



March 5, 2015

Kimberly Smith  
Benefits Collaborative Coordinator  
Health Programs Office  
Colorado Department of Health Care Policy & Financing  
1570 Grant St.  
Denver, CO 80203

Re: Department proposal to eliminate the child-specific definition of Medical Necessity and promulgate a unitary Medical Necessity definition

Dear Kimberly:

We appreciate the Department's desire to streamline regulations, but it is our position that an assessment of medical necessity as it concerns those under the age of 21 cannot be identical to such an assessment for adults, and that existing Colorado regulations recognize this important distinction. The pediatric definition should be retained in full. (10 CCR 2505-10 8.280.1). As is codified by the current pediatric definition, the pediatric benefit is governed by separate federal law and regulation and must be recognized as having special characteristics.<sup>1</sup> A primary and overarching goal behind providing this more robust benefit to children is to ensure early diagnosis and effective treatment of health problems "before they become more complex and their treatment more costly."<sup>2</sup>

This memo refers to three definitions: the "general" definition of medical necessity used by the State of Colorado (10 CCR 2505-10 8.076.1), the pediatric definition (10 CCR 2505-10 8.280.1), and the definition proposed in January 2015. Those definitions are attached as Exhibit A.

All services available under the pediatric benefit, whether or not offered through the State Plan, are included under Early and Periodic Screening, Diagnostic and Treatment (EPSDT) as laid out in federal law and regulations. As stated in the 2014 manual issued by the Centers for Medicare and Medicaid Services, EPSDT is more robust than the Medicaid benefit for adults, and states have an affirmative obligation to make sure that Medicaid-eligible children have access to all

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<sup>1</sup> See *C.F. v. Dep't Children and Families*, 934 So.2d 1 (Fl. Dist. Ct. App. 2005) (reversing the decision of an administrative hearing officer where the officer improperly applied a narrower definition of "medical necessity" than that contained in the federal EPSDT statute).

<sup>2</sup> CMS, State Medicaid Manual §§ 5010, 5121, 5310.

medically necessary services, whether for screening and diagnosis or for treatment.<sup>3 4</sup> States must provide such services to the extent necessary to “correct or ameliorate” defects, illnesses and conditions.<sup>5</sup>

#### I. Issue: Implied restriction of covered goods and services

As stated in the CMS Manual on EPSDT, “States are permitted to set parameters that apply to the determination of medical necessity in individual cases, but those parameters may not contradict or be more restrictive than the federal statutory requirement.”<sup>6</sup> The first line of HCPF’s proposed definition of medical necessity is at best ambiguous and may lead to misunderstanding that will prevent children from accessing necessary care, treatment, goods and services:

Medical necessity means a Medical Assistance program good or service that 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, injury, or disability.

What, exactly, is a “Medical Assistance program good or service”? If that category refers only to those “program goods or services” in the State Plan, this definition would omit services mandated under EPSDT that are available *outside* the State Plan. The definition does not make it clear that the broader slate of services available to children, and not simply the finite list of services included in Colorado regulations, must be included among program goods and services.<sup>7</sup> Colorado is required to assure that children receive all medically necessary services that can be provided by the Medicaid program, whether mandatory or optional, and whether or not covered under Colorado’s state plan.<sup>8</sup>

If, on the other hand, “program goods or services” refers to all services available under EPSDT, the effect would be to make available the expanded menu of services to all Medicaid-eligible Coloradans, child or adult. “Medical necessity” would thus mean the full slate of EPSDT services – State Plan and beyond – for any Medicaid user. We do not believe this is the intended result.

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<sup>3</sup> CMS, EPSDT- A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents, June 2014. Available at: [http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Downloads/EPSDT\\_Coverage\\_Guide.pdf](http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Downloads/EPSDT_Coverage_Guide.pdf), p. 1

<sup>4</sup> For example, medically necessary treatments must be provided even if the screening was not conducted by a Medicaid provider. Because of the heightened screening requirements, inpatient services are covered – i.e. are not optional – when necessary to complete a diagnosis. Unlike the adult Medicaid benefit, the pediatric benefit includes services, supplies and equipment that are within the categories of mandatory and optional services listed in SSA 1905(a), even if those are not listed in the State Medicaid Plan. Another way in which the adult and childrens’ benefits diverge, because of EPSDT, is in the dental benefit, under which children must be screened for individual level of risk and those at greater risk provided with more frequent dental visits. 2014 EPSDT guide, p. 10, 14-15.

<sup>5</sup> Section 1905(r)(5) of the Social Security Act.

<sup>6</sup> CMS, EPSDT – A Guide for States, p. 23

<sup>7</sup> 8.017.F.2

<sup>8</sup> Section 1905(a) of the Social Security Act.

Our preferred solution is that medical necessity for the pediatric benefit be defined separately, so that it is clear that EPSDT law and regulations set the parameters of medical necessity. Alternatively, a unified definition should indicate that medical necessity under the pediatric benefit is subject to the parameters set out in EPSDT, the child health component of Medicaid, and should either include or reference the language that now appears in 10 CCR 2505-10.8.280.1. The failure to do so would mean that providers or those assessing medical necessity would lack necessary information when determining eligibility.

## II. Other definitional limitations that concern parameters set by EPSDT law and regulation

We support the use of the terms “prevent,” “diagnose,” “cure,” “correct,” “reduce” or “ameliorate” as consistent with EPSDT. This language also appears in the current pediatric definition.

Regarding subsection (b) of the proposed definition, we note that what is “clinically appropriate” under the adult benefit is not identical to the pediatric benefit. What is “clinically appropriate” under the adult benefit can be restricted by State Plan or by state regulation. However, this more rigid approach is impermissible under EPSDT, and an EPSDT-specific definition highlights this issue for those who determine medical necessity, including courts and outside agencies. The definition must make it clear that what is clinically appropriate for children may include greater frequency, extent, and duration of services than is provided in the State Plan, and that flexibility in site or type of services is required.<sup>9</sup>

We believe subsection (c) should be removed. This subsection involves assessment of fraud, rather than medical necessity. The opening clause – “not primarily for the economic benefit of the provider” – could result inappropriately in denial of a benefit or service which satisfied all other requirements, as there is no clear rubric for determining whether an otherwise medically necessary service is *primarily* for the provider’s economic benefit. Regarding the second clause, on convenience to clients, caretakers and providers, it is CCLP’s position that this could become an obstacle to those with disabilities getting assistive devices. This also poses an obstacle for children who need in-home services, such as personal care or CNA services, should the assessing body see such services as a convenience to the parent. In this respect as well, we support the current pediatric definition, which does not contain similar language about fraud.

Regarding subsection (d), we object to the term “medical problem” for two reasons. First, the word “medical” may be read as overly restrictive. In addition to services like personal care, EPSDT services include “any other type of remedial care recognized under State law,” some of which are not, in a literal sense, medical.<sup>10</sup> Behavioral and psychological services, as well as assistance with ADLs and IADLs are coverable under EPSDT, and this broader focus is clear in the current pediatric definition.

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<sup>9</sup> 42 CFR 440.230(c).

<sup>10</sup> Section 1905(a)(6) of the Social Security Act.

Second, under EPSDT, the analysis must be whether there is no equally effective and less costly treatment option for *treatment of a particular child's condition*. The distinction is important; while an equally effective and less costly treatment option for a problem may exist for the general population (a hearing impairment, for example), the determination under EPSDT “must be made on a case-by-case basis, taking into account the particular needs of the child.”<sup>11</sup>

### III. Inconsistent terms

The proposed definition uses the term “medical necessity” inconsistently. As expressed in the general and proposed definitions, “Medical necessity” is a good or service that meets certain requirements. To call “necessity” a good or service is awkward at best. An alternative would be the following: “A Medical Assistance program good or service is medically necessary if it will, or is reasonably expected to . . . .” This alternative would align with subsequent language which states “A good or service is medically necessary only if . . . .”

The current pediatric definition does not contain this inconsistency.

### IV. The benefits of the existing EPSDT-specific definition

In each respect discussed above, the current EPSDT-specific definition adheres more closely to federal law and regulation than does the proposed version.

By introducing the medical necessity definition with a paragraph that defines EPSDT and cites relevant federal law and regulation, the current Colorado regulation makes it clear that certain federal laws and regulations apply. It is clear that coverage of certain services outside the state plan is required, and the use of the term “covered service” is, as a result, unambiguous. The range of applicable conditions is appropriately broad, and includes “illness, condition, primary [and] secondary” disabilities, as well as injury and ADLs.

Even in the existing definition, language regarding efficacy could be more clearly oriented toward the efficacy for the individual child, as is mandated by EPSDT. However, by pairing the definition with the preceding paragraph on EPSDT, the regulation essentially directs a reader to use the individual-centered focus mandated by EPSDT.

### V. Conclusions

In our view, the proposed unitary definition of medical necessity does not adequately address the federal requirements for the pediatric benefit in Colorado, and would increase the likelihood that children are inappropriately denied benefits or services. Services that should be approved could be denied because the assessor of medical necessity believes, for example, that:

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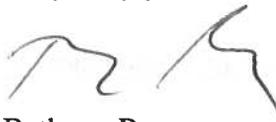
<sup>11</sup> CMS, EPSDT – A Guide for States, p. 23

- a service is not included on the State Plan and is not, therefore, a Medical Assistance program good or service;
- frequency for a service is greater than what is contemplated in the Benefits Coverage Standard and is thus not clinically appropriate;
- the provider gets too great an economic benefit from providing a service;
- the service is a convenience to the parent; or
- for the general population, a different service is effective and less costly.

For the reasons stated, as well as the many demands on Department time and resources, the existing pediatric benefit should be retained.

We appreciate the Department's receptiveness to comments on the medical necessity revision, and would value hearing your response. If you have particular concerns about the current pediatric definition that we should be considering, please let us know. Please don't hesitate to contact me should you have any questions.

Very truly yours,



Bethany Pray

cc: Gina Robinson  
Gretchen Hammer  
Judy Zerzan

## **Appendix A: Colorado Regulations on Medical Necessity and EPSDT**

### **I. General CO Medicaid definition of medical necessity:**

#### **10 CCR 2505-10 8.076.1 Definitions**

(8) Medical necessity means a Medical Assistance program good or service that 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, injury, or disability. It may also include a course of treatment that includes mere observation or no treatment at all. The good or service must be:

- i) Provided in accordance with generally accepted standards of medical practice in the United States;
- ii) Clinically appropriate in terms of type, frequency, extent, site, and duration;
- iii) Not primarily for the economic benefit of the provider or for the convenience of the client, caretaker, or provider; and
- iv) Performed in a cost effective and most appropriate setting required by the client's condition.

### **II. EPSDT-specific definition of medical necessity**

#### **10 CCR 2505-10.8.280.1 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)).

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.

III. Proposed definition of medical necessity

Medical necessity means a Medical Assistance program good or service that 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, injury, or disability. It may also include a course of treatment that includes mere observation or no treatment at all.

A good or service is medically necessary only if:

- a) Provided in accordance with generally accepted standards of medical practice in the United States; and
- b) Clinically appropriate in terms of type, frequency, extent, site and duration; and
- c) Not primarily for the economic benefit of the provider or for the convenience of the client, caretaker, or provider; and
- d) There is no equally effective and less costly treatment option for the medical problem; and
- e) It is delivered in the most appropriate setting required by the client's condition; and
- f) It is not experimental or investigational.

