

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

GAYNELL GRIER, <i>et al.</i> ,)	
)	
Plaintiffs,)	
)	
SANFORD BLOCH, MARK LEVINE,)	
and TIM JONES,)	
)	
Plaintiffs-Intervenors,)	
)	
v.)	Civil Action No. 79-3107
)	Judge John T. Nixon
M.D. GOETZ, Jr., Commissioner,)	
Tennessee Department of Finance and)	
Administration, <i>et al.</i> ,)	
)	
Defendants,)	
)	
and)	
)	
TENNESSEE ASSOCIATION OF)	
HEALTH MAINTENANCE)	
ORGANIZATIONS, <i>et al.</i> ,)	
)	
Defendants-Intervenors.)	

**ORDER AMENDING
REVISED CONSENT DECREE (MODIFIED)**

Upon review of defendants' Motion to Modify and/or Clarify the Revised Consent Decree and Memorandum in Support thereof (Doc. Nos. 1086, 1087) and the responses thereto (Doc. Nos. 1106, 1111, 1141, 1148, 1236) and after consideration of the testimony and evidence adduced during the hearings that took place between June 29, 2005 and July 19, 2005, and arguments on July 28, 2005, the Court has approved in part the requested changes to the revised consent decree that was entered on October 1, 2003 (Doc. 908). *See* Doc. Nos. 1246, 1248, 1256, 1261, 1282, 1328 (orders and memorandum ruling on defendants' motion and on

plaintiffs' motion to clarify) and 1394. This order incorporates the approved modifications into that decree, which this order supersedes. The provisions of this order that have been carried forward unchanged from the order of October 1, 2003 (Doc. 908) were entered by agreement of the parties prior to October 1, 2003; the remaining provisions of this order are modifications of the October 1, 2003 order that were granted following a contested hearing on the State's motion to modify. *See* Doc. 1282. Furthermore, all previous orders in this case to the extent they are not inconsistent with this order remain in effect, but to the extent previous orders are inconsistent or have previously been superseded or vacated, they no longer have any force or effect.

To ensure compliance with this Order and with the federal regulations which it embodies, and to clarify its terms, the Court, hereby permanently enjoins the state defendants as follows.

A. Applicability of Terms

This order and previous orders incorporated by reference shall apply fully to the state defendants, their agents, servants, employees, and attorneys, and those persons in active concert or participation with them, including any private or public entity that administers Medicaid-funded health benefits. These orders shall apply specifically, but not be limited to, the state defendants and their managed care contractors (MCC) which operate provider networks, whether designated as managed care organizations (MCOs), behavioral health organizations (BHOs), pharmacy benefit managers (PBMs), dental benefit managers (DBMs) or state government agencies.

B. Definitions

1. References to the "defendants" in this action shall mean the named state defendants.

2. The term “medical assistance” means health care, services, and supplies furnished to an eligible individual and funded in whole or in part under Title XIX of the Social Security Act (“The Medicaid Act”), 42 U.S.C. §§1396 *et seq.* Medical assistance includes the payment of the cost of care, services, drugs and supplies. Such care, services, drugs and supplies shall include services of qualified providers, as defined herein.

3. References to “TennCare benefits” or “TennCare services” include any medical assistance that is administered by the state defendants or their contractors and which is funded wholly or in part with federal funds under the Medicaid Act, but excluding:

- a. Medical assistance that can be appealed through an appeal of a pre-admission evaluation (PAE) determination; and
- b. Medicare cost sharing services that do not involve utilization review by the defendants or their contractors.

4. References to “beneficiaries”, “enrollee”, “recipients” or “patients” include any individuals eligible for, and enrolled in, Tennessee’s medical assistance program administered under the terms of the Medicaid Act or any federal Medicaid waiver, and amendments thereto, granted by the Secretary of Health and Human Services pursuant to Sections 1115 or 1915 of the Social Security Act. As concerns an MCC’s compliance, the term only applies to those for whom the MCC has received at least one day’s prior written or electronic notice from the TennCare Bureau of the individuals’ assignment to the MCC.

5. References to “adverse action” affecting TennCare benefits include, but are not limited to, delays, denials, reductions, suspensions, or terminations of TennCare benefits, as well as to any other acts or omissions of the defendants which impair the quality, timeliness or availability of such benefits.

Example: A person seeks dental care for her child, who is complaining of a painful tooth. The MCO refers her to one dental office where she cannot obtain an appointment for 6 weeks, and to a second provider that is 40 miles away. The beneficiary can pursue an appeal to challenge the delay in receiving TennCare –covered services regardless of the reason for the delay.

Example: TennCare seeks to “lock-in” a beneficiary to a particular pharmacy, so that the person can only obtain prescription medications from that specific provider. TennCare’s proposed action may limit or delay the beneficiary’s access to pharmacy services, and must therefore be treated as an adverse action affecting TennCare benefits. The beneficiary is entitled to prior notice and appeal rights as provided in this order.

6. References to “delay” include, but are not limited to:
 - a. Any delay in receipt of TennCare services, and no specific waiting period may be required before the beneficiary can appeal
 - b. An MCC’s failure to provide timely prior authorization of a TennCare service is a delay. In no event shall a prior authorization decision be deemed timely unless it is granted within the time required under state regulations (but no more than 21 calendar days of a request for such authorization), and a shorter period is required if a prompt response is medically necessary in light of the beneficiary’s condition and the urgency of his need, as defined by a prudent lay person.
 - c. Notwithstanding this definition, the reasonable time required for a beneficiary to exhaust an administrative grievance or other informal process shall not be counted when determining a delay. Circumstances in which a beneficiary may be required to exhaust an administrative process before an appeal can be commenced and/or processed consist of the following:
 - (i) Requests for a drug or service requiring prior authorization when prior authorization has not been sought;

- (ii) Requests for a drug or service by beneficiaries without a prescription or order for that drug or service; and,
- (iii) Requests for a service or reimbursement where the enrollee has not yet requested such service or reimbursement from his/her MCC such that the service or reimbursement has been denied.

7. References to “reduction”, “suspension”, or “termination” of TennCare services include acts or omissions on the part of the state defendants or others acting on their behalf which result in the interruption of a course of necessary clinical treatment for a continuing spell of illness or medical condition. For purposes of compliance with this order and the regulations which it embodies, the state defendants acknowledge that their managed care contractors are responsible for the management and provision of medically necessary covered services throughout a beneficiary’s illness or need for such services, and across the continuum of covered services, including, but not limited to behavioral health services and appropriate transition plans specified in the applicable TennCare contract. Therefore, the fact that a beneficiary’s medical condition requires a change in the site or type of TennCare service does not lessen the contractor’s obligation to provide covered treatment on a continuous and ongoing basis as medically necessary.

8. A “decision in favor of a beneficiary [or enrollee]” refers, in the case of a decision by an administrative law judge (ALJ), to the initial decision on the merits of the appeal, which shall be implemented in accordance with Paragraph C(13) and C(16)(c).

9. The term “provider” means a health care provider eligible by professional qualifications to participate in TennCare, and who is acting within her scope of practice.

10. The term “treating physician [or clinician]” refers to a health care provider who has provided diagnostic or treatment services for a beneficiary (whether or not those services were covered by TennCare), for purposes of treating, or supporting the treatment of, a known or suspected medical condition. The term excludes providers who have evaluated a beneficiary’s medical condition primarily or exclusively for the purpose of supporting or participating in a decision regarding TennCare coverage.

11. The term “benefit limits” means limits approved by the Center for Medicare and Medicaid Services (CMS) on coverage of a TennCare item or service imposed by defendants, which includes but is not limited to limits on the number of inpatient hospital days per year, physician services per year, outpatient facility services per year, laboratory and x-ray services per year, inpatient and outpatient substance abuse services over the course of a TennCare beneficiary’s lifetime, and/or prescriptions per month that will be covered by the TennCare program.

12. The term “prior authorization” means the process under which items or services must be approved by the TennCare Bureau or the MCC, prior to delivery, in order for such item or service to be covered by the TennCare program.

13. The term “readable” means that a notice or other written communication requires no more than a sixth grade level of reading proficiency to understand, as measured by the Fogg index or other readability instrument.

14. References to “continuation of services [or benefits] pending review [or appeal]” and references to “reinstatement of services [or benefits] pending review [or appeal]” include either:

- a. Those services currently or, (in the case of reinstatement) most recently, provided to a TennCare beneficiary; or
- b. Those services being provided to an enrollee in an inpatient psychiatric facility or residential treatment facility where the discharge plan has not been accepted by the enrollee or appropriate step-down services are not available; or
- c. Those services being provided to treat a patient's chronic condition across a continuum of services when the next appropriate level of covered services is not available.

Example: A TennCare enrollee is hospitalized after a stroke and, upon discharge from the hospital will continue to require physical therapy from a home health agency. If timely home health services are not in place at the time of discharge, the patient may obtain continuation of hospital care pending appeal, or until the home health services are available to ensure continuation of care upon discharge.

- d. Those service prescribed by the enrollee's provider on an open-ended basis or with no specific ending date where the MCC has not reissued prior authorization; or
- e. A different level of covered services, offered by the MCC and accepted by the enrollee, for the same illness or medical condition for which the disputed service has previously been provided.

Example: A TennCare beneficiary's treatment in an inpatient psychiatric hospital is being, or has been reduced, terminated or suspended, but he continues to need active care for his mental illness. Upon timely appeal of the adverse action affecting his inpatient care, the beneficiary may elect to continue inpatient services or to receive other appropriate covered TennCare services, such as residential treatment facility (RTF) services. If the beneficiary is eligible for continuation of services and is offered and elects to receive the lower level of care pending appeal, the BHO must arrange for a transfer from hospital to RTF in such a manner that there is no break in the beneficiary's treatment. If the beneficiary is eligible for reinstatement of services and is offered and elects to receive the lower level of care pending appeal, the BHO must provide those services within 24 hours of receipt of the beneficiary's request.

15. For purposes of this order, receipt of mailed notices is presumed to occur within 5 days of mailing.

16. Time-sensitive care is care which requires a prompt medical response in light of the beneficiary's condition and the urgency of her need, as defined by a prudent lay person; provided, however, that a case may be treated as non-time-sensitive upon the written certification of the beneficiary's treating physician.

17. As referred to in this order in the context of TennCare pharmacy services, a provider with prescribing authority is a health care professional authorized by law or regulation to order prescription medications for her patients, and who:

- a. participates in the provider network of the MCC in which the beneficiary is enrolled; or
- b. has received a referral of the beneficiary, approved by the MCC, authorizing her to treat the beneficiary; or
- c. in the case of a TennCare beneficiary who is also enrolled in Medicare, is authorized to treat Medicare patients.

18. As referred to in this order in the context of TennCare medical services appeals, "valid factual dispute" means any dispute that, if resolved in favor of the enrollee, entitles the enrollee to coverage of the medical services.

C. Prohibitions and Duties

1. ***Notice Contents.*** Whenever the federal regulations or this Order require that a TennCare beneficiary receive notice of an adverse action affecting medical assistance (other than

pharmaceutical notices which are addressed in paragraph C(1)(e) or as otherwise provided in this Order) the notices shall contain the following elements, written in concise, readable terms.

- a. The type and amount of TennCare services at issue and the identity of the individual, if any, who prescribed the services;
- b. A statement of reasons for the proposed action. The statement of reasons shall include the specific facts, personal to the beneficiary, which support the proposed action and sources from which such facts are derived. If the proposed action turns on a determination of medical necessity or other clinical decision, the statement of reasons shall:
 - (i) Identify by name those clinicians who were consulted in reaching the decision at issue;
 - (ii) Identify specifically those medical records upon which those clinicians relied in reaching their decision;
 - (iii) Specify what part(s) of the criteria for medical necessity or coverage was not met; and,
 - (iv) Inform the enrollee about the opportunity to contest the decision, including the right to an expedited appeal in the case of time-sensitive care and a right to reinstated or ongoing medical services pending appeal.

Attached as a part of Collective Exhibit A to this order is a sample notice that shall be used by the defendants as a template for the notices they issue.

- c. If the beneficiary has an ongoing illness or condition requiring medical care and the MCC or its network provider is under a duty to provide a discharge plan or otherwise arrange for the continuation of treatment following the proposed

adverse action, the notice must be given and shall include a reasonable explanation of the discharge plan, if any, and a description of the specific arrangements in place to provide for the beneficiary's continuing care.

Example: A TennCare beneficiary is receiving psychiatric treatment in a hospital and the BHO refuses to certify, or authorize, a continuation of his hospitalization. The beneficiary is still severely mentally ill, however, and the BHO is responsible for his continuing care. The notice of termination of inpatient hospital services must include information regarding the availability of case management services and must describe the other TennCare services that will be in place at the time of discharge. If those services are not initiated prior to discharge from the psychiatric hospital, the notice shall specify the time of the first appointment at which those services will be provided.

Attached as Collective Exhibit A to this order is a sample notice that satisfies the requirements of this provision, and that shall be used by the defendants as a template for the notices they issue. The State may modify the notice templates in Exhibit A whenever it deems a change is warranted. Any such change shall be provided to Plaintiffs 30-days before implementation and shall take effect at the end of the 30-day notice period unless Plaintiffs file an objection with the Court in which case the new notice shall not take effect until the court rules on Plaintiffs' objection. When the Plaintiffs do not object to a new notice, the State will have the obligation of submitting a notice of filing apprising the court of the new notice template.

- d. The required reference to the legal or policy basis for a proposed adverse action shall include a plain and concise statement of the applicable law, federal waiver provision or TennCare contract, as well as its official citation with a brief statement of the reasons for the adverse action based upon the individual enrollee's circumstances. The defendants and others acting on their behalf may

not cite or rely upon policies that are inconsistent with federal law, the TennCare waiver, properly promulgated rules or contract provisions.

- e. ***Content of Pharmaceutical Notices.*** Due to the highly automated procedures for prior authorization of medications, the need for an emergency 72-hour supply of prescribed medications, the ongoing changes and refinements to the State's preferred drug list, and implementation of "soft" pharmacy benefit limits, pharmaceutical notices must be treated differently from other medical services.
- (i) If the service at issue is a prescription drug for which a request for prior authorization has been denied, the defendants shall issue a notice through their PBM. Although this notice may not require all the information required under C(1)(a)-(b), it must meet the minimum requirements for a meaningful notice required under 42 C.F.R. §§ 431.206-210. Meaningful notice for the purposes of this subsection requires an identification of the medication prescribed, the reason(s) for the denial, and if such reason is medical necessity, the reason(s) why the medication is not medically necessary, and the regulations to support the denial of prior authorization. The statement of reason(s) the medication is not medically necessary may be indicated by reference to a list of pharmacy edits used by the TennCare PBM.
 - (ii) If the service at issue is a prescription drug for which prior authorization has not been sought, defendants shall issue a preprinted notice through their participating pharmacies that informs enrollees of (a) the need to obtain prior authorization, (b) how the enrollee and his or her provider can

seek prior authorization, (c) what must be shown to obtain an emergency 72-hour supply of prescribed medication, and (d) the administrative process they must exhaust before they may appeal. Attached as part of Collective Exhibit A to this order are sample notices that satisfy the requirements of this provision, and that shall be used by the defendants as a template for the notices they issue.

- f. The defendants and others acting on their behalf shall be bound by their own notices, and may not rely upon any reasons or legal authorities other than those which they include in their written notices to a TennCare beneficiary. The Bureau of TennCare or MCC, however, may remedy any defects or omissions in a notice after the filing of an appeal by issuing one corrected notice that must be received by the beneficiary prior to the issuance of a timely notice of hearing. When a corrected notice is issued, the enrollee shall not be required to file a new appeal or take additional steps to obtain a hearing on his original appeal. In the event that a beneficiary appeals an adverse action, the reviewing authority shall consider only factual reasons and legal authorities cited in the original notice, or, if that original notice has been corrected in conformity with this subparagraph, the corrected notice to the beneficiary, except that additional evidence beneficial to the enrollee may be considered on appeal.
- g. If the MCC's reasons or legal authorities in the original notice (or in any notice that has been corrected in conformity with Paragraph C(1)(f)), do not meet the requirements of C(1)(a-e), then the MCC denial shall be overturned and the beneficiary shall receive the service or item requested subject to the exclusions

contained in C(16)(h) and C(18). Nothing herein shall preclude the issuance of a new notice, but such new notice shall not cure the deficiencies of the original or corrected notice.

2. ***When notice is required.***

a. The defendants and their contractors shall provide notice in the circumstances, and within the time frames required by 42 C.F.R §§431.210-214, except as modified and adapted herein below.¹

b. Whenever an MCC has reason to expect that covered medical assistance for a TennCare beneficiary will be delayed beyond the time limits prescribed by the TennCare contract or the terms and conditions of the TennCare waiver, it shall immediately issue notice to the beneficiary. Among the MCC actions which can be reasonably anticipated to delay or disrupt access to medical assistance are the following:

- (i) Changes of primary care provider;
- (ii) Pharmacy “lock-in”;
- (iii) Decisions affecting the designation of a person as severely and persistently mentally ill (SPMI) or severely emotionally disturbed (SED);

¹ The parties intend that, in order to adequately protect the due process rights of the plaintiff class members in the context of managed care, subparagraph (C)(2)(d) expands the protections afforded by 42 C.F.R. § 431.213(f), by modifying the provision allowing same day notice in certain cases where the beneficiary’s clinician initiates the proposed action. As modified by this order, same day notice will not suffice in the circumstances specified in subparagraph (C)(2)(d); notice must be received by the beneficiary at least two business days in advance of the proposed action. In cases involving inpatient hospital treatment, where the beneficiary’s treating provider does not initiate the reduction, suspension or termination of such services, the ten day notice required by 42 C.F.R. § 431.211 may be shortened to two business days, if the defendants or their contractors comply with the other safeguards afforded by this order.

- (iv) Termination of a provider's contract, by either party to the contract;
- (v) Inability to provide an adequate provider network.

Attached as part of Collective Exhibit A to this order is a sample notice that satisfies the requirements of this provision, and that shall be used by the defendants as a template for the notices they issue.

- c. When a TennCare enrollee has been prescribed a covered service on an ongoing basis or with no specific ending date, and the service is subject to a prior authorization requirement, the MCC shall provide notice containing the information required by this order. The notice must be provided no more than 40 days, or less than 30 days, prior to the expiration of prior authorization for the service. In the event that the period of authorization is less than 30 days, the notice shall be issued upon authorization. This provision, however, does not require the Defendants to provide notice of the fact that drugs that have been prescribed on an ongoing basis or with unlimited refills have become subject to prior authorization. The fact that a drug becomes subject to prior authorization does not constitute an adverse action and does not trigger the notice requirement. Attached as part of Collective Exhibit A to this order is a sample notice that satisfies the requirements of this provision, and that shall be used by the defendants as a template for the notices they issue.

- d. The MCC shall provide at least two (2) business days' advance notice² of any provider-initiated reduction, termination, or suspension of:
- (i) Any behavioral health service for a severely and persistently mentally ill (SPMI) adult enrollee or severely emotionally disturbed (SED) child.
 - (ii) Any inpatient psychiatric or residential service;
 - (iii) Any service being provided to treat a patient's chronic condition across a continuum of services when the next appropriate level of medical service is not immediately available; or
 - (iv) Home health services.

The notice shall contain the information required by Paragraph subsection C (1)(a) and (b), supra, of this order, as well as a readable summary of the discharge plan or transitional care plan for enrollee's care following the proposed action. Attached as part of Collective Exhibit A to this order is a sample notice that satisfies the requirements of this provision, and that shall be used by the defendants as a template for the notices they issue.

- e. The defendants shall provide annual notice to TennCare enrollees of the notice and appeal rights established by this order, including enrollees' recourse when billed by a provider for TennCare covered services.

² The parties agree that, after this order has been in effect for at least six months, the defendants may apply to the Court to shorten the period of advance notice required by this subsection from two business days to two calendar days, upon a showing that the state and its contractors have established procedures that, in the context of a shortened notice period, ensure equivalent due process protections for beneficiaries. The plaintiffs may apply to the Court to lengthen the advance notice period to 10 days, as provided by 42 C.F.R. §431.211 for reductions, terminations or suspensions of inpatient hospital care initiated by the defendants or MCCs.

Attached as part of Collective Exhibit A to this order is a sample notice that satisfies the requirements of this provision.

- f. The Tennessee Department of Children's Services (DCS) must provide notice of any delay in providing a service that is administered by DCS. Such delay is immediately appealable on the child's behalf. The defendants cannot require that the delay last a particular length of time before issuing the notice or processing an appeal.

Example: A child enters state custody and is identified as having a need for TennCare-covered therapeutic foster care for treatment of a severe emotional disturbance. DCS temporarily places the child in a standard foster home while waiting for a therapeutic foster home placement to become available. DCS must provide notice as provided in this order that the delay in providing the prescribed service is immediately appealable on the child's behalf.

Attached as part of Collective Exhibit A to this order is a sample notice that satisfies the requirements of this provision, and that shall be used by the defendants as a template for the notices they issue.

- g. The State may impose benefit limits subject to these conditions. When a claim for service or reimbursement is denied by the State or MCC because a TennCare beneficiary has reached or exceeded a benefit limit, the State or MCC must issue a notice informing the beneficiary of the basis for the denial at the time the claim is denied (which may be after the service has been denied by a provider).
 - (i) Such notice need only be provided the first time a beneficiary exceeds a particular benefit limit within a particular time period, and the State or MCC need not issue repeated notices for denial of that same benefit for the remainder of the applicable period.

- (ii) The State or MCC need not provide any notice when a TennCare beneficiary approaches or reaches a benefit limit.

Attached as part of Collective Exhibit A to this order are sample notices that satisfy the requirements of this provision, and that shall be used by the defendants as a template for the notices they issue.

- h. No adverse action affecting TennCare benefits shall be effective unless the defendants and/or others acting on their behalf have complied with the notice requirements of the federal regulations, 42 C.F.R. §431.210-214, as enhanced herein. Defendants shall not withhold, or permit others acting on their behalf to withhold, any TennCare services in violation of this requirement. As provided below, the defendant state officials shall actively monitor compliance by their contractors and, in the event of a violation, shall impose the regulatory and contractual sanctions available to the defendants to enforce compliance with the TennCare contracts and applicable law.
- i. When prior authorization for a prescribed medication is denied, the State or MCC must issue a notice informing the enrollee and his or her provider of the denial at the time of the denial although the medication may have already been denied (not dispensed) by a provider. This notice must be issued within 24 hours of receipt of a completed prior authorization request. If the day for issuance of the notice falls on a Sunday or holiday, the notice must be issued no later than by the end of the next business day. The content of the notice must conform to the requirements of 42 C.F.R. §§ 431.206-210 and Paragraph C(1)(e)(i), supra.

- j. When a new request for prior authorization of medical services other than a prescription medication is denied, the State or MCC must issue a notice informing the enrollee of the denial at the time of the denial. This notice must be issued within the time required by state regulations (but no more than 21 days from the date of the request for authorization) although the service may have already been denied (not dispensed) by a provider. The content of the notice must conform to the requirements of 42 C.F.R. §§ 431.206-210, as enhanced by Paragraph C(1), supra. If the denial of prior authorization is for services prescribed or ordered on an ongoing basis, the notice must conform to Paragraph C(2)(c), supra, and C(8), infra.

3. ***Corrective Action***

- a. If it comes to the attention of the defendants
 - (i) prior to an appeal or in the early stages of an appeal (i.e., before the issuance of a timely notice of hearing) that a TennCare covered service will be or has been delayed, denied, reduced, suspended or terminated in violation of any of the notice requirements of this order, TennCare or the MCC may cure any such deficiencies by providing one corrected notice to a TennCare beneficiary. If the beneficiary has not yet filed an appeal, the time limit permitted for the beneficiary's response will be restarted upon issuance of the corrected notice.
 - (ii) in the later stages of an appeal (i.e., after the issuance of a timely notice of hearing) that a TennCare covered service will be or has been delayed, denied, reduced, suspended or terminated in violation of any of the notice

requirements of this order, defendants shall immediately provide or require their contractor to provide the TennCare covered service at issue in the quantity and for the duration prescribed, subject to the MCC's right to reduce or terminate the service in accordance with the procedures required by this order.

- b. In the event that the beneficiary lacks a prescription for a covered TennCare service, the defendant shall:
 - (i) Immediately afford the beneficiary access, at the earliest time practicable, to a qualified provider to determine whether the service should be prescribed; and
 - (ii) Inform said provider that the service will be authorized if prescribed and found to be medically necessary. Entitlement to said service will not be controlled by the contractor's utilization review process.
- c. In the case of a delay of access to a physician to secure the requested medical assistance, the defendants shall provide such access as soon as practicable. The TennCare beneficiary shall be entitled to continue to receive such service until such time as the contractor takes those actions required by federal regulations and this order as a prerequisite to taking any adverse action affecting TennCare benefits.

4. ***Individualized decisions required.*** The defendants shall not employ, and shall not permit others acting on their behalf to employ utilization control guidelines or other quantitative coverage limits, whether explicit or *de facto*, unless supported by an individualized

determination of medical necessity based upon the needs of each TennCare beneficiary and his or her medical history.

Example: A BHO adopts a policy that routinely permits approval of only 5 therapy sessions for a given diagnosis, and that requires TennCare beneficiaries to appeal in order to receive a larger amount prescribed by their clinician. Upon appeal, the beneficiary is entitled to the full number of therapy sessions ordered by the clinician. State officials must prohibit the contractor from continuing to impose an arbitrary limit and must impose sanctions on a BHO for violating this provision.

Example: A TennCare beneficiary with a chronic illness is prescribed home health services 8 hours per day, 7 days per week, on an open-ended basis. The beneficiary's MCO approves the care for only 30 days, based upon an individualized determination that the beneficiary is unlikely to require care beyond that period. Because the decision is not the result of applying an arbitrary limit of general application, the action is not prohibited by this order. However, it does constitute an adverse action affecting benefits. The defendants or their contractor must treat the time limit on the authorization as a reduction or termination of the service, and must comply with all applicable terms of this order, including continuation of services pending appeal.

5. ***Provider-initiated reductions, suspensions or termination for certain enrollees.***

a. The defendants shall ensure that before a provider-initiated reduction, suspension or termination occurs which affects services described in subparagraph 2(d) of this section, the TennCare beneficiary receives at least two (2) business days' prior written notice as provided in that subparagraph.³

b. If, prior to the actual termination, reduction or suspension of services covered by subparagraph (2)(d), the beneficiary makes a request for continuation of those services pending appeal, the defendants shall arrange for the continuation of those services until the beneficiary is afforded access to a written second medical opinion from a qualified provider who participates in the MCC's network. Services shall continue thereafter pending appeal only if and to the extent

³ This requirement is subject to the provision contained in note 2, above.

prescribed by that provider. Provided, however, that the services at issue may be immediately reduced, terminated or suspended if medically contraindicated, as determined in accordance with subsection (C)(18) of this order.

- c. If, within 10 days of receipt of the notice required by subparagraph (C) (2)(d), but after the actual reduction, termination or suspension of services, the beneficiary requests that the services be reinstated pending appeal, the defendants shall, within two business days, afford the beneficiary access to a written second medical opinion from a qualified provider who participates in the MCC's network. The services shall be immediately reinstated pending appeal, if and to the extent prescribed by that provider.

6. ***Record on review.*** Whenever the state defendants receive an appeal from a TennCare beneficiary regarding an adverse action affecting TennCare services, the defendants shall be responsible for obtaining from their contractor any and all records or documents pertaining to the contractor's decision to take the contested action. The defendants shall be responsible for correcting any violation of this order that is evident from a review of those records. Specifically,

- a. if, during the early stages of an appeal (i.e., before the issuance of a timely notice of hearing), it appears from the contractor's records that the adverse action is based on grounds other than those cited in the notice to the TennCare beneficiary, the defendants shall require the contractor to send out a revised notice to the beneficiary citing the correct grounds for the adverse action; or
- b. if, during the later stages of an appeal (i.e., after the issuance of a timely notice of hearing), it appears from the contractor's records that the adverse action is based

on grounds other than those cited in the notice, or the corrected notice issued in compliance with this Decree, to the TennCare beneficiary, the defendants shall overrule the contractor and take such further corrective action as is reasonably necessary to ensure future compliance.

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) Where the treating provider's opinion is consistent with the defendants' or MCC's opinion or objective evidence, it shall be accorded controlling weight.
 - (ii) Where the treating provider's opinion is:
 - (A) well-supported with clinical and laboratory findings derived from an examination of the enrollee or enrollee 's medical records, and objective evidence; or
 - (B) 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 MCC's opinion or objective evidence; provided, however, that the treating provider's opinion does not significantly deviate from the defendants' or MCC's opinion or objective evidence. If the treating provider's opinion significantly deviates from the defendants' or MCC's 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:

(A) 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

(B) 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 MCC's 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),

(A) 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.

(B) 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.

- (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, 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.
8. ***Continuation or Reinstatement of TennCare benefits.***
- a. The defendants and others acting on their behalf shall ensure that, pursuant to 42 C.F.R. §§ 431.230-231 as adapted by this order, plaintiff class members receive continuation or reinstatement of services, as defined in this order, pending appeal

when they submit a timely appeal and request for such services.⁴ The defendants and others acting on their behalf are prohibited from denials of continuation or reinstatement of services to which they are entitled under this order, including but not limited to, denials resulting from:

- (i) An MCC's failure to inform beneficiaries of the availability of such continued services;
- (ii) An MCC's failure to reimburse providers for delivering services pending appeal; or
- (iii) An MCC's failure to provide such services when timely requested.

b. Defendants are not required to provide continuation or reinstatement of benefits pending appeal when:

- (i) Coverage for an item or service has been denied because the plaintiff class member has exceeded a benefit limit applicable to that service or item.
- (ii) A request for prior authorization is denied for a prescription drug with the exception of:
 - (A) The State shall comply with the 72-hour emergency supply requirements of Paragraph C(14)(c);
 - (B) When the drug has been prescribed on an ongoing basis or with unlimited refills, subject to the limitations in paragraph (C)(2)(c).
- (iii) Coverage for a service or drug is denied because the service or drug is not a category or class of drugs covered by TennCare.

⁴ The parties intend that, in order to adequately protect the due process rights of the plaintiff class members in the context of managed care, this provision adapts the protections afforded by 42 C.F.R. § 431.230-231, by modifying the provision allowing continuation of services pending appeal. *Cf.* subsections (B)(14) and (C)(5), above.

- iv. Coverage for a prescription drug is denied because the enrollee has been locked into one pharmacy and the enrollee seeks to fill a prescription at another pharmacy.

9. ***Preservation of appeal and hearing rights.*** The defendants and others acting on their behalf are enjoined to provide the plaintiff class members those appeal rights that are prescribed by 42 C.F.R. Part 431, Subpart E and T.C.A. §§ 4-5-301 et seq.

- a. The defendants shall maintain a central registry for all appeals by enrollees as described herein. The establishment of a central registry for BHO services may be delegated to the Department of Mental Health and Developmental Disabilities. The purpose of these registries is merely clerical. The appeal will be entered into a system for tracking and monitoring and will be referred to the appropriate MCC.
- b. The defendants shall ensure that written requests for appeals made at county Department of Human Services or Health Department offices shall be stamped, and immediately forwarded to the defendants for processing and entry in the central registry.
- c. The defendants may restructure or reorganize the current Appeals Unit or its successor administrative unit to facilitate the prompt, fair and efficient resolution of TennCare appeals; provided, however, that such administrative changes shall not impair compliance with this order.
 - (i) The defendants will maintain an appeal resolution process accessible through a toll-free phone number to TennCare enrollees on a 24 hour a day, 7 days a week basis to assist in the informal resolution of appeals

(however, outside of regular business hours, only resolution of emergency appeals will be available).

- (ii) The defendants shall ensure that all TennCare enrollee appeals received by them are forwarded to the administrative unit responsible for processing appeals, and that they are processed in accordance with the terms of this order. All such appeals shall be immediately logged in the central registry.
- d. The defendants shall allow an enrollee no less than 30 days from receipt of written notice (original or corrected) or, if no notice is provided, from the time the enrollee becomes aware of an adverse action, to appeal any adverse action affecting TennCare services.
- e. Subject to paragraph (C)(9)(h), enrollees shall be entitled to a hearing before an administrative law judge that affords enrollees the rights to:
 - (i) Representation at the hearing by anyone of their choice, including a lawyer;
 - (ii) Review of information and facts relied on for the decisions by the MCC and the TennCare Bureau before the hearing;
 - (iii) Cross-examine adverse witnesses;
 - (iv) Present evidence, including the right to compel attendance of witnesses at hearings;
 - (v) Review and present information from their medical records;
 - (vi) Present evidence at the hearing challenging the adverse decision by her or his MCC;

- (vii) Ask for an independent medical opinion;
 - (viii) Continue or reinstate ongoing services pending a hearing decision as specified herein; and
 - (ix) A written decision setting out the administrative judge's ruling on findings of fact and conclusions of law.
- f. But for initial reconsideration by an MCC as permitted by this order, no person who is an employee, agent or representative of an MCC may participate in deciding the outcome of a TennCare appeal. No state official may participate in deciding the outcome of a beneficiary's appeal who was directly involved in the initial determination of the action in question.
- g. Consistent with the Code of Judicial Conduct, administrative law judges shall assist *pro se* enrollees in developing the factual record; they shall have authority to order second medical opinions at no expense to the enrollee.
- h. The State may dismiss without hearing any appeal that does not raise a valid factual dispute including but not limited to any appeal of a denial of prior authorization, any appeal of a denial based upon a benefit limit, and any appeal of a denial for refusal to pay a co-pay.

10. ***Prohibitions of denial of appeal rights.*** The defendants and others acting on their behalf are prohibited from denying such appeal rights on any grounds whatsoever, including, but not limited to, the following:

- a. Failing or refusing to accept as a request for appeal either of the following oral communications:

- (i) Oral requests by the beneficiary, or on his behalf, for information about appeal rights. Upon receipt of such a request, the defendants shall elicit from the beneficiary information as to whether he is dissatisfied and wishes to have his inquiry treated as an appeal.
 - (ii) Oral or written expressions by the beneficiary, or on his behalf, of dissatisfaction or disagreement with an adverse action that has been taken or is proposed.
- b. Refusing to provide an appeal because the beneficiary lacks an order or prescription from a provider supporting the appeal; provided however, that the State may create an administrative grievance or other informal process to address appeals by enrollees without an order or prescription, including but not limited to network access requests, and may require an enrollee to exhaust that administrative grievance or informal process, during which time the appeal timelines will be tolled, before the enrollee's appeal can go forward. If Defendants elect to create such an administrative grievance or informal process, it must be completed with reasonable promptness or the time limitations in Paragraph C(9) shall restart.
- c. Refusing to provide an appeal because the defendants or others acting on their behalf have agreed to cover a prescribed service in an amount that is less than the amount or duration sought by the beneficiary.
- d. Refusing to provide an appeal because the defendants or others acting on their behalf have agreed to provide a covered service that is different from that sought by the beneficiary.

Example. A beneficiary seeks residential mental health treatment in a particular facility, because it offers treatment for his particular disorder. The BHO offers residential treatment, but in another facility that the beneficiary believes cannot

adequately treat his condition. The beneficiary is entitled to appeal the BHO's action.

- e. Refusing to provide an appeal because the beneficiary seeks to contest a delay or denial of care resulting from the MCC's failure or refusal to make a needed service available, due to the inadequacy of the contractor's provider network.
- f. Refusing to provide an appeal because the class member seeks to contest a denial of his right under the TennCare waiver to choose his own primary care provider (PCP) from among a panel offered by the MCO, or seeks to contest a delay or denial of care resulting from the involuntary assignment of a PCP.
- g. Refusing to provide an appeal because the class member seeks to contest or change his assignment to a particular MCO or BHO.
- h. Refusing to provide an appeal because the class member seeks to contest denial of TennCare coverage for services already received, regardless of the cost or value of the services at issue.
- i. Refusing in-person hearings, failing to inform beneficiaries that they have the right to such hearings, or implying that they must agree to the conduct of hearings by phone conference.
- j. Refusing to provide an appeal because the class member seeks to contest a decision of the TennCare Partners program granting or withholding designation as severely and persistently mentally ill (SPMI) or severely emotionally disabled (SED).
- k. Prohibiting or discouraging, either directly or through a contractor or subcontractor, any individual from testifying for the enrollee. This prohibition shall not prevent the defendant state officials from asserting any privilege or exercising any rights available to them under the Uniform Administrative Procedures Act. This prohibition shall also not

prevent the defendant state officials from interviewing witnesses prior to any testimony or otherwise undertaking normal pre-testimony preparation.

- I. Refusing to provide an appeal because a provider:
 - (i) Fails or refuses to request prior authorization;
 - (ii) Refuses to render services because an enrollee has reached a benefit limit; or,
 - (iii) Refuses to render services because an enrollee fails to make a co-payment.

Provided, however, that the State may create an administrative grievance or other informal process to address appeals lacking a request for prior authorization pursuant to Paragraph C(14)(f).

These provisions do not affect the right of the defendants to deny or dismiss a request for a hearing under the circumstances specified in 42 C.F.R. § 431.223.

11. ***Parties to appeals limited to those permitted by federal regulation.*** The parties to a hearing before an ALJ under this order are limited to those permitted by federal regulations. The purpose of the hearing is to focus on the beneficiary's medical needs. The defendant state officials shall not permit their contractors to intervene or participate as parties in a TennCare beneficiary's hearing; provided, however, that nothing shall prevent MCC employees from participating as witnesses in ALJ hearings. Nothing in this provision bars participation by an MCC in any informal resolution phase of the appeal process prior to a hearing before the ALJ.

12. ***Impartiality of appeal process.*** The defendants shall not compromise the impartiality and integrity of the appeal process by:

- a. Impairing, or threatening to impair, the independence or autonomy of individuals charged with handling or deciding appeals, in order to influence the outcome of appeals;

- b. Refusing to enforce, or by aiding MCCs in refusing to comply with, decisions in favor of beneficiaries;
- c. Requiring that beneficiaries bear the expense of purchasing hearing transcripts;
- d. Encouraging or demanding the waiver of any rights protected by this order, or by discouraging beneficiaries from exercising any such right;

Example: A beneficiary receives a notice of hearing on her appeal, and requests a continuance in order to have additional time to retain counsel and prepare her case. The defendants must not condition, or argue to the ALJ that he should condition, the continuance upon a complete waiver of the time requirements imposed by this order. (However, any delay fairly attributable to the requested continuance may be considered in calculating compliance with such requirements, as provided in subsection C(16)(f), below.)

- e. Subject to subparagraph (C)(9)(h), the provisions of subparagraph (C)(10)(b), and subparagraph (C)(12)(f) and (C)(13), taking from the impartial decisionmaker the authority to decide some or all aspects of a beneficiary's appeal.

Example: A beneficiary appeals an MCO's denial of coverage. The MCO has determined that the services at issue are not covered by the TennCare contract. The beneficiary alleges the services are medically necessary and that beneficiary qualifies in an eligibility category for which the service is a covered benefit (i.e., under age 21). The impartial decisionmaker must decide both issues. The defendants may not assign the medical necessity issue to the impartial decisionmaker but remove the contract coverage issue for decision by another agency or person.

- f. Defendants may refuse to consider as a ground for appeal of a service denial challenges to an enrollee's eligibility category that an enrollee had the opportunity to raise previously unless the enrollee can show excusable neglect for not previously raising the eligibility category.

Example: An enrollee appeals an MCO's denial of coverage. The MCO has determined that the services at issue are not covered for the enrollee's eligibility category (i.e., the service is not offered for enrollees over 21). The enrollee was provided notice and opportunity to appeal her current eligibility category (over 21) but did not do so. Now on appeal, enrollee alleges she is under 21 and presents proof demonstrating excusable neglect, which prevented her from

challenging her eligibility category earlier (i.e, the enrollee had a serious illness or injury). The correct eligibility category is a proper ground for appeal.

- g. In the case of an administrative law judge, engaging in *ex parte* communications regarding the merits of beneficiary appeals with individuals responsible for processing or deciding such appeals;
- h. Failing to train personnel who are responsible for the appeal process regarding their obligations, and beneficiaries' rights, under this order;
- i. Otherwise attempting to influence the outcome of the appeal process; provided, however, that the TennCare Bureau may participate as a defendant or respondent in beneficiary appeals before administrative law judges, and in subsequent judicial review proceedings, and may review, modify, or overturn ALJ decisions in taking final agency action on an appeal.

13. ***When the beneficiary prevails.*** Defendants are permitted to seek final agency review by the TennCare Commissioner or his designee in any appeal in which the enrollee prevails by a decision of an administrative law judge (ALJ) who is not an employee or official of the Department of Finance and Administration or Bureau of TennCare. Provided however, that if the enrollee prevails at any stage of the appeal process and defendants seek final agency review, defendants may not await the conclusion of this review before providing prompt corrective action as defined by Paragraph C(16)(c), *infra*, and in accordance with 42 C.F.R. §431.246. Further, an ALJ's decision in an enrollee's appeal shall not be deemed precedent for future appeals. The defendants may also enact emergency rules or public necessity rules in accordance with the state Administrative Procedures Act.

14. *Special provisions relating to pharmacy services.*

- a. Defendants may require prior authorization by the TennCare Bureau as a condition of coverage for any drug or drug class so designated by defendants and shall have the authority to make all final decisions concerning the content of the preferred drug list (PDL) and the designation of drugs available to enrollees as covered services without prior authorization.
- b. When prior authorization is required and the drug is otherwise covered (e.g., drug is not a DESI, LTE, or IRS drug, drug is not in a non-covered TennCare therapeutic class, drug is not an over-the-counter medication, drug is not in excess of benefit limits), and when a provider with prescribing authority, as defined in paragraph B (17), prescribes a medication for a beneficiary, and the prescription is presented at a pharmacy that participates in the TennCare program, the beneficiary's rights are as follows:
 - (i) To receive the drug as prescribed, if the drug is on the TennCare PDL and prior authorization is either unnecessary or, if required, has been obtained;
or
 - (ii) To receive the drug as prescribed, if the prescribing provider has obtained prior authorization or established the medical necessity of the medication;
or
 - (iii) To receive an alternative medication on the TennCare PDL, if the pharmacist consults the prescribing provider when the beneficiary presents the prescription to be filled, and the provider prescribes the substituted drug, or

- (iv) To receive notice that the prescribed drug requires prior authorization, which has not been obtained. This written notice shall advise the enrollee of how he and his provider can seek prior authorization. Subject only to the emergency supply provisions in paragraph 14(c) below, no drug shall be dispensed for which prior authorization is required but has not been obtained.
- c. When an enrollee presents a prescription for which prior authorization is required but has not been obtained and in the judgment of the dispensing pharmacist there exists an immediate threat of severe adverse consequences to the enrollee if the drug as prescribed is not dispensed, the dispensing pharmacist shall dispense an emergency 72-hour supply of the prescribed medication. In no event, however, shall an enrollee be provided an emergency 72-hour supply if the prescription is denied for one of the following reasons:
- (i) The medication is classified by the FDA as less than effective (i.e., a DESI, LTE, or IRS drug); or
 - (ii) The medication is a non-covered drug for adults (e.g., 1) drugs in a non-covered TennCare therapeutic class — e.g., appetite suppressants, drugs to treat infertility, etc; 2) a drug in excess of benefit limits; or 3) an over-the-counter drug); or
 - (iii) Use of medication has been determined, in accordance with subsection (C)(18) of this order, to be medically contraindicated because of the patient's medical condition or possible adverse drug interaction.
- d. In some circumstances it is not feasible for the pharmacist to dispense an emergency 72-hour supply because the drug is packaged by the manufacturer to be sold as the original unit or because the usual and customary pharmacy practice would be to dispense the drug in the original packaging. Examples would include, but not limited to, inhalers, eye drops, ear drops, injections, topicals (creams, ointments, sprays), and drugs packaged in special dispensers (birth

control pills, steroid dose packs), and drugs that require reconstitution before dispensing (antibiotic powder for oral suspension). When coverage of an emergency 72-hour supply of a prescription would otherwise be required and when, as described above, it is not feasible for the pharmacist to dispense an emergency 72-hour supply, it shall be the responsibility of TennCare to provide coverage for either the emergency 72-hour supply or the usual dispensing amount, whichever is greater.

- e. The state must reimburse a pharmacist who dispenses a 72-hour supply of a non-authorized medication during an emergency situation as determined by the pharmacist.
- f. An enrollee may file an appeal where no prior authorization has been sought for a drug requiring such authorization (and therefore no prior authorization request has been denied). The state may establish an administrative grievance or informal process to address appeals by enrollees with a prescription that lacks the requisite prior authorization. The state may require an enrollee to exhaust this administrative grievance or informal process before the enrollee is notified of his right to appeal and before the enrollee may appeal, provided however, that the state completes the administrative process with reasonable promptness. The administrative process may include, but is not limited to:
 - (i) Performing the prior authorization analysis prior to processing the appeal, consistent with subparagraph (ii) of the Revised Order (Doc. 1256);
 - (ii) Requiring the enrollee to request his or her treating clinician to obtain prior authorization;

- (iii) Assisting the enrollee in obtaining access to a clinician who can obtain the required prior authorization in the event an enrollee is unable to reach his or her treating physician or does not have access to a clinician; or
 - (iv) Assisting the enrollee in any other manner to obtain the required prior authorization.
- g. Upon receiving an enrollee's request for reimbursement for a drug for which prior authorization is required but has not been obtained, the state must conduct the same prior authorization process or analysis it would have conducted prior to the dispensing of the drug. In the event prior authorization would have been granted, the enrollee shall be reimbursed. In the event the prior authorization would have been denied, the enrollee's request for reimbursement shall be denied, at which point the enrollee may appeal the state's decision to deny authorization of the drug.
- h. If prior authorization for a drug is denied, the defendants or their contractors shall provide written notice to the enrollee of his or her appeal rights as required by subparagraph C(1)(e) and C(2)(i) of this decree.

15. ***Special provisions relating to children in state custody.*** The defendants shall afford children in state custody the rights and protections established by 42 C.F.R. Part 431, Subpart E and the terms of this order. These children shall also receive the following enhanced protections:

- a. As provided in the implementation plan referred to in subparagraph (e), below, whenever there is an adverse action affecting TennCare services (regardless of

which contractor or government agency is administering such services), timely notices required by this order are to be sent to the individuals specified in the implementation plan. In the case of services administered by MCCs other than DCS, the responsible MCC shall provide notice to DCS, which shall ensure that timely notice is provided to the individuals listed herein. Delivery of notice triggering the right to appeal is not complete until notice is received by those individuals.

- b. The defendants shall accept an appeal from any individual listed above as an appeal on behalf of the child;
- c. The defendants shall maintain a contract with an entity that is mutually acceptable to the parties, to assist children in exercising the rights created by this order.
- d. The defendants shall maintain a contract for the provision of free legal representation for such children, as necessary to enable them to effectively exercise their appeal rights under this order.
- e. On January 5, 2000, the state defendants submitted a plan and implementation timetable governing compliance with this order as it affects children in state custody. The Court has approved that plan by order entered on January 14, 2000. (Doc. 539)
- f. Any plaintiff class member who is residing in a Youth Development Center (YDC) operated by the Tennessee Department of Children's Services may pursue an appeal governed by the provisions of this order only in the following circumstances, and in such circumstances her presence in the YDC shall not moot the appeal or impair her entitlement to corrective action under 42 C.F.R. §

431.246; provided, however, that an enrollee may not use the appeal process governed by this order to challenge her placement in the YDC, or to compel her discharge from the YDC:

- (i) The child was receiving services prior to entering the YDC and the MCC denied coverage. The appeal involves a question of reimbursement for services provided prior to the child's institutionalization, at a time when the child was still TennCare-eligible.
- (ii) The child will be TennCare eligible upon discharge. He seeks medically necessary TennCare services in the future, when he is no longer in the YDC but is unable to confirm upon inquiry on behalf of the child that those services will be available. If he is within 45 days of discharge from the YDC, or can show that, but for the unavailability of the services at issue, he would be within 45 days of discharge from the YDC, he may pursue an appeal to obtain those services upon discharge, and such an appeal shall be deemed to be an appeal of a denial or delay of services. In such circumstances, he need not first be discharged from the YDC in order to invoke his appeal rights.
- (iii) The child was eligible for TennCare services prior to entering the YDC but did not receive them as a result of an adverse action by the defendants or their contractors. He still needs the services and is not receiving the service in the YDC. He may seek through the appeal process an administrative directive instructing TennCare or the MCC to provide the service now. This relief is available as corrective action, available under

42 C.F.R. §§ 431.246 and 431.250(b), to remedy the failure to provide needed service in a timely fashion before he was institutionalized. DCS will have the opportunity to respond during the appeal process regarding the enrollee's need for the appealed services and whether the enrollee is receiving said services in the YDC, regardless of which MCC or contractor should have originally provided the service which resulted in the appeal.

With regard to appeals under subparagraph (ii) or (iii), above, TennCare will be responsible for ensuring that the YDC superintendent and the enrollee's attorney at the YDC receive notice of the enrollee's appeal and of any directive issued as a result of the appeal. Children appealing under this paragraph shall be entitled to representation pursuant to Paragraph (d) and the order of January 14, 2000 (Doc. 539). Except to the extent set out in this subparagraph, nothing in this subparagraph shall be construed as extending the availability of the appeal process under this order to individuals who are not eligible for, and enrolled in, Tennessee's medical assistance program, as defined in paragraph B(4), at page 3.

16. ***Timely prior approval and resolution of appeals.***

- a. Subject to the provisions of subparagraph (h) and (i) below, the failure of an MCC to act upon a request for prior approval within the time established by state regulations or within 21 days, whichever is greater, shall result in automatic authorization of the requested service.
- b. Managed care contractors shall make good faith efforts to complete reconsideration of beneficiary appeals within 14 days of notification by the

defendants in the case of a standard appeal, or within 5 days in the case of expedited appeals involving time-sensitive care. However, in the case of expedited appeals, when it is necessary for the MCC to have additional time to obtain medical records, the MCC may have up to 14 days from notification by defendants to complete their reconsideration review and the timeline for processing an expedited appeal may be increased to a total of 45 days. If a MCC fails to complete reconsideration of an appeal within the time required under this subparagraph, defendants may remedy the missed deadline, but in no event can a remedy of a missed deadline cause an expedited appeal to take longer than 45 days, as specified by this subparagraph, or a standard appeal to take longer than 90 days, as specified by 42 C.F.R. § 431.244(f). If a missed deadline causes a violation of the 45 or 90 day deadline, whichever is applicable, the defendants shall immediately resolve the appeal in favor of the beneficiary, subject to the provisions of subparagraphs (g), (h) and (i) infra.

c. Except as provided herein, the defendants shall ensure that, within five (5) days of a decision in favor of the enrollee at any stage of the appeal process, the MCC completes the corrective action to implement the decision, as described in subsection (d) below. The defendants may extend the five (5) day deadline for implementation under the following circumstances:

(i) The TennCare Bureau makes a written finding within the five (5) day period that good cause exists for extending the deadline to a date certain, not to exceed an additional period of 10 (ten) days. The TennCare Bureau may extend the deadline beyond the initial ten-day extension, but any such

extensions must be approved by the TennCare Director and justified in writing.

- (ii) For purposes of this section “good cause” is limited to circumstances that are beyond the control of the defendants or the MCC and that have been shown, based on documented, diligent efforts to implement the favorable decision, to prevent its timely implementation. Good cause does not include inability to timely provide necessary services due to the lack of an adequate provider network or refusal to pay for the services at issue.
 - (iii) Failure to meet the five (5) day deadline or, in cases of good cause, an alternative deadline established in accordance with this subsection, shall give rise to sanctions under Paragraph C(21).
 - (iv) The state defendants shall include in the monthly reports required by Paragraph D(3) copies of all good cause extensions granted under this paragraph and, upon request, any supporting documentation upon which such extensions relied.
- d. For purposes of meeting the preceding time limit for corrective action, the defendants shall ensure that, whenever an appeal is resolved in favor of the beneficiary:
- (i) The beneficiary actually receives the service at issue, or accepts and receives alternative services; or
 - (ii) If the beneficiary has already received the service at her own cost, the beneficiary has been reimbursed for her cost; or

- (iii) If the beneficiary has already received the service, but has not paid the provider, the defendants have ensured that the beneficiary is not billed for the service and ensured that the beneficiary's care is not jeopardized by non-payment.
- e. An appeal is not resolved by a decision adverse to the beneficiary until notice of the decision has been mailed to the beneficiary.
- f. The defendants shall ensure that all standard appeals, including, if not previously resolved in favor of the enrollee, a hearing with an ALJ, are resolved within 90 calendar days of the defendants' receipt of the enrollee's request for an appeal. In cases involving time-sensitive care, as defined in Paragraph B(16), the defendants shall ensure that expedited appeals, including, if not previously resolved in favor of an enrollee, a hearing before an ALJ, are resolved within 31 calendar days (extended to 45 calendar days when necessary to allow sufficient time to obtain the enrollee's medical records) of the defendants' receipt of the request for an appeal. Calculation of the deadline may be adjusted so that the defendants are not charged with any delays attributable to the beneficiary. However, no delay may be attributed to a beneficiary's request for a continuance of the hearing, if she received less than three week's notice of the hearing in the case of a standard appeal, or less than one week's notice in the case of an expedited appeal. A beneficiary may only be charged with the amount of delay occasioned by her acts or omissions, and any other delays shall be deemed to be the responsibility of the defendants.

Example: A beneficiary receives one week's notice of his expedited appeal hearing but requests an additional week to obtain counsel and prepare his case. The hearing is continued a month. Only one week of the delay is attributable to the beneficiary.

- g. Failure to meet the 90 day or 31 day (extended to 45 calendar days when necessary to allow sufficient time to obtain the enrollee's medical records) deadline, as applicable, shall result in automatic TennCare coverage of the services at issue pending a decision by the ALJ and/or review by the TennCare Commissioner or his designee that overturns or modifies the ALJ's decision, subject to the provisions of section (C)(18) relating to medical contraindication and subject to the provisions of subparagraphs (h) and (i) below. This conditional authorization will neither moot the pending appeal nor be evidence of the enrollee's satisfaction of the criteria for disposing of the case, but is simply a compliance mechanism for disposing of appeals within the time frames established by this order. In the event that the appeal is ultimately decided against the beneficiary, she shall not be liable for the cost of services provided past the deadline for resolution of the appeal.
- h. When, under the provisions of the subparagraph above, a failure to comply with the timeliness provisions of this order would require the immediate provision of a disputed service, the defendants may, upon written notification of plaintiffs' counsel, decline to provide the service pending a contrary order on appeal, based upon a determination that the disputed service is not a TennCare-covered service. A determination that a disputed service is not a TennCare-covered service may only be made with regard to a service that:

- (i) is subject to an exclusion that has been reviewed and approved by the federal Centers for Medicare and Medicaid Services and incorporated into a properly promulgated state regulation: OR
- (ii) which, under Title XIX of the Social Security Act, is never federally reimbursable in any Medicaid program

Such a determination may not be based upon a finding that the service is not medically necessary.

- i. In the event that the beneficiary lacks a prescription for a covered TennCare service, the defendant shall:
 - (i) Immediately afford the beneficiary access, at the earliest time practicable, to a qualified provider to determine whether the service should be prescribed; and
 - (ii) Inform said provider that the service will be authorized if prescribed and found to be medically necessary.

Entitlement to said service will not be controlled by the contractor's utilization review process.

17. ***Specific prohibitions pertaining to timely decision.*** The defendants are prohibited from denying members of plaintiff class timely resolution of their appeals for any reason or by any means. Delays which shall be deemed a violation of this prohibition specifically include, but are not limited to, those which result from:

- a. Affording the defendants' contractors an automatic period of 30 days from a decision favorable to the enrollee within which to cover the ordered services;

- b. Requiring enrollees who request a hearing before an administrative law judge to waive the 90 day or 31 day (unless extended to 45 days when necessary to obtain enrollee's medical records) deadline, as applicable, altogether as a condition of obtaining an opportunity to prepare for the hearing;
- c. Treating cases which involve denials coverage for services already received (sometimes referred to as "reimbursement appeals" and involving cases in which an enrollee has paid for services out of pocket or is being billed for services) as exempt from the 90-day time frame;
- d. Failing to inform enrollees of their right to receive disputed services, as provided in this order pending a decision on their appeal, when such appeals have not been decided by the ninetieth day following receipt of the request for a standard appeal, or thirty-first day (extended to the 45th day when necessary to obtain enrollee's medical records) in the case of an expedited appeal.

18. ***Medical contraindication.*** Whenever the terms of this order require the provision of TennCare benefits to an enrollee, the defendants and their contractors shall be relieved of such obligation upon compliance with this section. The defendants must provide the written certification of an appropriately licensed provider who is familiar with the beneficiary's medical condition. The provider must either be employed by the state or, if a licensed pharmacist determining contraindication with regard to a prescribed drug, must be making such determination consistent with pre-established standards and procedures approved by the state. The certification must document that the service in question is medically contraindicated, making it necessary to withhold the service in order to safeguard the health or safety of the beneficiary. In such cases, the defendants must immediately:

- a. Provide written notice to the beneficiary, and the notice must be accompanied by the provider's certification that the services must be withheld in order to protect the beneficiary's health or safety; and
- b. Forward a copy of the beneficiary notice and provider certification to counsel for the plaintiff class. In the case of pharmacist's determinations of contraindication, the defendants shall forward to plaintiffs' counsel monthly drug utilization review reports from the MCCs or their PBM subcontractors, documenting the application of the contraindication provision during the preceding month.

Attached as part of Collective Exhibit A to this order is a sample notice that satisfies the requirements of this provision, and that shall be used by the defendants as a template for the notices they issue.

19. ***Accommodation of persons with disabilities.*** The defendants and others acting on their behalf shall provide reasonable accommodation to class members with disabilities who require assistance in order to exercise the rights afforded by this order, including the right to appropriate notice. The defendants shall not reduce or terminate current contractual arrangements with private entities that assist TennCare beneficiaries through the appeal process without agreement of the plaintiffs or prior approval of the Court, based upon a showing that such changes will not impair access to the appeal process for people with disabilities.

20. ***Training and public notice requirements.***

- a. Within sixty days of the entry of this order or by October 15, 2006, whichever is later, the defendant state officials shall issue appropriate notices to their contractors, to TennCare providers and to TennCare beneficiaries informing them of the rights and responsibilities established by this order.

- b. The defendant state officials shall implement a training program for state personnel and MCCs to ensure that individuals whose job responsibilities are affected by this order are promptly informed of the order's terms. The defendants shall ensure that responsible state and MCC staff receive training as needed on an ongoing basis to maintain their awareness of, and compliance with, the terms of this order.
- c. The defendants shall ensure that notices of the right to appeal adverse decisions affecting services are conspicuously displayed in public areas of all providers participating in each MCC, of MCC facilities, of county health departments, and of county Department of Human Services offices.

21. ***Defendant's enforcement responsibilities.*** The defendant state officials shall promptly and faithfully enforce against their contractors any appeal decision rendered in favor of a beneficiary.

- a. If the beneficiary went without coverage of the disputed services while the appeal was pending:
 - (i) The defendants shall promptly reimburse the beneficiary for any costs incurred for obtaining the services at the beneficiary's expense; and
 - (ii) As to the MCC which wrongfully withheld the services, the defendants shall assess an amount sufficient to at least offset any savings the contractor achieved by withholding the services.
- b. The defendant state officials shall analyze beneficiary appeals and monitor MCC appeal procedures on an ongoing basis for the purpose of identifying patterns that reflect systemic problems or violations of the law. The defendants shall take

prompt corrective action, including the imposition of sanctions, when such patterns are identified. For purposes of this requirement, a systemic violation by an MCC includes, but is not limited to, a failure in 20% or more of appealed cases over a 60-day period to satisfy all the notice requirements imposed by this order.

- c. Without regard to whether a single violation is part of a systemic pattern of noncompliance and punishable as such, the defendants must impose individual sanctions on their contractor for each instance known to them in which the contractor violates this order by:
- (i) Failing to provide written notice of adverse action to a beneficiary as required by this order;
 - (ii) Failing to forward a beneficiary's appeal to the defendants;
 - (iii) Failing to provide continuation or restoration of services pending appeal when requested to do so;
 - (iv) Failing to take timely corrective action to implement an appeal decision in a beneficiary's favor.

For each violation occurring after September 15, 2000, the defendants shall impose a liquidated penalty of no less than \$250. For each such violation occurring after October 15, 2000, the defendants shall impose a liquidated penalty of no less than \$500. In addition to such liquidated penalty, the defendants shall levy a monetary sanction in an amount sufficient to at least offset any savings the contractor achieved by withholding the service at issue.

- d. The defendants shall provide plaintiffs' counsel on at least a monthly basis and at plaintiff counsel's request a copy of all decisions rendered by the appeals process

that reflect a reversal of a decision involving a state agency that is acting as an MCC and all directives issued by the TennCare Bureau to a state agency acting as an MCC during the preceding month.

D. Monitoring, Reports and Disclosures

1. The defendants shall continue to have primary responsibility for monitoring and enforcing compliance with this order and the regulations and laws incorporated herein. The defendants shall test compliance with this decree on an ongoing basis. In addition, the defendants shall test compliance with this decree on an ongoing basis. In addition, the defendants will enter into an agreement with the Tennessee Comptroller of the Treasury to monitor all aspects of compliance with this order, by any state agency or contractor subject to its terms. Under that agreement, the Comptroller is to have access to any and all records, documents or personnel needed to ascertain compliance, and shall employ all methods normally used to audit and evaluate compliance with financial and legal standards.

2. The Comptroller will submit quarterly reports to the defendants, who shall immediately file copies of the same with the court and provide copies thereof to counsel for the other parties to this case. The quarterly reports shall report on compliance with the terms of this order. The reports will address specifically, but not exclusively, the following areas:

- a. Compliance with notice and appeal procedures when the defendants or others acting on their behalf propose to take any adverse action affecting inpatient or residential behavioral health services.
- b. Compliance with requirements that provide special notice and appeal protections for children in state custody.

- c. The consistency and rigor of the defendant state officials' actions to enforce the terms of this order against their contractors.
 - d. The extent to which the defendant state officials are analyzing data to identify patterns of contractor non-compliance with federal or state requirements and taking appropriate action to correct systemic violations or other problems adversely affecting beneficiary care.
 - e. Compliance with the special provisions pertaining to pharmacy services.
 - f. The adequacy of beneficiary notices provided by state officials and their contractors.
 - g. Compliance with requirements for the public posting of notices informing beneficiaries of the rights and provisions incorporated in this order.
3. The defendants shall promptly provide to plaintiff's counsel copies of all reports which they generate or receive pertaining to the TennCare appeal process or to compliance with any aspect of this order. These reports shall include, but are not limited to, monthly reports compiled from the appeal central registry indicating
- a. The number of appeals by MCC, the type of care;
 - b. The number of days for resolution of the appeal;
 - c. Type of resolution (i.e., reversal or affirmance after reassessment by MCO or BHO; reversal or affirmance after review by TennCare or TennCare Partners; reversal or affirmance after hearing);
 - d. The amount of sanction imposed in each case where the MCC's action is reversed after review by TennCare or TennCare Partners, or after hearing; and
 - e. Listing sanctions actually collected during the month.

4. The defendants shall provide plaintiff's counsel, at least 30 days prior to their adoption and dissemination, copies of all sample beneficiary communications including form notices required under this order, policy memoranda, training materials, Comptroller's audit tools and protocol, proposed and final rules, or proposed waiver revisions or clarifications affecting any aspect of compliance with this order. The defendants shall promptly provide the plaintiffs' counsel copies of correspondence relating to the imposition of sanctions on an MCC for any systemic violation of this order. The defendants shall provide the plaintiffs copies of any proposed contract amendments affecting compliance with, or implementation of this order, at least ten days in advance of the execution of said amendments.

5. Upon ten (10) days prior written notice, the defendant state officials shall provide plaintiffs' counsel access to any documents or records under their control, or under the control of their contractors, which plaintiffs' counsel request to inspect for purposes of monitoring compliance with this order. The defendants shall not assert any privilege, other than attorney-client privilege, with regard to any document or other evidence requested by plaintiffs' counsel and pertaining to any matters covered by this order. Plaintiffs' counsel shall maintain the confidentiality of class members' TennCare and medical records. Any proprietary information shall be subject to a protective order, which the parties shall draft and submit to the Court.

6. The State defendants shall ensure that their counsel and medical consultants who participate in any phase of the appeal process governed by this decree acknowledge in writing their receipt of copies of this decree prior to their assumption of any responsibilities that could affect any aspect of the defendants' compliance.

7. Plaintiff's counsel shall be allowed to inspect the operation of any state agency that is involved in the implementation of this decree and of any contractor or subcontractor of the

State defendants with a responsibility under subparagraph (C)(15)(c)-(e) to advocate for or represent members of the plaintiff class in asserting the rights and implementing the protections established in this decree. To conduct such an inspection, plaintiffs' counsel must submit a written request to the Office of General Counsel of the TennCare Bureau (and send a contemporaneous copy to the General Counsel of the affected agency), which then shall schedule a mutually convenient date and time for the inspection within ten (10) business days of receiving the request. In conducting such inspections, the plaintiffs' counsel may, as reasonably necessary to monitor the defendants' compliance, inspect and request copies of documents, and examine electronic records in a hard copy form. Such requests and inspections must be conducted in such a manner as not to interfere unreasonably in the normal operation of the office being inspected. Plaintiffs' counsel may ask questions of defendant state's employees during such inspections, but any oral statements made shall not be admissible as evidence in any judicial or administrative proceeding. The plaintiffs' right to inspect documents and records in the course of such inspections is in addition to, and independent of, their right of inspection afforded by preceding paragraphs of this decree. Examination of documents or records in the course of an inspection authorized by this paragraph need not be preceded by advance notice identifying the documents to be examined. Nothing in this paragraph shall be construed to alter the scope of the plaintiffs' access to confidential documents accorded them under the other provisions of this decree. The right of inspection established by this paragraph shall be limited to those operations relevant to the implementation of this decree, and the use of any information obtained by the plaintiffs in the course of such inspection shall be strictly limited to monitoring and enforcement of the provisions of this decree. Nothing in this paragraph shall be construed to confer any rights to plaintiffs to inspect the operation of any MCO or BHO, nor shall it either limit or enhance any

rights the plaintiffs may have to inspect or otherwise obtain information from an MCO or BHO under any paragraph of this decree or any other legal authority.

E. Attorneys' Fees

Pursuant to the Court's Memorandum Order (Docket entry 1342), the plaintiffs are partially prevailing parties for purposes of their entitlement to an award of attorneys' fees under 42 U.S.C. § 1988 for legal services rendered by their counsel in connection with monitoring implementation and enforcement of the 2003 Consent Decree, and proceedings related to the defendants' motion to modify and/or clarify the 2003 Consent Decree (Doc. No. 908).

F. Effective Date

Except as otherwise explicitly provided herein, the provisions of this order which have not already taken effect under the terms of previous orders shall take effect within 30 days of entry of this order, except that Paragraph (C)(1)(e) shall take effect no later than six months after entry of this order.

G. Class Action Provisions

Upon entry of the Revised Consent Decree Governing TennCare Appeals, the Court pursuant to Rule 23, subdivisions (c) – (e), of the Federal Rules of Civil Procedure, amended the definition of the plaintiff class here in by revising the definition of the plaintiff class to prospectively include all present and future enrollees in the TennCare program. The class thus redefined shall be bound by the terms of this order. The Court determines that the notice provisions set for above are sufficient to fairly notify class members of the terms of this order.

H. Exclusions and Reservations

1. As they take effect, the provisions of this order shall supersede those provisions of all previous orders which address procedural due process for beneficiaries when medical assistance is delayed, reduced, suspended or terminated.

2. This order shall not affect the right of any individual class member to seek any and all relief that is otherwise available through administrative review proceedings against the state before the Tennessee Claims Commission based upon alleged actions or omissions of the state defendants, or through litigation authorized by other state or federal law. It is intended to adjudicate with respect to the class and its individual members only those claims for relief which were made on their behalf in the 1999 motion for contempt, and to thus bar further proceedings by class members seeking the same relief under 42 U.S.C. § 1983. The parties acknowledge the state may assert any and all defenses available in any such administrative, Claims Commission or other litigation.

3. The plaintiffs will not initiate contempt proceedings to enforce the terms of this order without having first made a good faith effort to apprise the defendants of any concerns regarding noncompliance.

IT IS SO ORDERED.


JOHN T. NIXON, SENIOR JUDGE
UNITED STATES DISTRICT COURT