State of Connecticut

GENERAL ASSEMBLY

MEDICAL INEFFICIENCY COMMITTEE
LEGISLATIVE OFFICE BLDG. SUITE 2000
STATE CAPITOL
HARTFORD, CONNECTICUT 06106
240-0490

March 25, 2010

Senator Paul Doyle
300 Capitol Avenue
Legislative Office Building, Room 2001
Hartford, CT 06102

Representative Toni Walker
300 Capitol Avenue
Legislative Office Building, Room 2002
Hartford, CT 06102

Re: Medical Inefficiency Committee Reported Recommendations

Dear Senator Doyle and Representative Walker,

The Medical Inefficiency Committee was established in last year's special session of the legislature, through Public Act 09-03 section 81 (b) and Public Act 09-07 section 107 (b), to advise the Department of Social Services on the amended definition of "medical necessity" utilized in the administration of the State Medicaid program. The statute also required the committee to provide feedback to the General Assembly on the impact of the amended definition.

Members of the Committee (attached) were not appointed until December, and have been working diligently since then to produce this first report. The Committee has been assisted in its work by Brie Johnston, Clerk to the Human Services Committee, and Robin Cohen, Principal Analyst, Office of Legislature Research. Our task was both simple and complex. Simple in that both patients and providers should have a definition of medically necessary to guide them in receiving and providing medical care. It was complex because medical care is not easily subject to definition; it is ever changing and often costly. To assist us in our task we held a public hearing on February 8, 2010 and asked for recommendations from a variety of groups and officials, which recommendations are contained in the appendix of our report. We also asked the Department Social Services to attend all of our meetings and provide their recommendations.

As a result of this extensive input, a review of other definitions of medical necessity used in other programs and states, and a deliberative process over several weeks, we have rejected the Department of Social Services' proposed definition as non-compliant with the statutory charge to avoid any changes in the Medicaid medical necessity definition which would "reduce the quality of care provided to Medicaid beneficiaries," Subsection (a)(1). We have instead proposed our own recommended definition designed to both improve efficiency and avoid any such reduction. The Committee understands that our proposed definition has been raised as legislation, House Bill 5296, by the Human Service Committee and will be considered for enactment in the 2010 legislative session.

This report does not end the work of the Medical Inefficiency Committee. The statute requires us to continue to advise the Department of Social Services on the amended definition and provide additional reports in January 2011 and January 2012, in accordance with the provisions of section 11-4a of the general statues. As you may be aware, three additional vacancies remain on the Committee; one from the Governor's office, one from Minority Leader McKinney's office, and one from Minority Leader Cafero's office. We are hopeful these appointments will be made soon.

If you require further explanation on the report, members of the committee are available for consultation.

Sincerely,

J. Kevin Kinsella, Ph.D.
Co-Chair

Alicia Woodsby, MSW
Co-Chair

Cc: Governor Rell
Representative Donovan
Senator Williams
Representative Cafero
Senator McKinney

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2009 - 2010 Membership

Co-Chairs

Mr. Kevin Kinsella, Hartford Hospital
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Dr. Daniel Koenigsberg, Hospital of St. Raphael
Ms. Randi Faith Mezzy, Connecticut Legal Services
Mr. Sheldon Toubman, New Haven Legal Assistance

PA 09-7, Sec. 107. (*Effective from passage*)
Medical Inefficiency Committee

(a)(1) Not later than July 1, 2010, the Department of Social Services shall amend by regulation the definition of "medically necessary" services utilized in the administration of Medicaid to reflect savings in the current biennial budget by reducing inefficiencies in the administration of the program while not reducing the quality of care provided to Medicaid beneficiaries.

(2) The Commissioner of Social Services shall implement policies and procedures utilizing said amended definition to achieve the purposes of subdivision (1) of this subsection while in the process of adopting the definition in regulation form, provided notice of intention to adopt the regulation is printed in the Connecticut Law Journal within forty-five days of implementation, and any such policies or procedures shall be valid until the time the final regulation is effective.

(b) There is established a Medical Inefficiency Committee to advise the Department of Social Services on the amended definition and the implementation of the amended definition required under subsection (a) of this section, and to provide feedback to the department and the General Assembly on the impact of the amended definition.

(c) The committee shall consist of the following members: Three appointed by the Governor, two appointed by the speaker of the House of Representatives, two appointed by the president pro tempore of the Senate and one each appointed by the majority leaders of the House of Representatives and the Senate and the minority leaders of the House of Representatives and the Senate.

(d) All appointments to the committee shall be made no later than thirty days after the effective date of this section. Any vacancy shall be filled by the appointing authority, except that vacancies left unfilled for more than sixty days may be filled by joint appointment of the speaker of the House of Representatives and the president pro tempore of the Senate.

(e) The speaker of the House of Representatives and the president pro tempore of the Senate shall select the chairpersons of the committee from among the members of the committee. Such chairpersons shall schedule the first meeting of the committee, which shall be held no later than sixty days after the effective date of this section.

(f) The administrative staff of the joint standing committee of the General Assembly having cognizance of matters relating to human services shall serve as administrative staff of the committee.

(g) Not later than January 1, 2010, January 1, 2011, and January 1, 2012, the committee shall submit a report on its findings and recommendations to the Governor and the joint standing committees of the General Assembly having cognizance of matters relating to public health, human services and appropriations and the budgets of state agencies, in accordance with the provisions of section 11-4a of the general statutes. The committee shall terminate on the date that it submits the third such report or January 1, 2012, whichever is later.

Table of Contents

Cover letter 1

Committee Membership List 3

Committee Charge 4

Table of Contents 5

Recommendations

- Background 6
- Proposed Definition of Medical Necessity 9
- Data and Reporting 10
- Purpose and Rationale 11
- Summary 15

Appendices

A. Medical Appropriateness Summary 16
B. Correspondence with the Office of the Attorney General 17
C. Medical Necessity Definition Matrix 22
D. Response from the Office of Legislative Research 27
E. Department of Social Services Prior Authorizations and Request Grid 29
F. Summary of Informational Forum and Public Hearing Testimony 33

Recommendations

The state budget passed in 2009 charged the Department of Social Services (the Department) with amending the definition of "medically necessary" services utilized in the administration of Medicaid to reflect savings in the current biennial budget by reducing inefficiencies in the administration of the program, while not reducing the quality of care provided to Medicaid beneficiaries. The statute also established a Medical Inefficiency Committee (the Committee) to advise the Department on the amended definition and implementation, and to provide feedback to the Department and the General Assembly on the impact of the amended definition. The Department attended all of the meetings of the Medical Inefficiency Committee and was an integral part of the process of developing the Committee's first report.

The Medical Inefficiency Committee began its work by reviewing the state's current definitions of Medical Necessity and Medical Appropriateness, and the unified definition proposed by the Department, which integrates Medical Necessity and Medical Appropriateness into one definition. This is the same definition that the Department currently uses for the State Administered General Assistance Program (SAGA), which was changed when the Department used the launch of the SAGA managed care program as an opportunity to remove the requirement that SAGA be defined the same way as Medicaid, and eliminated, or restricted access to, some forms of health care for SAGA recipients which continued to be provided Medicaid recipients. The above-mentioned definitions are as follows:

Background

The current definitions of Medical Necessity and Medical Appropriateness in Medicaid contained in various state regulations:

MEDICAID MEDICAL NECESSITY DEFINITION:
"Medical Necessity or Medically Necessary" means health care provided to correct or diminish the adverse effects of a medical condition or mental illness; to assist an individual in attaining or maintaining an optimal level of health; to diagnose a condition; or prevent a medical condition from occurring.

MEDICAID MEDICAL APPROPRIATENESS DEFINITION:
"Medical Appropriateness or Medically Appropriate" means health care that is provided in a timely manner and meets professionally recognized standards of acceptable medical care; is delivered in the appropriate medical setting; and is the least costly of multiple, equally-effective alternative treatments or diagnostic modalities.

The unified definition replacing the medical necessity and medical appropriateness definitions, which DSS had proposed and is currently used for SAGA:

"Medically necessary services" means those health services required to prevent, identify, diagnose, treat, rehabilitate or ameliorate a health problem or its effects, or to maintain health and functioning, provided such services are:

a) consistent with generally accepted standards of medical practice
b) clinically appropriate in terms of type, frequency, timing, site and duration;
c) demonstrated through scientific evidence to be safe and effective and the least costly among similarly effective alternatives, where adequate scientific evidence exists;
d) efficient in regard to the avoidance of waste and refraining from provision of services that, on the basis of the best available scientific evidence, are not likely to produce benefit.

The key differences between the definitions identified by the Committee include the following:

- The Department's proposed definition removes the distinct mention of mental illness as a medical condition.

- The Department's definition integrates the Medicaid definitions of Medical Necessity and Medical Appropriateness.

- The Department's proposed definition removes the standard for assisting an individual in "attaining or maintaining an optimal level of health," and replaces it with "maintain health and functioning." Thus, it removes the word "optimal."

- The Department's proposed definition exchanges the standard requiring "the least costly of multiple, *equally-effective* alternative treatments" with a standard that calls for "the least costly among *similarly effective* alternatives."

- The Department's proposed definition requires that the service or treatment be "consistent with generally accepted standards of medical practice," instead of using the phrase in the current definition that it meet "professionally recognized standards of acceptable medical care."

- The Department's proposed definition adds the standards that the service or treatment "be demonstrated through scientific evidence to be safe and effective," and that it be "efficient in regard to the avoidance of waste and refraining from provision of services that, on the basis of the best available scientific evidence, are not likely to produce benefit," thus placing the burden on the treating provider to justify his or her treatments, and requiring scientific evidence to overcome that burden. It allows for the denial of treatments that have less than a 50% chance of being successful, even if it they are scientifically-supported standards of care.

Lack of Examples of Problems with Current Definition:

Because the Committee's duties include the identification of any inefficiency in the current Medicaid medical necessity definition, it requested examples from the Department of cases in which it was unable to deny services which it felt should be denied because of the terms of that definition. The Committee repeatedly asked the Department's representatives, at several public meetings of the Committee, to provide such examples. Department was provided ample opportunity to provide such cases and, in response to the initial objection by the Department that it could not reveal details of any cases because of confidentiality, the Committee made clear that fully redacted

stories—with no personally identifying information—would be acceptable for the Committee's purposes.

The Department then indicated it would finally provide examples of actual cases where the current definition has been a problem at an extensive briefing it would be providing to the Committee, on March 3, 2010. At this briefing, the Department provided a lengthy presentation, but failed to provide any examples where the current definition was an obstacle to the Department denying inefficient treatment.

Based on the offers from the Department to provide examples in which the current Medicaid definition has actually presented a problem, and its inability to produce any such examples, the Committee concludes that the Department has not been in any way restricted in its ability to deny care which it deems to be inappropriate or inefficient under the current Medicaid definition of medical necessity.

The Medical Inefficiency Committee's Proposed Definition of Medical Necessity

"Medically necessary" or "Medical necessity" means those health services required to prevent, identify, diagnose, treat, rehabilitate or ameliorate an individual's medical condition, including mental illness, or its effects, in order to attain or maintain that individual's achievable health and independent functioning, provided such services are:

1. consistent with generally accepted standards of medical practice, which are defined as standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, the views of physicians practicing on relevant clinical areas, and any other relevant factors;
2. clinically appropriate in terms of type, frequency, timing, site, extent and duration, and considered effective for the individual's illness, injury, or disease;
3. not primarily for the convenience of the patient, physician, or other health care providers,
4. not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that individual's illness, injury or disease; and
5. based on an individualized assessment of the recipient and his or her medical condition.

In addition, we believe these rules, some of which are required by federal Medicaid law, should be applied:

Clinical policies, medical policies, clinical criteria, or any other generally accepted clinical practice guidelines used to assist in evaluating the medical necessity of a requested service shall be used solely as guidelines and shall not be the basis for a final determination of medical necessity.

Upon a denial of a request for services, the individual or healthcare provider shall be notified that upon request, they shall be provided with a copy of the specific guideline or criteria, or portion thereof, other than the published medical necessity definition, considered by the Department of Social Services or its agent in making its determination.

Data Collection and Reporting

Over the past couple of months of the Committee's work, it became evident that the compilation and analysis of appropriate data before and after the change in the definition of medical necessity is essential. The data "grid" supplied by DSS is a very good start for general gathering of medical necessity denials by service category and then breaking each category down by specific reasoning for a denial or partial denial, i.e. which part of the definition was the basis for the denial (Appendix E). However, the Committee also notes that a more extensive set of data will be necessary for it to discharge its statutory obligation to monitor the results of all changes in the definition. The data may show particular repetitive determinations for a particular disease, a certain medical device, a type of surgery or imaging process, etc. The mining of this data to obtain more specific detail is something the Committee strongly suggests.

The Committee is charged with ensuring "quality of care" is maintained for our most fragile populations in the most "cost effective" way. Accordingly, the Committee recommends that DSS and all of its contractors conducting medical necessity reviews produce to the Committee on a quarterly basis the following additional data:

1. A breakdown of what happened to the denials- how many went to appeal, how many were reversed there, how many denials were upheld
2. Clinical data and other records for a random sampling of individual denial cases for each service category, with all documents redacted for any personally identifying information
3. Comparable data provided by the MCOs for the current period under the capitated system, using the current definition of medical necessity, so the Committee can tell if the change in the definition is in fact resulting in additional denials in any service category

The Committee strongly endorses the Department's commitment to transparency in its March 3, 2010 presentation to the Committee, and supports the request that the Committee partner with the Department in ongoing monitoring of the impact of the review process and medical necessity decisions on quality of care and inefficiency.

Purpose and Rationale

With assistance from the Office of Legislative Research, the Committee reviewed definitions of medical necessity from federal law, surrounding states, and Connecticut's commercial insurance industry, and the recommendations of the Connecticut State Medical Society and the American Medical Association as part of a national settlement of class action litigation brought by physicians against the largest HMOs. The Committee's definition of medical necessity combines critical elements in the current Medicaid Medical Necessity definition with the Medical Necessity definition adopted in the class action settlements. The Committee's definition is consistent with the definition adopted for commercial health plans in Connecticut in Public Act 07-75. As noted by the Connecticut State Medical Society (CSMS), "the Medicaid population, which is generally more vulnerable than the commercial population and possesses fewer resources to pay for denied services, should be afforded at least the same protections as the commercial managed care population is entitled to under state law."

Mental Illness:

The Committee's definition maintains the qualification of mental illness as a medical condition. Given the long history of disparate access and treatment for mental health conditions in health care, the qualification was determined to be a necessary and rational distinction. People with serious mental illness **die an average of 25 years earlier** than other Americans, largely of treatable health conditions.[1]The enormity of this health disparity coupled with the recommendations by the state's Healthcare Advocate at the Committee's Informational Forum on February 8, 2010, led to the decision to maintain this component from the current Medicaid medical necessity definition. Despite society's avowed intent to treat mental illness on an equal par with other classes of medical illness, it simply hasn't happened. One sees the disproportion in many settings. Reimbursement for psychiatric co-morbidities was a particularly egregious example cited by the Healthcare Advocate who also noted that the majority of the incoming cases at the office pertain to mental illness. Hence, while clearly medical in nature, we do not subscribe to the suggestion that mental health is implied in medical illness and need not be specified.

An Individual's Achievable Health and Independent Functioning:

The Committee's definition recognizes the Department's concerns that the word "optimal" may set an unrealistic standard of care, because of the implication that everyone is capable of excellent health. Most other medical necessity definitions do not use this term, and the Department believes that it could lead to the excessive use of resources in a situation where there is no benefit at all. However, the Committee's definition provides for services that allow an individual to attain or maintain their achievable health and independent functioning. This addresses the need to consider independence as one of the goals of the Medicaid program. For example, in DSS Provider Bulletin PB 2003-113 (November 2003), DSS notes that "one of the purposes of the Medicaid program is to enable each state, in accordance with all applicable statutory and regulatory requirements, to furnish rehabilitation and other services to help eligible families and individuals attain or retain capability for independence or self-care." Throughout the Committee's definition there is an emphasis on the

[1] Parks, Joe, MD, et al., National Association of State Mental Health Program Directors (NASMHPD) Medical Directors Council. Morbidity and Mortality in People with Serious Mental Illness. October 2006.

individual, in order to protect Medicaid clients from a one-treatment-fits-all approach. The need for individualized determinations of Medical Necessity is a cornerstone of Medicaid law and policy.

Generally Accepted Standards:

The Committee's definition addresses the importance of defining "generally accepted standards," and including the significance of credible scientific evidence. The language is consistent with the definitions of medical necessity from Rhode Island Medicaid, Connecticut's commercial definition, and both the Connecticut State Medical Society's and the American Medical Association's recommendations. This is important because there will be times when a procedure or service has not risen to the level of a generally accepted standard.

The Committee's definition also is consistent with the definitions of medical necessity from Rhode Island Medicaid, Connecticut's commercial definition, and both the Connecticut State Medical Society's and the American Medical Association's recommendations, in its use of the phrase "clinically appropriate in terms of type, frequency, timing, site, extent and duration, and considered effective for the patient's illness, injury, or disease." The term "extent" is included in these definitions and is taken to mean the degree of involvement, such as limited (or focal) or extensive (or disseminated) disease. The revisions in this section also include language specific to the individual patient, which is consistent with the requirements of federal law, as recognized by DSS in its bulletins, see, e.g., PB 2003-113 (assessments of both medical necessity and medical appropriateness "must be based on an individualized assessment of the recipient and his or her medical condition, including documentation from the recipient's doctor and other provisions and may include communication with the recipient"). It allows the provider to point out whether or not a determination based on a general standard fits a particular patient's case. According to the Office of the Healthcare Advocate (OHA), "although it is generally understood that individualized assessments are supposed to be performed in each case, this does not happen." OHA further notes the failure to consider co-morbidities in behavioral health is an especially egregious example.

Medical Efficiency and Burden of Proof:

Section 4 of the Committee's definition addresses the importance of cost-effectiveness and efficiency in decision-making, and is also consistent with the definitions of medical necessity from Rhode Island Medicaid, Connecticut's commercial definition, and both the Connecticut State Medical Society's and the American Medical Association's recommendations. The Department's proposed definition would place the burden of proof upon the provider to demonstrate the need for the care. The Committee's definition maintains the deference due treating providers' medical judgment, as required by federal Medicaid law, while allowing a review by state officials or Managed Care Organization ("MCO") staff of satisfaction of the approved medical necessity criteria. *See* S. Rep. No. 4040, 89th Cong., Ist Sess., reprinted in 1965 U.S.Code Cong. & Admin. News 1943, 1986. See, e.g., Marchetti v. Aronson, 7 Conn. L. Rptr. No. 7, 203, 204 (Conn. Super. 1992) ("[T]he Medicaid statute and regulations create a presumption in favor of the medical judgment of the attending physician in determining the medical necessity of treatment."). The case law under the federal Medicaid statute over the last two decades, including in Connecticut, confirms that the burden is on the state Medicaid agency to justify a denial of treatment recommended by the treating provider. *See, e.g., Weaver v. Reagan*, 886 F. 2d 194, 199-200 (8th Cir. 1989) (" 'The decision of whether or not certain treatment or a particular type of surgery is "medically necessary"

rests with the individual recipient's physician and not with clerical personnel or government officials.' ").

While the Committee recognizes the benefits of using scientific evidence wherever available, its proposed definition, unlike the Department's, follows the broader view of acceptable evidence in the definitions used by other programs and states, given the frequent absence of the availability of such evidence.

Therapeutic Equivalence:

The Committee's definition rejects the Department's proposed change from "equally effective" to "similarly effective." The term "similarly effective" sets a lesser standard, and therefore does not meet the statutory requirement that any new definition maintains the same quality of care. Instead, the Committee uses the standard of "equivalent therapeutic or diagnostic results", which, according to the CSMS, "is broadly supported by national medical groups and has also been adopted by other states across the country."

Avoidance of Waste:

The Committee's definition removes the language contained in Section (d) of the Department's proposed definition. The Committee determined this provision to be misplaced. It is an organizational goal, rather than a standard based on individual patient treatment. Cost-effectiveness and efficiency are addressed in Sections 3 and 4 of the Committee's definition, and avoidance of waste is covered in other areas of the Department's regulations, e.g., durable medical equipment ("DME") regulations which allow DSS to repair or replace an item of DME depending upon whether it is more cost-effective to repair or replace.

Clinical Criteria:

The Committee's definition clarifies that private clinical practice guidelines should serve as guidelines only and may not be the basis of a medical necessity denial—only the published, and publicly available, medical necessity definition may be the basis of a denial. Furthermore, it requires that any such guidelines or criteria considered in a particular case be provided to the patient and the provider upon denial of a claim. The report from the Office of the Healthcare Advocate (OHA) noted a pattern of the use of private clinical criteria to deny claims in cases that are brought to appeal. Clarification of the function of clinical practice guidelines and transparency in denials will ensure that MCOs do not deny on the basis of private criteria. Furthermore, OHA cited data that coverage determinations are much narrower for behavioral health services than for the medical/surgical side of the benefit, and attributed this pattern to the clinical criteria used for behavioral health conditions.

Finally, in recognition that the vast majority of denials will likely not be made by the Department but by MCOs, the Committee agrees with the Department that, as part of compliance with the statute, the MCOs, as well as the Department, should be required to regularly report on numbers of denials (or partial denials) under each provision of the new definition of medical necessity, and for each category of health services, as provided in the attached form developed by the Department.

This should allow the Committee sufficient data to be able to discharge its obligation to monitor the implementation of the new definition.

Summary

As charged by the Legislature, the Committee has sought to meet the twin goals of reducing inefficiencies and maintaining quality of care. It has recognized the need for the Department to have a workable definition of Medical Necessity to discharge its responsibilities while protecting the care of patients.

The Committee has examined and compared definitions of Medical Necessity and Medical Appropriateness as proposed by the Department, those which currently apply to the residents of Connecticut and surrounding states, those encoded in Federal statutes, and those recommended by the American Medical Association and the Connecticut Medical Association. Input has been sought from the Department at all stages of the deliberations, assistance has been rendered by the Office of Legislative Research, and clarification has been obtained from the Office of the Attorney General. Expert and general public opinion has been sought in a public forum with which to augment the Committee's deliberations.

This document presents the Committee's recommendation for the amended definition of Medical Necessity. In addition, it specifies and discusses particular aspects of the definition about which questions arose in discussions with the Department. The Committee thanks the Legislature and the Governor for the opportunity to be of service to the residents of Connecticut.

Authority of the Department of Social Services (DSS) to Change the Definition of Medical Appropriateness and of the Medical Inefficiency Committee to make recommendations related to such changes

Since some of the provisions in the DSS proposed new medical necessity definition would contradict the current Medicaid "medical appropriateness" definition contained in the DSS' regulations, the Committee raised a concern about whether DSS had authority to do this. The governing statute, P.A. 09-07, Section 107, only refers to authority to alter the current Medicaid definition of "medically necessary services." Accordingly, the Committee wrote to Attorney General Richard Blumenthal on January 13, 2010 asking whether, under this provision, DSS had authority to modify the definition of medical appropriateness. The Attorney General wrote back to the Committee on February 4, 2010 stating unequivocally that under the above statute DSS had no authority to amend the definition of medical appropriateness. However, he stated that under a different statute, C.G.S. §17b-3(a)(2), the agency does have authority to amend any of its regulations, including this one. The significance of this is that the procedure in §17b-3(a)(2) involves a fairly lengthy notice and comment requirement, whereas Section 107 exempted DSS from having to go through that process, but for any changes to the "medical necessity" definition. Accordingly, under the Attorney General's legal opinion, DSS may not make any changes to the current medical necessity definition which contradict the current regulatory medical appropriateness definition without going through the full amendment process set forth in C.G.S. §17b-3(a)(2) to change the latter definition.

State of Connecticut

GENERAL ASSEMBLY

MEDICAL INEFFICIENCY COMMITTEE

LEGISLATIVE OFFICE BLDG. SUITE 2000
STATE CAPITOL
HARTFORD, CONNECTICUT 06106
240-0490

January 13, 2010

Richard Blumenthal
Attorney General
Office of the Attorney General
55 Elm Street
Hartford, CT 06106

Re: Authority of DSS to Change Medicaid Medical Appropriateness Definition

Dear Attorney General Blumenthal:

The Medical Inefficiency Committee, of which we were appointed as co-chairs, was established in last year's special session, under P.A. 09-03, Section 81(b) and P.A. 09-07, Section 107(b), to "advise the Department of Social Services (DSS) on the amended definition and the implementation of the amended definition required under subsection (a) of this section, and to provide feedback to the department and the General Assembly on the impact of the amended definition." The "amended definition" referred to in this section is contained in Section 107 (a)(1) of P.A. 09-07, which provides: "Not later than July 1, 2010, the Department of Social Services shall amend by regulation the definition of 'medically necessary' services utilized in the administration of Medicaid…." We write to ask whether this language extends to DSS changing the long-standing Medicaid regulatory definition of "medical appropriateness"

As you may be aware, Governor M. Jodi Rell and DSS sought to replace the current Medicaid definitions of both medical necessity and medical appropriateness[2] in the regular session of the

[2] The current definitions are contained in various state regulations and read:

MEDICAID MEDICAL NECESSITY DEFINITION:
"Medical Necessity or Medically Necessary" means health care provided to correct or diminish the adverse effects of a medical condition or mental illness; to assist an individual in *attaining or maintaining* an *optimal level of health*; to diagnose a condition; or prevent a medical condition from occurring.

legislature last year. They proposed legislation providing for the replacement of those two definitions with a unified definition of medical necessity which has been used for several years in the SAGA medical program, which covers low-income adults who are neither elderly nor disabled and who are not parents of minor children, and which is run primarily through the non-profit community health centers.[3] As explained in the section of the Governor's early 2009 budget document proposing this change, which is entitled "Update Medical Necessity and Appropriateness Definition under Medicaid," the proposed "revised medical necessity definition combines the concepts of medical necessity and appropriateness…" (excerpt, page 520, attached).

The legislature did not adopt this proposal. Rather, in its final budget passed in August and allowed to go into effect by Governor Rell, it provided that DSS "shall amend by regulation the definition of 'medically necessary' services utilized in the administration of Medicaid to reflect savings in the current biennial budget by reducing inefficiencies in the administration of the program while not reducing the quality of care provided to Medicaid beneficiaries."

In light of the absence of any reference in this legislation to the definition of "medical appropriateness" or to changing that definition, though DSS had proposed legislation specifically authorizing it to do so, a concern has been raised in our Committee that DSS may not have authority under this statutory provision to change the definition of medical appropriateness. This would then impact our decision-making with regard to making recommendations with respect to any changes by DSS to that definition particularly.

Accordingly, it has been suggested that we should ask for guidance from you before expending any effort in addressing any proposed changes to the current Medicaid definition of medical appropriateness (as opposed to the current Medicaid definition of medical necessity, which must be changed by July 1, 2010).

MEDICAID MEDICAL APPROPRIATENESS DEFINITION:
"Medical Appropriateness or Medically Appropriate" means health care that is *provided in a timely manner* and meets professionally recognized standards of acceptable medical care; is delivered in the appropriate medical setting; and is the least costly of multiple, *equally-effective* alternative treatments or diagnostic modalities.

[3] The unified definition replacing the medical necessity and medical appropriateness definitions, which DSS had proposed during the regular session, reads:

"Medically necessary services" means those health services required to prevent, identify, diagnose, treat, rehabilitate or ameliorate a health problem or its effects, or to maintain health and functioning, provided such services are:

a) consistent with generally accepted standards of medical practice
b) clinically appropriate in terms of type, frequency, timing, site and duration;
c) *demonstrated through scientific evidence* to be safe and effective and the least costly among *similarly effective* alternatives, where adequate scientific evidence exists;
d) efficient in regard to the avoidance of waste and refraining from provision of services that, *on the basis of the best available scientific evidence*, are not likely to produce benefit.

We therefore ask these two questions:

(1) Does DSS have authority under P.A. 09-07, Section 107 to change the current Medicaid definition of medical **appropriateness**?
(2) If not, must any changes to the current Medicaid definition of medical **necessity** made pursuant to Section 107(a)(1) be consistent with the current Medicaid definition of medical appropriateness?

Although the statutory language provides that our committee is tasked 'to advise the Department of Social Services on the amended definition and the implementation of the amended definition required under subsection (a) of this section,' the Department's representative suggested at our last meeting on January 7, 2010 that the Department is considering moving forward with its proposed changes to both the medical necessity and medical appropriateness definitions even without our input. However, he indicated a possible willingness to wait if our committee can act quickly enough. Our next meeting has been scheduled for January 21, 2010. It would be very helpful to our work to know the answer to the above questions before then.

On behalf of the Medical Inefficiency Committee, we thank you for your attention to this matter.

Respectfully yours,

Dr. Kevin Kinsella	Alicia Woodsby
Co-Chair	Co-Chair

RICHARD BLUMENTHAL
ATTORNEY GENERAL

55 Elm Street
P.O. Box 120
Hartford, CT 06141-0120

Office of The Attorney General
State of Connecticut

February 4, 2010

Dr. Kevin Kinsella
Ms. Alicia Woodsby
Co- Chairs, Medical Inefficiency Committee
Legislative Office Building
Hartford, CT 06106

Dear Dr. Kinsella and Ms. Woodsby:

I recently received your correspondence regarding the legislature's directive to the Department of Social Services (DSS) contained in P.A. 09-07, § 107, to "amend by regulation the definition of medically necessary services utilized in the administration of Medicaid to reflect savings in the current biennial budget by reducing inefficiencies in the administration of the program while not reducing the quality of care provided to Medicaid beneficiaries." You inquire whether DSS has the authority under this statute to also change the Medicaid regulatory definition of "medical appropriateness," and if, not, must any changes in the definition of "medically necessary" be consistent with the current definition of "medical appropriateness".

With regard to the first question, we conclude that DSS does not have authority under P.A. 09-07, § 107 to amend the definition of medical appropriateness," but does have the authority under Conn. Gen. Stat. §17b-3(a)(2) to adopt regulations amending the definition of that term. With regard to your second question, we conclude that in complying with the legislature's mandate to amend the definition of "medically necessary," DSS has the statutory authority to define the terms "medically necessary" and "medical appropriateness" consistently, although it is not required by law to do so.

As noted in your letter, in P.A. 09-07, § 107, the General Assembly directed DSS to amend the definition of "medically necessary" and went so far as to authorize DSS to adopt policies and procedures utilizing the amended definition while in the process of adopting the definition in regulation form. "The process of statutory interpretation involves a reasoned search for the intention of the legislature." *State v. Courchesne*, 262 Conn. 537, 544 (2003), quoting *Bender v. Bender*, 258 Conn. 733, 741 (2001). "[T]he language of the statute is the most important factor to be considered." *Courchesne*, 262 Conn. at 563. See Conn. Gen. Stat. § 1-2z. Section 107 of the Act does not reference at all the definition of "medical appropriateness." Therefore, we conclude that the definition of "medical appropriateness" may not be amended under P.A. 09-07 §107.

However, DSS has full authority to amend the definition of "medical appropriateness" under Conn. Gen. Stat. §17b-3(a)(2): "The commissioner shall have the power and duty to … (2)

adopt and enforce such regulations … as are necessary to implement the purposes of the department as established by statute." DSS may redefine the term "medically necessary" to make it consistent with the current definition of "medical appropriateness" pursuant to P.A. 09-07, or may amend the definition of "medical appropriateness" to make it consistent with an amended definition of "medically necessary" through the adoption of regulations under Conn. Gen. Stat. § 17b-3(a)(2). This conclusion is consistent with the laudable goal of providing flexibility to DSS with the advice of your committee to achieve the requirements of the legislature set forth in P.A. 09-07.

While the primary obligation of DSS under P.A. 09-07 is to adopt a definition of the term "medically necessary" in accord with the legislative direction set forth in the Act, DSS has the statutory authority to give the terms "medically necessary" and "medical appropriateness" consistent definitions by using the authority set forth in P.A. 09-07, §107 and Conn. Gen. Stat. §17b-3(a)(2).

We trust that the foregoing responds to your concerns.

Very truly yours,

RICHARD BLUMENTHAL

Source	Statute/Regulation Cite	Definition
Federal Law		
Federal Medicaid Law	42 USC §1396(2)--Appropriations	Appropriates funds to states "for purpose of enabling each state, as far as practicable under the conditions in such state, to furnish,,,"(2) rehabilitation and other services to help such families and individuals attain or retain capability for independence or self-care…"
Federal EPSDT law	42 USC § 1396d(r)(5)	In addition to specified screening, diagnosis, and treatment, law requires other necessary health care, diagnostic services, treatment, and other measures described in law 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."
Federal Medicaid law	42 USC § 1396a(a)(10)(B)	Requires medical assistance made available to categorically eligible individuals to be "no less in amount, duration, or scope than the medical assistance made available to a medically needy recipient."
Federal Medicaid regulation	42 CFR §440.230	Implements above statute, and allows state Medicaid agency to place appropriate limits on a service based on such criteria as medical necessity or utilization control
Federal Medicaid regulation	42 CFR §438.210	Requires each Medicaid managed care contract, for purpose of utilization control, to specify what constitutes medically necessary services in a manner that is no more restrictive than that used in the state Medicaid program and addresses the extent to which the managed care entity is responsible for covering services related to : (1) preventing, diagnosing, and treating health impairment, (2) the ability to achieve age-appropriate growth and development, and (3) the ability to attain, maintain, or regain functional capacity.
Individual States' Medicaid Definitions		
Connecticut	Medicaid--Reference to MN Appears in over 40 DSS regulations, including reimbursement to acute care general hospitals	As found in Sec. 17b-262-300 (14) "Medical necessity" or "medically necessary" means health care provided to correct or diminish the adverse effects of a medical condition or mental illness; to assist a client in attaining or maintaining an optimal level of health; to diagnose a condition; or to prevent a medical condition from occurring

	HUSKY managed care contracts	Same as above
	State Administered General Assistance regulation (Connection Agency Regulations, 17b-192-2(14)	"Health services required to prevent, identify, diagnose, treat, rehabilitate, or ameliorate a health problem or its effects, or to maintain health and functioning, provided such services are: 1. consistent with generally accepted standards of medical practice, 2. clinically appropriate in terms of type, frequency, timing, site, and duration; 3. demonstrated through scientific evidence to be safe and effective and the least costly among similarly effective alternatives, where adequate scientific evidence exists; and 4. efficient in regard to the avoidance of waste and refraining from provision of services that, on the basis of the best available scientific evidence, are not likely to produce benefit
Massachusetts	130 Code of Massachusetts Regulations §450.204	A service is considered "medically necessary" if it: 1. is reasonably calculated to prevent, diagnose, prevent the worsening of, alleviate, correct, or cure conditions in the [MassHealth] member that endanger life, cause suffering or pain, cause physical deformity or malfunction, threaten to cause or to aggravate a handicap, or result in illness of infirmity; and 2. there is no other medical service or site of service, comparable in effect; available; and suitable for the member requesting the service, that is more conservative or less costly to the MassHealth agency. Services that are less costly to the MassHealth agency include, but are not limited to, health care reasonably known by the provider, or identified by the MassHealth agency pursuant to a prior authorization request, to be available to the member through a third party *(130 Code of Massachusetts Regulations §450.204).* The regulations allow the state Medicaid agency to impose sanctions on

		providers for (1) providing or prescribing a service or (2) admitting a member to an inpatient facility when the services or admission are not medically necessary. This definition applies to all Medicaid services, regardless of whether they are provided on a managed care or fee-for-service basis.
New York	NY State Social Services Law, Part 365	"Medically necessary medical, dental, and remedial care, services, and supplies" in the Medicaid program are those "necessary to prevent, diagnose, correct, or cure conditions in the person that cause acute suffering, endanger life, result in illness or infirmity, interfere with such person's capacity for normal activity, or threaten some significant handicap and which are furnished an eligible person" in accordance with state law." Officials in the state's Medicaid agency report that this definition applies to both the fee-for-service and managed care populations.
Rhode Island	No cite available	Rhode Island's Department of Human Services, Center for Child and Family Health, uses the following definition of medical necessity in its Medicaid managed care program, RIte Care. Specifically, the Center defines "medical necessity" or "medically necessary" as: health care services that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing, or treating an illness, injury, disease, or its symptoms, and that are (a) in accordance with generally accepted standards of medical practice; (b) clinically appropriate, in terms of type, frequency, extent, site, and duration, and considered effective for the patient's illness, injury, or disease; and (c) not primarily for the convenience of the patient, physician, or other health care providers, and not more costly than an alternative services or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results

		as to the diagnosis or treatment of that patient's illness, injury or disease. The department further defines "generally accepted standards of medical practice" as standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and the views of physicians practicing in relevant clinical areas and any other relevant factors." This definition also applies to the state's fee-for-service Medicaid program.
Other Definitions		
National Settlement	In re Managed Care Litigation in the U.S. District Court for the Southern District of Florida	Health care services that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are: a) in accordance with generally accepted standards of medical practice; b) clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient's illness, injury or disease; and c) not primarily for the convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease. For these purposes, "generally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community or otherwise consistent with the standards set forth in policy issues involving clinical judgment.
State Law—	38a-513c, 38a-482a	Requires individual and group health insurance policies to contain

Commercial Insurance Industry (based on above settlement definition)		definition. It means "health care services that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing, or treating an illness , injury, disease or its symptoms, and that are (1) in accordance with generally accepted standards of medical practice; (2) clinically appropriate, in terms of type, frequency, extent, site, and duration and considered effective for the patient's illness, injury, or disease; and (3) not primarily for the convenience of the patient, physician, or other health care provider and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease. "Generally accepted standards of medical" are standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community or otherwise consistent with the standards set forth in policy issues involving clinical judgment.

To: Medical Inefficiency Committee

From: Robin Cohen, Office of Legislative Research (OLR)

Re: Follow up questions regarding commercial and Medicaid medical necessity complaints and resolution

You asked OLR to find out what the commercial insurance industry experience has been with respect to complaints of care denials based on medical necessity, and in particular, around the term "equivalent" as found in the subsection (3) of the commercial definition in the Connecticut General Statutes (CGS §§38a-482a and 38a-513c). You also asked us to check with Rhode Island's Medicaid program to learn about that state's experience with medical necessity appeals.

We sent an email to the Insurance Department, Office of Healthcare Advocate, and Attorney General's Office and asked for the number of medical necessity complaints received in 2008 and 2009, both related to the definition in general and those specific to the term "equivalent."

The Insurance Department provided the most information. It provided a chart (attached) that shows that in 2008, 56% of appeals based on medical necessity in general were affirmed (i.e., insurers' decision was affirmed) and 37% were reversed. The number of affirmed cases increased in 2009. We concluded that in nearly two thirds of the appeals, the insurers' decisions were upheld. The charts do not tell us on what aspect of the medical necessity definition (e.g., equivalent) the decisions rested.

Richard Kehoe of the Attorney General's Office reported that over the past 10 years, that office has had about 8,000 health insurance complaints or cases. Of these, he estimated that 20% involved disputes over medical necessity.

Vicki Veltri, General Counsel to the Office of Healthcare Advocate, reported that her office has received 2,000 cases in each of the last five years that involved medical necessity, or in her terms, cases that arose because of an "alleged improper application of statute by insurers."

Rhode Island never got back to us after repeated attempts by our office to get the information.

State of Connecticut Insurance Department - Medical Necessity Appeals

External Appeals Program

Decisions	2008		2009 *(To date)*	
Affirmed	97	56%	107	61%
Reversed	64	37%	62	35%
Revised	11	6%	6	3%
	172		**175**	
Pending	0		9	
Ineligible/Incomplete/Withdrawn	37		86	
Total	**381**		**445**	

Medical Necessity Complaints

Complaints	2008	2009
Pre-authorization Denials	102	96
Retrospective Claims Denials	28	32
Total	**130**	**128**

Prior Authorization Request & Determinations

MCO Name: _____

Reporting period: _____

Total MM, Clients under age 21 _____

	Approvals	Denials	Partial Denials	Approvals per 1,000 MM	Denials per 1,000 MM
Inpatient Services and Outpatient Surgery					
a) Not consistent with generally accepted standards of medical practice;					
b) Not clinically appropriate in terms of type, frequency, timing, site and duration;					
c) Not demonstrated through scientific evidence to be safe and effective and the least costly among similarly effective alternatives, where adequate scientific evidence exists;					
d) Not efficient in regard to the avoidance of waste or, on the basis of the best available scientific evidence, not likely to produce benefit;					
e) other					

Total MM, Clients age 21 _____

Approvals	Denials	Partial Denials	Approvals per 1,000 MM	Denials per 1,000 MM

	Approvals	Denials	Partial Denials	Approvals per 1,000 MM	Denials per 1,000 MM
Durable Medical Equipment					
a) Not consistent with generally accepted standards of medical practice;					

Approvals	Denials	Partial Denials	Approvals per 1,000 MM	Denials per 1,000 MM

7/06

b) Not clinically appropriate in terms of type, frequency, timing, site and duration;					
c) Not demonstrated through scientific evidence to be safe and effective and the least costly among similarly effective alternatives, where adequate scientific evidence exists;					
d) Not efficient in regard to the avoidance of waste or, on the basis of the best available scientific evidence, not likely to produce benefit;					
e) other					

	Approvals	Denials	Partial Denials	Approvals per 1,000 MM	Denials per 1,000 MM
Home Health					
a) Not consistent with generally accepted standards of medical practice;					
b) Not clinically appropriate in terms of type, frequency, timing, site and duration;					
c) Not demonstrated through scientific evidence to be safe and effective and the least costly among similarly effective alternatives, where adequate scientific evidence exists;					
d) Not efficient in regard to the avoidance of waste or, on the basis of the best available scientific evidence, not likely to produce benefit;					
e) other					

	Approvals	Denials	Partial Denials	Approvals per 1,000 MM	Denials per 1,000 MM
Therapies (OT, PT, Speech, Chiropractor)					

7/06

a) Not consistent with generally accepted standards of medical practice;										
b) Not clinically appropriate in terms of type, frequency, timing, site and duration;										
c) Not demonstrated through scientific evidence to be safe and effective and the least costly among similarly effective alternatives, where adequate scientific evidence exists;										
d) Not efficient in regard to the avoidance of waste or, on the basis of the best available scientific evidence, not likely to produce benefit;										
e) other										
	Approvals	Denials	Partial Denials	Approvals per 1,000 MM	Denials per 1,000 MM	Approvals	Denials	Partial Denials	Approvals per 1,000 MM	Denials per 1,000 MM
Pharmacy										
a) Not consistent with generally accepted standards of medical practice;										
b) Not clinically appropriate in terms of type, frequency, timing, site and duration;										
c) Not demonstrated through scientific evidence to be safe and effective and the least costly among similarly effective alternatives, where adequate scientific evidence exists;										
d) Not efficient in regard to the avoidance of waste or, on the basis of the best available scientific evidence, not likely to produce benefit;										
e) other										

7/06

	Approvals	Denials	Partial Denials	Approvals per 1,000 MM	Denials per 1,000 MM	Approvals	Denials	Partial Denials	Approvals per 1,000 MM	Denials per 1,000 MM
All Other										
a) Not consistent with generally accepted standards of medical practice;										
b) Not clinically appropriate in terms of type, frequency, timing, site and duration;										
c) Not demonstrated through scientific evidence to be safe and effective and the least costly among similarly effective alternatives, where adequate scientific evidence exists;										
d) Not efficient in regard to the avoidance of waste or, on the basis of the best available scientific evidence, not likely to produce benefit;										
e) other										

Age listed is that as of date of the request.
* Partial Denials were partially approved and partially denied.

Medically necessary means those health services required to prevent, identify, diagnose, treat, rehabilitate or ameliorate a health problem or its effects, or to maintain health and functioning, provided such services are:

a)consistent with generally accepted standards of medical practice;

b) clinically appropriate in terms of type, frequency, timing, site and duration;

c) demonstrated through scientific evidence to be safe and effective and the least costly among similarly effective alternatives, where adequate scientific evidence exists;

d)efficient in regard to the avoidance of waste or, on the basis of the best available scientific evidence, not likely to produce benefit;

Medical Inefficiency Committee
Public Hearing – February 8, 2010
Summary of Testimony

Matthew Katz – Connecticut State Medical Society: Physicians, not the Department of Social Services (DSS), must determine what is medically necessary for patients. The DSS proposal would "significantly reduce the quality of care" for Medicaid beneficiaries. "At a minimum…the Medicaid population, which is generally more vulnerable than the commercial population and possesses fewer resources to pay for denied services, should be afforded at least the same protections as the commercial managed care population is entitled to under state law…" The committee's alternative is very similar to the definition adopted by major insurers, and is preferable to the one proposed by DSS.

Susan Raimondo – National Multiple Sclerosis Society: People with multiple sclerosis could be negatively impacted by the DSS proposal to change the definition of medical necessity. The MS Society believes that "it is crucial to include independence and function in a definition of medical necessity." DSS must work with the committee to modify its proposal.

Sharon Pope – Connecticut Bar Association Elder Law Section: Several major court cases have upheld the current definition of medical necessity in both federal and state statute. The DSS proposal would diminish Medicaid's obligation to reimburse required services, force providers to justify all treatments, and allow the provision of less effective treatments. The definition should be left unchanged in state statute.

Barbara Albert – Hartford resident, dual eligible: Personal experiences demonstrate the perils of using inappropriate medications. Doctors and other providers are already overburdened and inhibited by Medicaid. The DSS proposal would only exacerbate the problems that exist, and would be detrimental to patients.

Cheri Bragg – Keep the Promise Coalition: People with mental illnesses often need to change or adjust medications to find the most effective treatment, and the current definition of medical necessity ensures "equivalent" treatment. The DSS proposal would change "equivalent" to "similarly effective," and this could endanger the health of people using a very specific combination of medications. The alternative language proposed by the committee would be much better for people with mental illnesses.

Connecticut Hospital Association: Connecticut's hospitals provide high quality care to all patients. This would be compromised by the DSS proposal, because providers would be more restricted in their ability to prescribe the most effective treatment. The committee must ensure that any new definition takes this into account.

Jay Kaplan – Pro Health Physicians: This testimony does not really address the issue of defining medical necessity, but gives a number of suggestions regarding health care reform in general.

Mary Alice Lee – Connecticut Voices for Children: (PowerPoint presentation) Children, particularly those with special needs, are a vulnerable population. The DSS proposal could endanger their health, not only because they may not receive the appropriate treatment, but they also may be unable to articulate the problems or symptoms they are experiencing. The committee needs to consider children when discussing revisions to the definition of medical necessity.

Jennifer Jaff – Advocacy for Patients with Chronic Illness: Many patients currently in commercial insurance plans already experience problems with imposed limitations on medications, resulting in inappropriate treatments. There are numerous examples of people experiencing serious effects from less effective or incorrect medications. The DSS proposal would inevitably cause this problem to extend to the Medicaid population. The committee must prevent DSS from implementing this definition.

Kevin Lembo – State Healthcare Advocate: The committee's proposed definition is "appropriately broad enough to ensure that services are not unfairly restricted. On the other hand, the definition is specific in its direction to contractors about what must, and must not be taken into consideration."