VIA EMAIL

June 12, 2009

Julie Hudman
Director
Department of Health Care Finance
825 North Capitol Street, N.E.
Washington, D.C. 20002

Re: Comments on the Proposed Medical Necessity Regulations

Dear Dr.Hudman:

I am submitting these comments on behalf of the Children's Law Center (CLC)[1], which represents more than 1,000 low-income children and families in the District of Columbia every year, including 500 foster children and youth and several hundred caregivers of foster children and youth. CLC's comments on the Department of Health Care Finance's Medical Necessity proposed regulations are based on our years of experience advocating for Medicaid services for many of our clients.

We appreciate the long and thoughtful process the Department of Health Care Finance (DHCF) has undergone in promulgating these regulations and the opportunity to provide our comments. In general, we feel these regulations are appropriate and provide useful guidance to beneficiaries and providers; however, we believe the changes suggested below are necessary to conform with federal law and ensure the children of DC are provided with the medical care to which they are entitled.

9000.1 and 9000.2

It is unclear why these regulations apply to services administered by managed care organizations (MCOs) (9000.1(d)), but do not apply to medical necessity determinations for transportation services (9000.2(b)). Currently, transportation services are provided to Medicaid recipients through an independent contractor and it seems inconsistent that these regulations do not extend to this contractor as well as the MCOs. We believe the standards set forth in these regulations should extend to all Medicaid contractors.

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[1] The Children's Law Center envisions a future for the District of Columbia in which every child has a safe home, a meaningful education and a healthy mind and body. We work toward this vision by providing free legal services to more than 1,000 children and families each year and by using the knowledge we gain from representing our clients to advocate for changes in the law. The Children's Law Center is the largest civil legal services organization in the District of Columbia and the only organization providing comprehensive representation to children.

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9000.5

Frequently, for individuals under the age of twenty-one (21), as part of their medically necessary care it is appropriate to also provide services to their parent and/or caregiver to allow them to adequately assist in the child's treatment and compliance with the prescribed treatment or service. Therefore, we suggest the follow language for the opening sentence of this section:

> A proposed or furnished treatment, item or service shall be considered medically necessary in the case of individuals under age twenty-one (21) if the treatment, item or service *provided to that individual or his/her parent or caregiver*, is covered under the State Plan … [continue as written in the current proposed regulation]

9000.5 (c)(iii)

The clause "without regard to whether the underlying condition is congenital or developmental anomaly" should be removed as there could be other reasons (for example, a physical disability cased by an injury) for an underlying condition and this phrase seems to be limiting, or, at best, confusing.

9000.7

The regulations should better define what is meant by the word "agency." It is unclear if this means a government agency or if the term extends to other types of organizations (such as MCOs). Also, it is unclear how, if at all, "agency" as used in this section differs from a "public agency" as used in 9000.10(c).

9000.8

This section lists preventive treatments which are considered medically necessary when covered under the State Plan. Section (b) includes services under EPSDT (42 U.S.C. § 1396d(r)). EPSDT services must be provided to individual under age 21 regardless of whether they are in the State Plan, therefore subsection (b) needs to be placed in a separate section of the regulations.

We suggest this separate section to replace subsection (b) read as follows (incorporating the federal EPSDT language as well as some additional DC-specific provisions) :

> For individuals under age twenty-one (21) provided services pursuant to the EPSDT program, regardless of whether the services are covered under the State Plan, the following early and periodic screening, diagnostic and treatment services shall be considered medically necessary:
>
> (1) Screening services--
>
> (A) which are provided--
>
> (i) at intervals which meet reasonable standards of medical and dental practice, as determined by the State after consultation with recognized medical and dental organizations involved in child health care and, with respect to immunizations under subparagraph (B)(iii),

in accordance with the schedule referred to in section 1928(c)(2)(B)(i) [42 USCS § 1396s(c)(2)(B)(i)] for pediatric vaccines, and

(ii) at such other intervals, indicated as medically necessary, to determine the existence of certain physical or mental illnesses or conditions; and

(B) which shall at a minimum include--

(i) a comprehensive health and developmental history (including assessment of both physical and mental health development),

(ii) a comprehensive unclothed physical exam,

(iii) appropriate immunizations (according to the schedule referred to in section 1928(c)(2)(B)(i) [42 USCS § 1396s(c)(2)(B)(i)] for pediatric vaccines) according to age and health history,

(iv) laboratory tests (including lead blood level assessment appropriate for age and risk factors),

(v) health education (including anticipatory guidance)

(vi) nutritional assessments,

(vii) developmental assessments;

(viii) HIV screening for children in the care and custody of the District's Child and Family Services Agency (CFSA), and

(xi) medical examinations required by CFSA for children in their care.

(2) Vision services--

(A) which are provided--

(i) at intervals which meet reasonable standards of medical practice, as determined by the State after consultation with recognized medical organizations involved in child health care, and

(ii) at such other intervals, indicated as medically necessary, to determine the existence of a suspected illness or condition; and

(B) which shall at a minimum include diagnosis and treatment for defects in vision, including eyeglasses.

(3) Dental services--

(A) which are provided--

(i) at intervals which meet reasonable standards of dental practice, as determined by the State after consultation with recognized dental organizations involved in child health care, and

(ii) at such other intervals, indicated as medically necessary, to determine the existence of a suspected illness or condition; and

(B) which shall at a minimum include relief of pain and infections, restoration of teeth, and maintenance of dental health.

(4) Hearing services--

(A) which are provided--

(i) at intervals which meet reasonable standards of medical practice, as determined by the State after consultation with recognized medical organizations involved in child health care, and

(ii) at such other intervals, indicated as medically necessary, to determine the existence of a suspected illness or condition; and

(B) which shall at a minimum include diagnosis and treatment for defects in hearing, including hearing aids.

(5) Such other necessary health care, diagnostic services, treatment, and other measures described in subsection (a) of this section to correct or ameliorate defects and physical and mental

illnesses and conditions discovered by the screening services, whether or not such services are covered under the State Plan.

9000.10

In <u>subsection (c)</u> the regulations should better define what is meant by the word "public agency." It is unclear if this means a government agency or if the term extends to other types of organizations (such as MCOs). Also, it is unclear how, if at all, "public agency" as used in this section differs from "agency" as used in 9000.7.

<u>Subsection (h)</u> states that medical evidence can include "objective evidence…regarding the cost of health care treatment alternatives under consideration." Federal law (42 U.S.C. §1396d(r)) does not include cost as a factor when individuals under 21 are receiving medically necessary EPSDT services. Therefore the following statement should be added to subsection (h):

> This subsection does not apply to individuals under age twenty-one (21) provided services pursuant to the EPSDT program.

9000. 11

With respect to children eligible for EPSDT, the clinical judgment of the treating professional (9000.10(a)) must be given the greatest weight when making a determination as to whether the treatment or service is medically necessary. While we appreciate the language in this section which states that the 9000.10(a) through (c), a (d) if available, be taken into account, this language does not go far enough. Relevant case law holds (See *Collins v. Hamilton*, 349 F.3d 371 (7th Cir.2003), *Pediatric Specialty Care, Inc. v. Arkansas Dep't of Human Services*, 293 F.3d 472 (8th Cir. 2002)) and our experience with individual children highlights that the judgment of treating physician should carry the most weight in any medical necessity determination.

9000.13 and 9000.14

These sections seem unnecessary to include in these regulations. They contain a list of covered services per the State Plan and therefore do not seem directly related to medical necessity. The lists of required and optional services also seems incomplete (as compared to the current State Plan) and there is some confusing overlap (for example, "medical and surgical services provided by a dentist" is listed at both 9000.13(j) and 9000.14 (a)). In addition, as the State Plan is subject to amendments and waivers, these sections would constantly need to be updated or they could quickly become inaccurate.

9000.15

When read in conjunction with 9000.13(g), 9000.15 is quite confusing. 9000.13(g) states that EPSDT services as defined in 42 U.S.C. § 1396d(r) are covered as part of the required services under the State Plan. 9000.15 enumerates some specific EPSDT-covered services and notes that they are also required. We are concerned that as written 9000.15 could be misread to suggest that EPSDT services not on this list are somehow not covered. We suggest 9000.15 be rewritten as follows:

For individuals under age twenty-one (21) provided services pursuant to the EPSDT program, all other necessary health care, diagnostic services, treatment, and other measures described in 42 U.S.C. § 1396d(r) to correct or ameliorate defects and physical and mental illnesses and conditions discovered by the screening services, whether or not such services are covered under the State Plan.

9000.16 and 9000.17

These sections seem to suggest there are different standards for accessing prescription drugs for people who are in some sort of institutional setting (hospital, residential facility) versus those who are in the community and receiving outpatient care. Under this section it seems that DHCF is making it more difficult for beneficiaries in outpatient care to receive necessary medications which are not on the DHCF preferred drug list or part of an MCO's formulary or prescribed for off-label use. Unfortunately, if it becomes more difficult to access such medications once outpatient, this may lead to individuals spending more time in inpatient facilities. DCHF should maintain one standard for all beneficiaries regardless of whether they are inpatient or outpatient.

Many children with mental health needs are prescribed drugs for off-label use because doctors find that drugs tested for one problem in adults can be effectively used to treat a different problem in children. Therefore, when DHCF determines whether an off-label use is medically necessary, we hope considerable deference will be given to treating providers and that any DHCF reviewers will be experts in psychotropic drugs and children.

9001, 9002, 9003

All timelines should run from the date a beneficiary *receives* a written notice, rather than running from the time the written notice is *mailed (see 9001.6(c), 9001.6(f), 9001.7, 9001.9(e), 9002.12, 9002.14, 9003.9)* As written, the regulations will have a negative impact on many beneficiaries who may not receive their mail in a timely fashion (due to a move or other circumstances). It is more appropriate for timelines to begin, as stated in 9003.6, from the date of receipt of a notice.

9001.3

For clarity and consistency an additional section should be added to 9001.3:

(g) The beneficiary has no responsibility either to:
i. Repay DHCF for any treatment or services found to be medically unnecessary; or

ii. Pay the treating provider whose medical assistance payments
payments are the subject of recovery.

9002.1

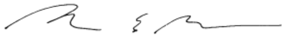
DHCF has chosen to include a list of which treatments, items and services require prior authorization in this regulation. Therefore, should the Department decide to amend this regulation,

such changes must take place through the regulatory process – notice must be given and an opportunity for comments must be allowed (DC ST § 2-505). Publication on DHCF's website doesn't conform with the rulemaking process.

Several items on the list of services which require prior authorization are services which are mandatory for individuals under 21 provided services pursuant to the EPSDT program – vision, dental and hearing services (42 U.S.C §1396d(r)(2), (3) and (4). The introductory language in 9002.1 should note that services described in 42 U.S.C §1396d(r)(2), (3) and (4) relating to services for individuals under 21 are exempted from the prior authorization requirement.

Thank you for considering these comments. If you have any questions or we can provide any other information, please do not hesitate to contact me at 202-467-4900 extension 565 or at sgreer@childrenslawcenter.org.

Sincerely,



Sharra E. Greer
Policy Director