment at all. ~~The good or service must be:~~

b. ~~P~~ Is provided in accordance with ~~generally accepted~~ professionally recognized standards ~~of medical practice~~ for health care in the United States;

c. ~~C~~ Is clinically appropriate in terms of type, frequency, extent, site, and duration;

d. ~~N~~ Is not primarily for the economic benefit of the provider or primarily for the convenience of the client, caretaker, or provider; ~~and~~

e. ~~Performed in a cost effective and~~ Is delivered in the most appropriate setting(s) required by the client's condition~~.~~;

f. Is not experimental or investigational; and

g. Is not more costly than other equally effective treatment options.

8.1. ~~. See also,~~ ~~For~~ EPSDT-medical necessity specific criteria~~, see~~ is located at 10 C.C.R. 2505-10, Section 8.280.4.E. ~~(EPSDT-specific criteria).~~

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8.280 EARLY AND PERIODIC SCREENING, DIAGNOSIS AND TREATMENT ~~[Eff. 10/01/2007]~~

8.280.1 DEFINITIONS

Early and Periodic Screening, Diagnosis and Treatment (EPSDT) means the child health component of Medicaid. The EPSDT program requires coverage of periodic and interperiodic screens, vision, dental and hearing care, diagnostic services needed to confirm the existence of a physical or mental illness or condition, and all medical assistance services that are recognized under Section 1905 of the Social Security Act, even if not offered under the state plan pursuant to federal laws applicable to the program (including 1905(a), 42 U.S.C. §§1396a(a)(42), 1396d(a)(4)(B) and 1396d(r)).

EPSDT Case Management means an activity that assists Medicaid clients in getting and/or coordinating services based on individual need.

EPSDT Outreach means methods to inform recipients or potential recipients, such as those found to be presumptively eligible, to enter into care.

EPSDT Outreach and Case Management Entity means an entity that has contracted with the Department to provide the activities specified in 8.280.3 below.

~~Medical Necessity means that a covered service shall be deemed a medical necessity or medically necessary if, in a manner consistent with accepted standards of medical practice, it:~~

~~1. Is found to be an equally effective treatment among other less conservative or more costly treatment options, and~~

~~2. Meets at least one of the following criteria:~~

~~a. The service will, or is reasonably expected to prevent or diagnose the onset of an illness, condition, primary disability, or secondary disability.~~

~~b. The service will, or is reasonably expected to cure, correct, reduce or ameliorate the physical, mental cognitive or developmental effects of an illness, injury or disability.~~

~~c. The service will, or is reasonably expected to reduce or ameliorate the pain or suffering caused by an illness, injury or disability.~~

~~d. The service will, or is reasonably expected to assist the individual to achieve or maintain maximum functional capacity in performing Activities of Daily Living.~~

~~Medical necessity may also be a course of treatment that includes mere observation or no treatment at all.~~

Personal Care Services means assistance with non-skilled activities of daily living in order to meet the client's physical, maintenance and supportive needs. This assistance may take the form of hands-on assistance (actually performing a task for the person), or prompting or cueing the client to complete the task.

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8.280.4 EPSDT SERVICES

8.280.4.E. Other EPSDT Benefits

~~Other health care services may include other EPSDT benefits if the need for such services is identified. The services are a benefit when they meet the following requirements:~~

~~1. The service is in accordance with generally accepted standards of medical practice.~~

~~2. The service is clinically appropriate in terms of type, frequency, extent, and duration.~~

~~3. The service provides a safe environment or situation for the child.~~

~~4. The service is not for the convenience of the caregiver.~~

~~5. The service is medically necessary.~~

~~6. The service is not experimental or investigational and is generally accepted by the medical community for the purpose stated.~~

~~7. The service is the least costly.~~

1. All goods and services described in Section 1905(a) of the Social Security Act are a covered benefit under EPSDT when medically necessary as defined at 10 C.C.R. 2505-10, Section 8.076.1.8, regardless of whether such goods and services are covered under the Colorado Medicaid State Plan.

2. For the purposes of EPSDT, medical necessity includes a good or service that will, or is reasonably expected to, assist the client to achieve or maintain maximum functional capacity in performing one or more Activities of Daily Living; and meets the criteria set forth at Section 8.076.1.8.b – g.

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