IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

GAYNELL GRIER, et al., individually and on behalf of others similarly situated,	)	
Plaintiffs,	)	
and	)	Case No. 3:79-3107
	)	Judge Nixon
SANFORD BLOCH, et al., and all others similarly situated,	)	
	)	Class Action
Plaintiffs-Intervenors,	)	
v.	)	
M.D. GOETZ, JR., Commissioner, Tennessee Department of Finance and Administration, et al.,	)	
Defendants,	)	
and	)	
TENNESSEE ASSOCIATION OF HEALTH MAINTENANCE ORGANIZATIONS, et al.,	)	
Defendants-Intervenors.	)	

ORDER

Pending before the Court is Defendants' Motion to Approve the State's Proposed Revision to Paragraph C(7) of the Consent Decree (Doc. No. 1338), along with supporting memoranda (Doc. Nos. 1339, 1343), to which Plaintiffs have responded in opposition (Doc. Nos. 1341, 1344).

I. BACKGROUND

At issue in the present motion is Paragraph C(7) of the Revised Consent Decree Modified ("Consent Decree"), which relates to the proof required to overrule a physician's "clinical judgment" that an item or service is medically necessary. (Doc. No. 908 at 15-16.) The Court previously held that the first sentence of Paragraph C(7) of the Consent Decree could be revised, and ordered the State, upon consultation with the other parties, to submit its proposal for modification. (See Doc. Nos. 1248, 1256, 1282.) The parties have been unable to agree on a joint proposal, and Plaintiffs and Defendants have submitted two separate proposed revisions to the first sentence of Paragraph C(7) for the Court's consideration.

These proposed revisions stem from the Court's ruling on Defendants' requests (l) and (n) to modify and/or clarify Paragraph C(7) of the Consent Decree. (See Doc. Nos. 1086, 1248, 1256, 1282.) Defendant's request (l) stated: "The State may rely upon all relevant information, not just the enrollees' medical records, in determining TennCare coverage of medical services and in considering and deciding medical appeals. Paragraph C(7) of the Revised Consent Decree (Modified) shall be deleted." (Doc. No. 1086 at 5.) Defendants' request (n) stated: "The State may place the burden of proof in all medical appeals upon the enrollee." (Id.) Plaintiffs opposed request (l) contending that the Consent Decree "does not prohibit the State from relying upon all relevant information in determining TennCare coverage of medical services and deciding medical appeals." (Doc. No. 1111 at 8.) Plaintiffs also opposed deletion of Paragraph C(7), contending that the request was not suitably tailored to changed law or circumstances. (Id.) Finally, Plaintiffs opposed request (n) in so far as it sought to modify Paragraph C(7). (Id. at 8-9.)

On July 29, 2005, the Court issued its first order regarding Defendants' request (l):

> [T]he State may rely upon all relevant information, not just the enrollees' medical records in determining TennCare coverage of medical services and in considering and deciding medial appeals. Defendants' request to delete Paragraph C(7) of the 2003 Revised Consent Decree (Modified) is denied, but the first sentence of Paragraph C(7)(b) may be revised. . . .

(Doc. No. 1248 at 8-9.) Later, the Court explained:

> [T]he first sentence of Paragraph C(7)(b) may be revised such that the weight given to the treating physician's opinion shall increase if it is well-supported with evidence from an enrollee's medical records and/or other relevant information. For example, on the one hand, a treating physician's conclusory statements, without more, should not bind the State. On the other hand, the State may not require the treating physician to justify <u>any</u> deviation from the standard course of treatment when the physician's opinion is reasonably supported with evidence from the enrollee's medical records.

(Doc. No. 1256 at 12.)

On November 15, 2005, the Court issued its Memorandum Opinion explaining in further detail the reasons for its previous Orders. The Court rejected the State's contentions that Paragraph C(7) prohibited its use of all relevant information or that it encouraged providers to not send medical records to the MCC or State during an appeal. (Doc. No. 1282 at 84.) Although permitting an increase in time to obtain medical records in expedited appeals, the Court found it was improper to deny appeals without taking into consideration the enrollee's medical history. (<u>Id.</u> at 85.) Furthermore, the Court stated that "Paragraph C(7)(b) currently presumes that a provider's clinical judgment is correct, and if a provider has decided or believes an enrollee needs a service, such service must be medically necessary." (<u>Id.</u> at 87.) The Court found that removal of this presumption was not warranted, but permitted a revision of the first sentence in Paragraph C(7)(b) "to make providers explain their decisions when such decisions are unsupported, as well as make it easier to include [the use of] evidence-based guidelines."

(Id. at 87.) Accordingly, the Court ordered the parties

> to revise the first sentence of Paragraph C(7)(b) such that the weight given to the treating physician's opinion shall increase if it is well-supported with evidence from an enrollee's medical records and/or other relevant information. On the one hand, a treating physician's conclusory statements, without more, should not bind the State. On the other hand, the State may not require the treating physician to justify any deviation from the standard course of treatment when the physician's opinion is reasonably supported with evidence from an enrollee's medical records. In making this revision, the Court recommends that the parties consider the standard used to evaluate medical opinions in Social Security disability cases. See 20 C.F.R. § 404.1527(d)(2); see, e.g., Wilson v. Comm'r of Soc. Sec., 378 F.3d 541, 544 (6th Cir. 2004); Buxton v. Halter, 246 F.3d 762, 773 (6th Cir. 2001); King v. Heckler, 742 F.2d 968, 973 (6th Cir. 1984).

(Id. at 88.)

Defendants and Plaintiffs have been unable to agree on an appropriate revision, and have submitted two separate proposals for the Court's consideration.

A. DEFENDANTS' PROPOSED REVISION TO PARAGRAPH C(7)(b) OF THE CONSENT DECREE

Defendants propose the following revision to Paragraph C(7)(b):

7. Decisions to be supported by substantial and material evidence.

In any appeal of an adverse action affecting TennCare benefits, throughout all stages of such appeal, the defendants shall ensure that decisions must be based upon substantial and material evidence. In cases involving clinical judgments, this requirement specifically means that:

a. Appeal decisions must be supported by medical evidence, and it is the defendants' responsibility to elicit from beneficiaries and their treating providers all pertinent medical records that support an appeal; and

b. Medical opinions shall be evaluated as follows:

i. Opinions from treating providers that are well-supported by medically acceptable clinical findings and laboratory diagnostic techniques and are not otherwise inconsistent with other substantial evidence will be given

controlling weight.

ii. Substantial evidence may include objective clinical evidence regarding the treatment of specific medical conditions or the use of specific health technologies, including evidence-based treatment guidelines and technology assessments, and the results of well-supported clinical trials and studies, provided such evidence is considered in the context of the individual enrollee's medical history.

iii. The defendants may require treating physicians to explain their decisions in relation to standards prescribed by the defendants when such decisions are inconsistent with other substantial evidence.

iv. A treating provider's conclusory statements, without the support of substantial evidence, are not binding on the State.

v. Reliance upon insurance industry guidelines or utilization control criteria of general application, without consideration of the individual enrollee's medical history, does not satisfy this requirement and cannot be relied upon to support an adverse action affecting TennCare services.

(Doc. No. 1338, Ex. 1 at 1-2.)

Defendants contend that their proposal "accurately reflects the Court's Order and Memorandum Opinion on this issue (Doc. Nos. 1256 and 1282) and accurately captures the spectrum of deference that should be afforded a treating physician's opinion depending on the support that can be found in an individual's medical records and other objective clinical evidence for that opinion." (Doc. No. 1338 at 1-2.) Defendants also assert that the "proposal is in keeping with the policy decision to move to an evidence-based medical regime," and is consistent with the medical necessity rules the State intends to promulgate. (Id. at 2.) Defendants inform the Court that their proposal and revisions to the medical necessity rules have been constructed through an open and transparent process that afforded all relevant stakeholders opportunity to comment. (Doc. No. 1339 at 3.) In revising the medical necessity rules, the State emulated "nationally-recognized authoritative sources on evidenced-based medicine and health technology

assessment," and other states' medical necessity rules. (Id. at 3-4; Doc. No. 1339, Ex. 1, Wendy Long Decl. ¶¶ 4-6.) Defendants heeded the Court's recommendation to consider the standard used to evaluate medical opinions in Social Security disability cases, but found that the standard was not entirely relevant in the "health insurance reimbursement context." (Doc. No. 1339 at 7; Doc. No. 1339, Ex. 1, Wendy Long Decl. ¶ 3.)

Finally, Defendants assert that their proposal is entitled to substantial deference "so long as the State's proposed revision does not violate federal law and is consistent with this Court's orders." (Doc. No. 1339 at 9-10 (citing Rufo v. Inmates of Suffolk County Jail, 502 U.S. 367, 392 n.14 (1992) (giving significant weight to the views of local government officials in implementing modifications); Frew v. Hawkins, 540 U.S. 431, 442 (2004) (presuming that State officials "have a high degree of competence in deciding how best to discharge their governmental obligation.")).) Defendants argue that this deference is especially high in the context of medical necessity determinations, as states have great flexibility in defining medical necessity criteria. (Doc. No. 1339 at 10 (citing 67 Fed. Reg. 40,989, 41,047 (June 14, 2002)).) For these reasons, Defendants urge this Court to adopt their proposal.

B. PLAINTIFFS' PROPOSED REVISION TO PARAGRAPH C(7)(b) OF THE CONSENT DECREE

Plaintiffs object to Defendants' proposal on the ground that it does not comport with this Court's Memorandum Opinion according a treating physician's opinion the presumption of correctness if it is reasonably supported with evidence from the enrollee's medical records and/or other relevant information. (Doc. No. 1341 at 4-12.) Plaintiffs also object to Defendants' proposal for failing to comport with the requirement that medical necessity determinations be

individualized. (Id.) Plaintiffs assert that Defendants have not followed the Court's directive to "strike a balance similar to the long standing standard used to evaluate medical opinions in the Social Security context." (Id. at 15.) Plaintiffs argue that the State's "proposal erodes the basic purpose of the . . . [Consent Decree]: to provide strong safeguards against direct and substantial pecuniary interests in denying or delaying needed services." (Id. at 12-15.) Finally, Plaintiffs assert that Defendants' proposal does not warrant substantial deference because it is inconsistent with this Court's Orders and Memorandum Opinion. (Doc. No. 1344 at 3-4.) As a result, Plaintiffs urge the Court to adopt their proposal, which states:

> **7. Decisions to be supported by substantial and material evidence.**
>
> In any appeal of an adverse action affecting TennCare benefits, throughout all stages of such appeal, the defendants shall ensure that decisions are based upon substantial and material evidence. In cases involving clinical judgments, this requirement specifically means that:
>
> a. Appeal decisions must be supported by medical evidence, and it is the defendants' responsibility to elicit from beneficiaries and their treating providers all pertinent medical records that support an appeal; and
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> b. Medical opinions, including clinical judgments that evidence-based medicine guidelines fit the unique medical condition of an individual beneficiary, shall be evaluated as follows:
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> i. Opinions from treating clinicians that are well supported with evidence from an enrollee's medical records and/or other relevant information will be accorded the highest weight since they are the medical professionals most able to provide a detailed, longitudinal picture of the enrollee's medical condition(s) and they bring a unique perspective to the medical evidence that cannot be obtained from the objective medical findings alone or from reports of individual examinations, such as consultative examinations or brief hospitalizations.
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> ii. If a treating clinician's opinion is not reasonably supported with evidence from the enrollee's medical records, the state or MCC shall request that the clinician provide additional medical evidence and/or other relevant information to support his or her opinion. If the provider fails to offer such

information, his opinion shall not bind the defendants.

iii. If the treating clinician's opinion is not given controlling weight by defendants or their MCCs, the notice of adverse action must include good reasons for the weight given to the treating clinician, including but not limited to the nature and extent of treatment, medical signs and findings, consistency of opinion with the medical record as a whole and practice specialty. If the defendants invoke nationally recognized evidence-based treatment guidelines, they shall describe those guidelines and the evidence supporting their judgment that the guidelines fit the unique medical condition of the individual beneficiary.

c. Reliance upon insurance industry guidelines or utilization control criteria of general application, without consideration of the individual enrollee's medical history, does not satisfy this requirement and cannot be relied upon to support an adverse action affecting TennCare services.

(Doc. No. 1341, App'x C at 1-2.)

II. DISCUSSION

A. THE COURT'S REVISION TO PARAGRAPH C(7)(b) OF THE CONSENT DECREE

The Court has considered both parties' proposals and finds that neither sufficiently implements the Court's prior rulings.

Defendants' proposal does not comport with this Court's Memorandum Opinion. Principally, the Court finds that Defendants' proposal again attempts -- despite the fact that this Court denied Defendants' initial attempt -- to remove the presumption in Paragraph C(7)(b) that a treating physician's clinical judgment is correct. The main offender is Defendants' proposed paragraph 7(b)(i): "Opinions from treating providers that are well-supported by medically acceptable clinical findings and laboratory diagnostic techniques <u>and are not otherwise inconsistent with other substantial evidence</u> will be given controlling weight." (Doc. No. 1338, Ex. 1 at 1) (emphasis added). Substantial evidence is defined in Defendants' proposed paragraph

7(b)(ii) as "objective" evidence, such as the standard treatment or use of technology for specific medical conditions, evidence-based treatment guidelines, and trials and studies. (Id.) This "objective" evidence must be considered in the context of the individual enrollee's medical history. (Id.)

Defendants' proposed paragraph 7(b)(i) is clearly modeled after 20 C.F.R. § 404.1527(d)(2), which grants controlling weight to the treating source's opinion if it is "well-supported by medically acceptable clinical and laboratory diagnostic techniques and is not inconsistent with the other substantial evidence in [a claimant's] case record." (emphasis added). Defendants, however, have changed the meaning of "substantial evidence" and omitted the phrase "in [a claimant's] case record," such that their proposal has a drastically different meaning.

In the Social Security context, "substantial evidence in [a claimant's] case record" refers to information provided by the treating source and the claimant. It may also include opinions from physicians or other sources who do not have a prior relationship with the claimant, but who are asked to provide an "objective" opinion. This "objective" opinion, however, is provided only after examining the claimant or examining the claimant's medical or case record. See 20 C.F.R. §§ 404.1512, 404.1513, 404.1528. Thus, in the Social Security context, the focus is on the consistency of the evidence in the "case record." Defendants' proposal, however, shifts the focus from consistency of the evidence in the case record to consistency of the case record with external information. Rather than comparing the treating provider's opinion with the enrollee's medical record, Defendants' proposal only compares the treating provider's opinion with the "objective" evidence (e.g., evidence-based treatment guidelines, clinical trials and studies). This

changes the Social Security Administration's standard regarding the weight given to the treating source's opinion. While Defendants were not required to adopt the Social Security standard (the Court merely recommended they do so) Defendants' transformation of that standard violates other provisions of this Court's prior ruling.

Specifically, pursuant to Defendants' proposal, where an inconsistency arises between the treating provider's opinion and the "objective" evidence, the treating provider's opinion is minimized and Defendants have the authority to request the treating provider to justify his or her opinion. (Doc. No. 1338, Ex. 1 ¶ 7(b)(i-iii).) This standard essentially requires treating physicians to justify any deviation from the standard course of treatment, even when the physician's opinion is reasonably supported with evidence from the enrollee's medical records. The Court explicitly prohibited the use of this standard. (See Doc. No. 1256 at 12, Doc. No. 1282 at 84-88.) To now adopt it would not only eviscerate the presumption of correctness the Consent Decree accords a treating physician's opinion, but also would reverse this Court's prior ruling. As Defendant's proposal is in direct violation of this Court's prior rulings, it is not accorded substantial deference. The Court understands Defendants' desire to increase the use of evidence-based treatment guidelines and create a uniform method of practicing medicine. However, Defendants' proposal is overzealous and diminishes the value of a treating physician, who brings a unique perspective to the medical evidence that cannot be obtained from objective evidence alone. For these reasons, the Court declines to approve Defendants' proposal.

In contrast, Plaintiffs' proposal hews more closely to this Court's prior rulings. Nevertheless, it too does not adequately capture the varying levels of deference that this Court mandated should be accorded to a treating physician's opinion. Plaintiffs' proposal only

discusses the "highest" weight that a treating physician's opinion may be accorded, but does not discuss the intermediary standards. (See Doc. No. 1341, App'x C at 1.) Furthermore, Plaintiffs' proposal needs to be refined to permit a greater consideration of "objective" evidence. As a result, the Court declines to approve Plaintiffs' proposal in toto.

As the parties have not been able to devise a framework that adequately implements the Court's prior rulings, the Court ORDERS the following revision to Paragraph C(7)(b):

7. Decisions to be supported by substantial and material evidence.

In any appeal of an adverse action affecting TennCare benefits, throughout all stages of such appeal, the defendants shall ensure that decisions are based upon substantial and material evidence. In cases involving clinical judgments, this requirement specifically means that:

a. Appeal decisions must be supported by medical evidence, and it is the defendants' responsibility to elicit from beneficiaries and their treating providers all pertinent medical records that support an appeal; and

b. Medical opinions shall be evaluated as follows:

i. Where the treating provider's opinion is consistent with the defendants' or MCCs' opinion or objective evidence, it shall be accorded controlling weight.

ii. Where the treating provider's opinion is:

(1) well-supported with clinical and laboratory findings derived from an examination of the enrollee or enrollee's medical records, and objective evidence; or

(2) well-supported with clinical and laboratory findings derived from an examination of the enrollee or the enrollee's medical records, but not with objective evidence,

the opinion shall be accorded controlling weight, even if it is inconsistent with the defendants' or MCCs' opinion or objective evidence; provided, however, that the treating provider's opinion does not significantly deviate from the defendants' or MCCs' opinion or objective evidence. If the treating provider's opinion significantly deviates from the defendants' or MCCs' opinion or objective evidence, the defendants' or MCCs may require the treating provider to further explain his or her opinion.

iii. Where the treating provider's opinion is:

(1) not well-supported with clinical and laboratory findings derived from an examination of the enrollee or the enrollee's medical records, but is well-supported by objective evidence; or

(2) not well-supported with either clinical and laboratory findings derived from an examination of the enrollee or the enrollee's medical records, or objective evidence,

the opinion shall be accorded minimal weight if it is inconsistent with the defendants' or MCCs' opinion or objective evidence. The defendants or MCCs may require the treating provider to further explain his or her opinion.

iv. In the event the defendants or MCCs require further explanation from the treating provider as described in Paragraph C(7)(b)(ii) and (iii),

(1) the treating provider's opinion shall be accorded controlling weight, if the treating provider submits an explanation or other clinical or objective evidence and the defendants or MCCs deem such additional information to be sufficient to cure the original deficiency.

(2) the treating provider's opinion shall be accorded minimal weight, if the treating provider fails to submit an explanation or other clinical or objective evidence, or the

defendants or MCCs deem any additional information submitted by the treating provider to be insufficient to cure the original deficiency.

v. Objective evidence may include the standard treatment for specific medical conditions or the use of specific health technologies, including evidence-based treatment guidelines and technology assessments, and the results of well-supported clinical trials and studies, recommendations from other health care providers, clinical guidelines, standards or recommendations from respected medical organizations or governmental health agencies, analyses from independent health technology assessment organizations, and policies of other health plans.

In considering whether the treating provider's opinion is well-supported by objective evidence, as described in Paragraph C(7)(b)(ii)-(iii), or whether any objective evidence submitted to cure the original deficiency is sufficient, as described in Paragraph C(7)(b)(iv), the defendants or MCCs shall consider the validity and reliability of the objective evidence (including any objective evidence upon which the defendants or MCCs rely) in accordance with the medical necessity rules enacted by the defendants.[1]

vi. Opinions from treating providers are valued because they are the medical professionals most able to provide a detailed, longitudinal picture of the enrollee's medical condition(s) and may bring a unique perspective to the medical evidence that cannot be obtained from objective evidence alone, or from reports of individual examinations, such as consultative examinations or brief hospitalizations.

vii. The notice of adverse action shall include a statement of reasons for the weight given to the treating provider,

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[1] This provision anticipates that Proposed Rules §§ 1200-13-16.01(21), 1200-13-16.06(6), 1200-13-16.06(7) shall be clarified or revised in accordance with this Order. See infra Part II.B.

> including, but not limited to, the supportability of the opinion with clinical and laboratory findings and objective evidence, and the consistency of the opinion with the medical record as a whole, including any objective evidence upon which the defendants or MCCs rely. If the defendants or MCCs invoke objective evidence as the basis for the adverse action, they shall describe with specificity the objective evidence supporting their judgment and how it applies to the unique medical condition of the individual beneficiary.

c. Reliance upon objective evidence, as defined in Paragraph C(7)(b)(v), without consideration of the individual enrollee's medical history is prohibited and cannot be relied upon to support an adverse action affecting TennCare services.[2]

Defendants object to the notice requirement in revised Paragraph C(7)(b)(vii), which is derived from Plaintiffs' proposal. Defendants argue that this provision is new and onerous because it will compound the possibility that errors in notices will result in services being directed when there is no sound medical reason for providing those services. (Doc. No. 1343 at 13.) Defendants also contend that because this is a new provision, Plaintiffs must demonstrate that a significant change in circumstances has occurred to warrant modification of the Consent Decree, and that the modification is suitably tailored to the circumstances. Rufo v. Inmates of Suffolk County Jail, 502 U.S. 367 (1992).

To begin with, the requirement to provide a notice with reasons after an adverse medical necessity decision is not new. Basic due process requires that the Defendants provide the reasons for denying a service. (See Doc. No. 1282 at 63-64, 99-100.) Most importantly,

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[2] The Court previously ruled that only the first sentence of Paragraph C(7)(b) could be revised. (See Doc. No. 1282 at 88.) Nevertheless, the Court finds it appropriate to slightly modify the second sentence of Paragraph C(7)(b) to incorporate the revisions to the first sentence of Paragraph C(7)(b).

however, the Consent Decree already requires that "[i]f the proposed action turns on a determination of medical necessity or other clinical decision, the statement of reasons shall: . . . ii. Specify what part(s) of the criteria for medical necessity or coverage was not met." (Doc. No. 908 at 7, ¶ C(1)(b).) Revised Paragraph C(7)(b)(vii) simply follows this mandate.

Even if revised Paragraph C(7)(b)(vii) is considered to be a "new" requirement, Defendants' implicit contention that a significant change in facts has not occurred to warrant its addition is disingenuous. This Court explicitly held that a significant change in facts has occurred warranting modification of the Consent Decree. (Doc. No. 1282 at 9-36.) This holding is not limited to Defendants' requested modifications. Separate and apart from the changed circumstances noted in the Court's Memorandum Opinion, the revision of Paragraph C(7)(b) constitutes a significant change in circumstances warranting this particular modification.

For the following reasons, the Court finds that subsection (vii) of revised Paragraph C(7)(b) is suitably tailored to the changed circumstances. Paragraph C(7)(b) has changed drastically, requiring a more specific outline of the factors that need to be included in the statement of reasons that is already required by Paragraph C(1)(b) of the Consent Decree. Moreover, Defendants' assertion that the reason-giving requirement will be onerous is unpersuasive because Defendants concede that revised Paragraph C(7)(b)'s analytical framework will apply only in a small percentage of cases. Importantly, if Defendants are truly interested in educating providers on the use of evidence-based treatment, it is in their interest to provide the reasons why a requested service is not medically necessary so that the provider will learn not to make the same mistake again. At oral argument Plaintiffs-Intervenors underscored this educational idea by pointing out that Defendants' proposal attempts to create a dialogue between

the treating provider and the Defendants. The Court agrees that revised Paragraph C(7)(b) should increase such dialogue, but it cannot be one-sided. Indeed, it is ironic that Defendants require a very high level of reason-giving in order to credit a provider's opinion, but seek to exempt themselves from that same standard.

The Court is further unpersuaded that the risk of errors in the notice diminishes the need for reason-giving. This Court has already ruled on when errors in notices can be corrected without providing the service. (See Doc. No. 1282 at 99-100, Doc. No. 1328 at 7-11.) Defendants primarily object to providing such reasons at the prior authorization stage. (Doc. No. 1343 at 13.) A notice at that stage is early in the process. Therefore, if it is defective, it can be remedied without granting the service. In sum, Defendants' objection to the notice requirement in revised Paragraph C(7)(b)(vii) is overruled.

B. DEFENDANTS' PROPOSED MEDICAL NECESSITY RULES

Plaintiffs contend that the Proposed Medical Necessity Rules ("Proposed Rules") do not comport with this Court's prior rulings, and the Court agrees. As written, the Proposed Rules do not accord the treating physician the presumption of correctness that is embodied in, and which this Court declined to eliminate from, the Consent Decree. Similarly, the Proposed Rules do not appear to allow for the spectrum of deference given by Paragraph C(7)(b) of the Consent Decree to a treating physician's opinion.

The inconsistency between the Proposed Rules and the Consent Decree, as revised by this Court's rulings, arises in the definition of "Hierarchy of Evidence." The definition states:

(21) HIERARCHY OF EVIDENCE shall mean a ranking of the weight given to medical evidence depending on objective indicators of its validity and reliability including the nature and source of the medical evidence, the empirical characteristics of the studies or trials upon which the medical evidence is based, and the consistency of the outcome with comparable studies. The hierarchy in descending order, with Type I given the greatest weight is:

(a) Type I: Meta-analysis done with multiple, well-designed controlled clinical trials;

(b) Type II: One or more well-designed experimental studies;

(c) Type III: Well-designed, quasi-experimental studies;

(d) Type IV: Well-designed, non-experimental studies; and

(e) Type V: Other medical evidence defined as evidence-based:

(i) Recommendations from the treating physician or other health care provider;

(ii) Clinical guidelines, standards or recommendations from respected medical organizations or governmental health agencies;

(iii) Analyses from independent health technology assessment organizations; or

(iv) Policies of other health plans.

(Doc. No. 1338, Proposed Rule § 1200-13-16.01(21)) (emphasis added).

This Proposed Rule appears to create a separate framework for analyzing the validity and reliability of a physician's clinical judgment, despite the fact that the Court's prior ruling regarding Paragraph C(7)(b) already created such a framework. See supra Part II.A. Defendants argue that Proposed Rule § 1200-13-16.01(21) does not substitute Paragraph C(7)(b). In particular, Defendants assert that Proposed Rule § 1200-13-16.01(21) does not substitute an individualized determination by a treating physician with scientific trials or studies. The literal reading of Proposed Rule § 1200-13-16.01(21), however, does exactly that. Due to the literal reading of Proposed Rule § 1200-13-16.01(21) and because Defendants have not adequately explained the interplay between Proposed Rule § 1200-13-16.01(21) and Paragraph C(7)(b) of

the Consent Decree, the Court cannot accept Defendants' assertion that they do not intend to apply the rule such that generalized objective evidence will not substitute a treating physician's opinion.[3]

In addition, it appears that the principal purpose of the Hierarchy of Evidence is to assess the reliability and validity of objective evidence. The Court agrees that the State needs a method of comparing and contrasting the various types of objective evidence. What is problematic, however, is the inclusion of a physician's clinical judgment in this analytical framework. By its very nature, a physician's clinical judgment is not objective. It is a subjective application of the physician's medical knowledge (which includes objective evidence) to an individual patient's circumstances. In contrast, objective evidence does not take into consideration an individual patient's circumstances. In fact, the only evidence in the Hierarchy of Evidence that includes an analysis of an individual patient's circumstances is a "[r]ecommendation[] from the treating physician . . . ." (Doc. No. 1338, Proposed Rule § 1200-13-16.01(21)(e)(i).) All the other evidence involves generalized trials, studies, policies, guidelines, standards, and analyses that do not involve an analysis of the individual patient's circumstances. (See Doc. No. 1338, Proposed Rule § 1200-13-16.01(21)(a)-(d), (e)(ii)-(iv).) By ranking "[r]ecommendations from the treating physician . . . ." with generalized trials, studies, policies, guidelines, standards and analyses, Defendants are attempting to rank apples with oranges.

Finally, and perhaps most fundamentally, it appears illogical that a treating physician's well-reasoned application of objective evidence to an individual patient's circumstances is less

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[3] The Court notes that other than Proposed Rule § 1200-13-16.06(5), which does not permit a treating physician's conclusory statements to bind the State, the Proposed Rules do not explicitly or implicitly implement Paragraph C(7)(b) of the Consent Decree.

valid and reliable than a clinical trial that does not even consider an individual patient's circumstances. Thus, the Court agrees with Plaintiffs that:

> The "Hierarchy of Evidence" should only come into play if the treating physician and the Bureau of TennCare or MCC, based on evidence in the patient's record, propose different treatment based on research results from different evidence sources that are applicable to the patient's condition [, as described in revised Paragraph C(7)(b)(i)-(v). (See supra at 12-14.)] In such circumstances, the course of treatment that is supported by the most authoritative "evidence" as ranked under the "Hierarchy of Evidence" may sometimes outweigh the care prescribed by the treating clinician based on less authoritative "evidence." On the other hand, if there is a dispute about whether the patient's condition actually fits the situation covered in the research, clinical judgment is required in order to decide whether the research results are even relevant to the care of that patient. In weighing competing clinical judgments on that issue, the treating clinician's judgment is entitled to deference, unless that judgment . . . significantly deviates from evidence-based treatment guidelines endorsed or established by the State or the MCC [, as outlined in revised Paragraph C(7)(b)(i)-(v). (See supra at 12-14.)].

(Doc. No. 1341 at 7.)

For these reasons, the inclusion of subsection (e)(i), ranking a treating physician's recommendation in relation to different types of objective evidence in the definition of Hierarchy of Evidence, is inconsistent with revised Paragraph C(7)(b), and this Court's rulings. This inconsistency may be rectified by removing subsection (e)(i) from the definition of Hierarchy of Evidence or by explaining the interplay between revised Paragraph C(7)(b) and Proposed Rule § 1200-13-16.01(21).

Concomitantly, because Proposed Rule § 1200-13-16.06(7)(b) explains how the definition of Hierarchy of Evidence is used in medical necessity determinations, it also should be revised or its interplay with revised Paragraph C(7)(b) should be explained. In the event Proposed Rule § 1200-13-16.01(21)(e)(i) is removed from the Hierarchy of Evidence, then

Proposed Rule § 1200-13-16.06(7)(b) may be revised as follows:

> Medical items or services with "C" rated evidence <u>or a physician's clinical judgment that is not supported by objective evidence</u>, will be considered safe and effective only if the provider shows that the requested service is the optimal intervention for meeting the enrollee's specific condition or treatment needs, and
>
> (i) Does not place the enrollee at greater risk of morbidity or mortality than an equally effective alternative treatment; and
>
> (ii) Is the next reasonable step for the enrollee <u>in light of the enrollee's past medical treatment</u>.

(emphasis supplied to highlight alterations). Defendants should note the Court's suggested revision to Proposed Rule § 1200-13-16.06(7)(b)(ii). The Court finds that the present language regarding "tried-and-failed attempt at evidence-based care" is too restrictive, especially as this Proposed Rule deals with the situation where there is insufficient objective evidence. Instead, Defendants should focus on the totality of the enrollee's past medical treatment.[4]

Similarly, Plaintiffs assert that the first sentence of Proposed Rule § 1200-13-16.06(4), regarding the weight accorded a treating physician's recommendation, order or prescription, does not adequately implement revised Paragraph C(7)(b). The first sentence of Proposed Rule § 1200-13-16.06(4) states that "[i]n making a medical necessity determination, TennCare or its designee <u>will consider</u> a recommendation, order, or prescription for a covered medical item or service from a treating physician or other treating health care provider." (Doc. No. 1338, Proposed Rule § 1200-13-16.06(4))(emphasis added). At first blush, the phrase "will consider"

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[4] Defendants may also wish to conform Proposed Rule § 1200-13-16.06(6), which involves the definition of Hierarchy of Evidence in medical necessity determinations, to the present ruling or explain its role in relation to revised Paragraph C(7)(b).

does not appear to adequately capture the spectrum of deference accorded a treating physician's opinion as set forth in revised Paragraph C(7)(b). However, Defendants are required to "consider" a treating physician's recommendation, order, or prescription in accordance with the Consent Decree. Therefore, the "consideration" given will be controlled by revised Paragraph C(7)(b) of the Consent Decree. While Defendants could certainly clarify that Paragraph C(7)(b) of the Consent Decree provides the standard for "considering" the treating physician's recommendation, order or prescription, a revision of Proposed Rule § 1200-13-16.06(4) is not required.

In conclusion, the definition of Hierarchy of Evidence and its application in the Proposed Rules must be clarified in accordance with, or revised to conform with, this Court's rulings. The Court has arrived at this conclusion after much thought, and does not issue this ruling lightly. The Court recognizes the research that the State has conducted in creating the Proposed Rules, and the deference it must accord State officials. However, it cannot permit certain sections of the Proposed Rules to stand when they are clearly inconsistent with the Consent Decree.

III. CONCLUSION

Both parties' proposed revisions to Paragraph C(7)(b) of the Consent Decree do not fully implement the Court's prior rulings; therefore, the Court ORDERS the parties to adopt the Court's revision to Paragraph C(7)(b) of the Consent Decree. Certain of the State's Proposed Medical Necessity Rules are inconsistent with the Court's revised Paragraph C(7)(b) of the Consent Decree, and must be MODIFIED or EXPLAINED in accordance with this Order.

It is so ORDERED.

Entered this the 22nd day of March, 2006.

JOHN T. NIXON, SENIOR JUDGE
UNITED STATES DISTRICT COURT