Tennessee Department of Finance and Administration

Bureau of TennCare

Chapter 1200-13-13
TennCare Medicaid

Statement of Necessity Requiring Public Necessity Rules

I am herewith submitting amendments to the rules of the Tennessee Department of Finance and Administration, Bureau of TennCare, for promulgation pursuant to the public necessity provisions of the Uniform Administrative Procedures Act, T.C.A. § 4-5-209 and the Medical Assistance Act, T.C.A. § 71-5-134.

On August 3, August 9 and November 15, 2005, a federal district court issued Orders and an Opinion in which the Court approved modifications of certain provisions of the *Grier Consent Decree*. The *Grier Consent Decree* imposes obligations upon the Bureau of TennCare with respect to providing due process rights to individuals enrolled in the TennCare program, a managed care program for both the Medicaid and expansion population.

On November 14, 2005, the Bureau of TennCare received federal approval for certain amendments to pharmacy benefits covered under the TennCare Demonstration Project (No. 11-W-0015 1/4). The federal government approved these changes to the coverage of pharmacy benefits through an amendment to Tennessee's State Plan.

Tennessee Code Annotated, Section 4-5-209, provides that a state agency is authorized to promulgate public necessity rules when the modifications to the rules are required by a court order. Tennessee Code Annotated, Section 71-5-134, states that in order to comply with or to implement the provisions of any federal waiver or state plan amendment obtained pursuant to the Medical Assistance Act as amended by Acts 1993, the Commissioner of Finance and Administration is authorized to promulgate public necessity rules pursuant to Tennessee Code Annotated, Section 4-5-209.

I have made a finding that these amendments are required to conform the current TennCare Medicaid rules to reflect changes resulting from court orders and a state plan amendment.

For a copy of this public necessity rule, contact George Woods at the Bureau of TennCare by mail at 310 Great Circle Road, Nashville, Tennessee 37243 or by telephone at (615) 507-6446.

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J. D. Hickey
Deputy Commissioner
Tennessee Department of Finance
and Administration

Public Necessity Rules
of
Tennessee Department of Finance and Administration

Bureau of TennCare

Chapter 1200-13-13
TennCare Medicaid

Amendments

Paragraph (18) of rule 1200-13-13-.01 Definitions is deleted in its entirety and replaced with a new paragraph (18) which shall read as follows:

(18) CONTINUATION OR REINSTATEMENT shall mean that the following services or benefits are subject to continuation or reinstatement pursuant to an appeal of an adverse decision affecting a TennCare service(s) or benefit(s), unless the services or benefits are otherwise exempt from this requirement as described in rule 1200-13-13-.11, if the enrollee appeals within ten (10) days of the date of the notice of action or prior to the date of the adverse action, whichever is later.

(a) For services on appeal under *Grier Revised Consent Decree*:

1. Those services currently or in the case of reinstatement, most recently provided to an enrollee; or

2. Those services 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

3. Those services provided to treat an enrollee's chronic condition across a continuum of services when the next appropriate level of covered services is not available; or

4. Those services 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

5. 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.

(b) For eligibility terminations, coverage will be continued or reinstated for an enrollee currently enrolled in TennCare who has received notice of termination of eligibility and who appeals within ten (10) days of the date of the notice or prior to the date of termination, whichever is later.

Paragraph (26) of rule 1200-13-13-.01 Definitions is deleted in its entirety.

Subparagraph (b) of paragraph (27) of rule 1200-13-13-.01 Definitions is deleted in its entirety and replaced with a new subparagraph (b) which shall read as follows:

(b) An MCC's failure to provide timely prior authorization of a TennCare service. A prior authorization decision shall not be deemed timely unless it is granted within fourteen (14) days of the MCC's receipt of a request for such authorization.

A new paragraph (37) is added to rule 1200-13-13-.01 Definitions and subsequent paragraphs are re-numbered accordingly. New paragraph (37) shall read as follows:

(37) FINAL AGENCY ACTION shall mean the resolution of an appeal by the TennCare Bureau or an initial decision on the merits of an appeal by an impartial administrative judge or hearing officer when such initial decision is not modified or overturned by the TennCare Bureau. Final agency action shall be treated as binding for purposes of these rules.

Paragraph (77) of rule 1200-13-13-.01 Definitions is deleted in its entirety and replaced with a new paragraph (77) which shall read as follows:

(77) PRIOR APPROVAL STATUS shall mean the restriction of an enrollee to a procedure wherein services, except in emergency situations, must be approved by the TennCare Bureau or the MCC prior to the delivery of services.

A new paragraph (78) is added to rule 1200-13-13-.01 Definitions and subsequent paragraphs are re-numbered accordingly. New paragraph (78) shall read as follows:

(78) PRIOR AUTHORIZATION shall mean the process under which services, except in emergency situations, must be approved by the TennCare Bureau or the MCC prior to the delivery in order for such services to be covered by the TennCare program.

Paragraph (101) of rule 1200-13-13-.01 Definitions is deleted in its entirety and replaced with a new paragraph (101) which shall read as follows:

(101) TENNCARE APPEAL FORM shall mean the TennCare form(s) which are completed by an enrollee or by a person authorized by the enrollee to do so, when an enrollee appeals an adverse action affecting TennCare services.

Paragraph (111) of rule 1200-13-13-.01 Definitions is deleted in its entirety and replaced with a new paragraph (111) which shall read as follows:

(111) TIME-SENSITIVE CARE shall mean (1) the TennCare Bureau has determined that the care is time-sensitive or (2) the enrollees' treating physician certifies in writing that if enrollees do not get this care within ninety (90) days:

(a) They will be at risk of serious health problems or death,

(b) The delay will cause serious problems with their heart, lungs, or other parts of their body, or

(c) They will need to go to the hospital.

A new paragraph (115) is added to rule 1200-13-13-.01 Definitions and the subsequent paragraph is re-numbered accordingly. New paragraph (115) shall read as follows:

(115) VALID FACTUAL DISPUTE shall mean a dispute which, if resolved in favor of the enrollee, would result in the proposed action not being taken.

Subparagraph (b) of paragraph (4) of rule 1200-13-13-.03 Enrollment, Disenrollment, Re-enrollment, and Reassignment is deleted in its entirety and replaced with a new subparagraph (b) which shall read as follows:

(b) A TennCare Medicaid enrollee may change health plans if the TennCare Bureau has granted a request for a change in health plans or an appeal of a denial of a request for a change in health plans has been resolved in his/her favor based on hardship criteria. Requests for hardship MCO reassignments must meet all of the following six (6) hardship criteria for reassignment. Determinations will be made on an individual basis.

1. A member has a medical condition that requires complex, extensive, and ongoing care; and

2. The member's PCP and/or specialist has stopped participating in the member's current MCO network and has refused continuation of care to the member in his/her current MCO assignment; and

3. The ongoing medical condition of the member is such that another physician or provider with appropriate expertise would be unable to take over his/her care without significant and negative impact on his/her care; and

4. The current MCO has been unable to negotiate continued care for this member with the current PCP or specialist; and

5. The current provider of services is in the network of one or more alternative MCOs; and

6. An alternative MCO is available to enrolled members (i.e., has not given notice of withdrawal from the TennCare Program, is not in receivership, and is not at member capacity for the member's region).

A hardship MCO change request will not be granted to a Medicare beneficiary who, with the exception of pharmacy services, may utilize his/her choice of providers, regardless of network affiliation.

Requests to change MCCs submitted by TennCare enrollees shall be evaluated in accordance with the hardship criteria referenced above. Upon denial of a request to change MCCs, enrollees shall be provided notice and appeal rights as described in applicable provisions of rule 1200-13-13-.11.

Subparagraph (g) of paragraph (6) of rule 1200-13-13-.08 Providers is deleted in its entirety and replaced with a new subparagraph (g) which shall read as follows:

(g) The provider failed to inform the enrollee prior to providing a service not covered by TennCare that the service was not covered and the enrollee may be responsible for the cost of the service. Services which are non-covered by virtue of exceeding limitations are exempt from this requirement. Notwithstanding this exemption, providers shall remain obligated to provide notice to enrollees who have exceeded benefit limits in accordance with rule 1200-13-13-.11.

Part 3. of subparagraph (a) of paragraph (1) of rule 1200-13-13-.11 Appeal of Adverse Actions Affecting TennCare Services or Benefits is deleted in its entirety and subsequent parts are renumbered accordingly.

Subparagraph (a) of paragraph (1) of rule is amended by adding renumbered parts 5. and 6. of rule 1200-13-13-.11 Appeal of Adverse Actions Affecting TennCare Services or Benefits which shall read as follows:

5. Appropriate notice shall be given to an enrollee by the State or MCC when an enrollee exceeds a benefit limit. Such notice shall not be subject to the requirements of rule 1200-13-13-.11(1)(c)1. During the applicable time period for each benefit limit, such notice shall only be provided the first time a claim is denied because an enrollee has exceeded a benefit limit. The State or MCC will not be required to provide any notice when an enrollee is approaching or reaches a benefit limit.

6. Appropriate notice shall be given to an enrollee by a provider when an enrollee exceeds a non-pharmacy benefit limit in the following circumstances:

   (i) The provider denies the request for a non-pharmacy service because an enrollee has exceeded the applicable benefit limit; or

   (ii) The provider informs an enrollee that the non-pharmacy service will not be covered by TennCare because he/she has exceeded the applicable benefit limit and the enrollee chooses not to receive the service.

   During the applicable time period for each non-pharmacy benefit limit, providers shall only be required to provide this notice the first time an enrollee does not receive a non-pharmacy service from the provider because he/she has exceeded the applicable benefit limit. Such notice shall not be subject to the requirements of rule 1200-13-13-.11(1)(c)1. Providers will not be required to provide any notice when an enrollee is approaching or reaches a non-pharmacy benefit limit.

Part 2. of subparagraph (b) of paragraph (1) of rule 1200-13-13-.11 Appeal of Adverse Actions Affecting TennCare Services or Benefits is deleted in its entirety and replaced with a new part 2. which shall read as follows:

2. An MCC must notify an enrollee of its decision in response to a request by or on behalf of an enrollee for medical or related services within fourteen (14) days of receipt of the request for prior authorization. If the request for prior authorization is denied, the MCC shall provide a written notice to the enrollee.

Part 4. of subparagraph (b) of paragraph (1) of rule 1200-13-13-.11 Appeal of Adverse Actions Affecting TennCare Services or Benefits is deleted in its entirety and subsequent parts are re-numbered accordingly.

Subpart (iv) of part 1. of subparagraph (c) of paragraph (1) of rule 1200-13-13-.11 Appeal of Adverse Actions Affecting TennCare Services or Benefits is deleted in its entirety and replaced with a new subpart (iv) which shall read as follows:

(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 the right to continuation or reinstatement of benefits pending appeal, when applicable.

Parts 2. and 3. of subparagraph (c) of paragraph (1) of rule 1200-13-13-.11 Appeal of Adverse Actions Affecting TennCare Services or Benefits are deleted in their entirety and replaced with a new part 2. which shall read as follows:

2. Remedying of Notice. If a notice of adverse action provided to an enrollee does not meet the notice content requirements of 1200-13-13-.11(1)(c)1., TennCare will not automatically resolve the appeal in favor of the enrollee. TennCare or the MCC may cure any such deficiencies by providing one corrected notice to enrollees. If a corrected notice is provided to an enrollee, the reviewing authority shall consider only the factual reasons and legal authorities cited in the corrected notice, except that additional evidence beneficial to the enrollee may be considered on appeal.

Subparagraph (d) of paragraph (1) of rule 1200-13-13-.11 Appeal of Adverse Actions Affecting TennCare Services or Benefits is deleted in its entirety and replaced with a new subparagraph (d) which shall read as follows:

(d) Special Provisions Pertaining to Pharmacy Notice

1. If an enrollee does not receive medication of the type and amount prescribed because the pharmacy services are not covered by TennCare, the enrollee shall receive appropriate notice as described below. Such notice shall not be subject to the requirements of rule 1200-13-13-.11(1)(c)1.

(i) When the enrollee has exceeded a benefit limit. Pharmacists will verify TennCare coverage for all prescriptions presented by TennCare enrollees through the PBM. If the PBM denies coverage because an enrollee has exceeded the applicable pharmacy benefit limit and the drug is not included on the Pharmacy Short List, the PBM will provide appropriate notice to the enrollee, informing his/her of the right to appeal the denial. This notice will only be provided upon the first denial of coverage of a pharmacy service sought by the enrollee that exceeds the applicable monthly limits.

(ii) When a request for prior authorization for a prescription has already been denied. Pharmacists will verify TennCare coverage for all prescriptions presented by TennCare enrollees. If the PBM denies coverage because a prior authorization request has already been denied, the enrollee will receive notice as described in rule 1200-13-13-.11(1)(d)1.(II). No additional notice will be provided to the enrollee.

(iii) When a request for prior authorization has not been obtained for a prescription. Pharmacists will verify TennCare coverage for all prescriptions presented by TennCare enrollees. If the pharmacist denies coverage because a request for prior authorization has not been obtained, the following will apply:

(I) The pharmacists will attempt to contact the prescribing physician to seek prior authorization from the PBM or make a change in the prescription. If the pharmacist remains unable to resolve the enrollee's request for the prescription:

I. The pharmacist will dispense a 72-hour interim supply of the medication in an emergency situation if such supply would not exceed applicable pharmacy benefit limits. An emergency situation is a situation that, in the judgment of dispensing pharmacists, involves an immediate threat of severe adverse consequences to the enrollee, or the continuation of immediate and severe adverse consequences to the enrollee, if the outpatient drug is not dispensed when the prescription is submitted. The 72-hour interim supply shall only be dispensed by the pharmacist once per prescription. If the pharmacist determines that an emergency situation does not exist, the pharmacist will not dispense the 72-hour interim supply and shall not provide a written notice to the enrollee for this determination. Enrollees may not appeal the denial by the pharmacist of a 72-hour interim supply of a prescription.

II. The pharmacist will provide the enrollee with a notice that advises the enrollee how prior authorization may be requested for the prescription.

(II) If the prescribing physician seeks prior authorization for the prescription, the PBM will respond to this request within twenty-four hours of receipt if the prescribing physician has provided all of the information necessary to facilitate the determination. If the PBM grants this

request, the PBM will provide notice to the enrollee informing him/her of this resolution. If the PBM denies this request, the PBM will provide the enrollee with appropriate notice, informing him/her of the right to appeal the denial and to continuation or reinstatement of benefits, when applicable.

(III) If an enrollee seeks prior authorization before he/she contacted the prescribing physician, the PBM will advise the enrollee that he/she must attempt to contact the prescribing physician and allow twenty-four (24) hours to lapse from the denial of coverage for the prescription.

(IV) If an enrollee seeks prior authorization after attempting to contact the prescribing physician and has allowed twenty-four (24) hours to lapse since the denial of coverage for the prescription, the PBM will review this request within three business days of its receipt. If the request is resolved as a result of the prescribing physician making a therapy change, the PBM will provide notice to the enrollee informing him/her of this resolution. If the PBM denies this request, the PBM will provide the enrollee with appropriate notice, informing him/her of the right to appeal the denial and to continue or reinstate benefits, when applicable.

(iv) When the requested drug is not a category or class of drugs covered by TennCare. Pharmacists will verify TennCare coverage for all prescriptions presented by TennCare enrollees. If the PBM denies coverage because the drug is not a category or class of drugs covered by TennCare, the PBM will provide appropriate notice to the enrollee, informing him/her of the right to appeal the denial.

(v) When the enrollee has been locked-into one pharmacy, as described in rule 1200-13-13-.13 and the enrollee seeks to fill a prescription at another pharmacy. Pharmacists will verify TennCare coverage for all prescriptions presented by TennCare enrollees. If the PBM denies coverage because the pharmacy is not the enrollee's "lock-in" pharmacy, the PBM will provide appropriate notice to the enrollee, informing him/her of the right to appeal the denial.

(vi) When an enrollee submits a pharmacy reimbursement and billing claim:

(I) TennCare will first determine whether the claim has been previously denied. If the claim was paid upon approval of prior authorization or the enrollee received an alternative prescription ordered by his/her prescribing physician, TennCare will provide appropriate notice to

the enrollee, informing them that the request has already been resolved.

(II) If the claim had already been denied, TennCare will determine the reason for such denial and follow the applicable processes identified in sections 1200-13-13-.11(1)(d)1.(i) to 1.(iii).

(III) If a claim had not already been submitted to the MCC or TennCare, TennCare will determine whether such claim is eligible for reimbursement. If TennCare denies the claim, TennCare will determine the reason for such denial and follow the applicable processes identified in rule 1200-13-13-.11(1)(d)1.(i) to 1.(iii).

Paragraph (3) of rule 1200-13-13-.11 Appeal of Adverse Actions Affecting TennCare Services or Benefits is amended by adding new subparagraphs (d), (e), and (f) which shall read as follows:

(d) Valid Factual Disputes. When TennCare receives an appeal from an enrollee, TennCare will dismiss this appeal unless the enrollee has established a valid factual dispute relating to an adverse action affecting TennCare services.

1. Processing of Appeals. TennCare shall screen all appeals submitted by TennCare enrollees to determine if the enrollees have presented a valid factual dispute. If TennCare determines that an enrollee failed to present a valid factual dispute, TennCare will immediately provide the enrollee with a notice, informing him/her that the enrollee must provide additional information as identified in the notice. If the enrollee does not provide this information, the appeal shall be dismissed without the opportunity for a fair hearing within ten (10) days of the date of the notice. If the enrollee adequately responds to this notice, TennCare shall inform the enrollee that the appeal will proceed to a hearing. If the enrollee responds but fails to provide adequate information, Tenncare will provide a notice to the enrollee, informing him/her that the appeal is dismissed without the opportunity for a fair hearing. If the enrollee does not respond, the appeal will be dismissed without the opportunity for a fair hearing, without further notice to the enrollee.

2. Information Required to Establish Valid Factual Disputes. In order to establish a valid factual dispute, TennCare enrollees must provide the following information: Enrollee’s name; member SSN or TennCare ID#; address and phone; identification of the service or item that is the subject of the adverse action; and the reason for the appeal, including any factual error the enrollee believes TennCare or the MCC has made. For reimbursement and billing appeals, enrollees must also provide the date the service was provided, the name of the provider, copies of receipts which prove that the enrollee paid for the services or copies of a bill for the services, whichever is applicable.

(e) Appeals When Enrollees Lack a Prescription. If a TennCare enrollee appeals an adverse action and TennCare determines that the basis of the appeal is that the enrollee lacks a prescription the following will apply:

1. TennCare will provide appropriate notice to the enrollee inform him/her that he/she will be required to complete an administrative process. Such administrative process requires the enrollee to contact the MCC to make an appointment with a provider to evaluate the request for the service. The MCC shall be required to make such appointment for the enrollee within a 3-week period or forty-eight (48) hours for urgent care from the date the enrollee contacts the MCC. Appeal timeframes will be tolled during this administrative process.

2. In order for this appeal to continue, the enrollee shall be required to contact TennCare after attending the appointment with a physician and demonstrate that he/she remains without a prescription for the service. If the enrollee fails to contact TennCare within sixty (60) days from the date of the notice described in subparagraph (e)1., TennCare will dismiss the appeal without providing an opportunity for a hearing for the enrollee.

(f) Appeals When No Adverse Action is Taken. Enrollees shall not possess the right to appeal when no adverse action has been taken related to TennCare services. If enrollees request a hearing when no adverse action has been taken, their request shall be denied by the TennCare bureau without the opportunity for a hearing. Such circumstances include but are not limited to when enrollees appeal and no claim for services had previously been denied.

Part 10. of subparagraph (b) of paragraph (4) of rule 1200-13-13-.11 Appeal of Adverse Actions Affecting TennCare Services or Benefits is deleted in its entirety and replaced with a new part 10. which shall read as follows:

10. Final agency action within ninety (90) days for standard appeals or thirty-one (31) days (or forty-five (45) days when additional time is required to obtain an enrollee's medical records) for expedited appeals, from the date of receipt of the appeal.

Subparagraph (f) of paragraph (4) of rule 1200-13-13-.11 Appeal of Adverse Actions Affecting TennCare Services or Benefits is deleted in its entirety and replaced with a new subparagraph (f) which shall read as follows:

(f) Review of Hearing Decisions

1. Impartial hearing officers shall promptly issue an Order of their decision. Impartial hearing officers shall provide enrollees with copies of such Orders.

2. The TennCare Bureau shall have the opportunity to review all decisions of impartial hearing officers to determine whether such decisions are contrary to applicable law, regulations or policy interpretations, which shall include but not be limited to decisions regarding the defined

package of covered benefits, determinations of medical necessity and decisions based on the application of the *Grier Revised Consent Decree*.

(i) Any such review shall be completed by TennCare within five (5) days of the issuance of the decision of the impartial hearing officer.

(ii) If TennCare modifies or overturns the decision of the impartial hearing officer, TennCare shall issue a written decision that will be provided to the enrollee and the impartial hearing officer. TennCare's decision shall constitute final agency action.

(iii) If TennCare does not modify or overturn the decision of the impartial hearing officer, the impartial hearing officer's decision shall constitute final agency action without additional notice to the enrollee.

(iv) Review of final agency action shall be available to enrollees pursuant to the Tennessee Administrative Procedures Act, Tennessee Code Annotated §§ 4-5-301, et seq.

(v) An impartial hearing officer's decision in an enrollee's appeal shall not be deemed precedent for future appeals.

Subparts (iii) and (iv) of part 1. of subparagraph (g) of paragraph (4) of rule 1200-13-13-.11 Appeal of Adverse Actions Affecting TennCare Services or Benefits are deleted in their entirety and replaced with new subpart (iii) which shall read as follows:

(iii) Continuation or reinstatement of services within ten (10) days of the receipt of MCC-initiated notice of action to terminate, suspend or reduce other ongoing services.

Parts 5. and 6. of subparagraph (g) of paragraph (4) of rule 1200-13-13-.11 Appeal of Adverse Actions Affecting TennCare Services or Benefits are deleted in their entirety and replaced with new parts 5. and 6. which shall read as follows:

5. Expedited appeals shall be concluded within thirty-one (31) days or forty-five (45) days when additional time is required to obtain an enrollee's medical records, from the date the appeal is received from the enrollee. If an enrollee makes a timely request for continuation or reinstatement of a disputed TennCare service pending appeal, receives the continued or reinstated service, and subsequently requests a continuance of the proceedings without presenting a compelling justification, the impartial hearing officer shall grant the request for continuance conditionally. The condition of such continuance is the enrollee's waiver of his right to continue receiving the disputed service pending a decision if:

(i) The impartial hearing officer finds that such continuance is not necessitated by acts or omissions on the part of the State or MCC;

(ii) The enrollee lacks a compelling justification for the requested delay; and

(iii) The enrollee received at least three (3) weeks notice of the hearing, in the case of a standard appeal, or at least one (1) week's notice, in the case of an expedited appeal.

6. Notwithstanding the requirements of this part, TennCare enrollees are not entitled to continuation or reinstatement of services pending an appeal related to the following:

(i) When a service is denied because the enrollee has exceeded the benefit limit applicable to that service;

(ii) When a request for prior authorization is denied for a prescription drug, with the exception of:

(I) Pharmacists shall provide a single 72-hour interim supply in emergency situations for the non-authorized drug, unless such supply would exceed applicable pharmacy benefit limits; or

(II) When the drug has been prescribed on an ongoing basis or with unlimited refills and becomes subject to prior authorization requirements.

(iii) When coverage of a prescription drug is denied because the requested drug is not a category or class of drugs covered by TennCare;

(iv) When 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;

(v) When a request for reimbursement is denied and the enrollee appeals this denial;

(vi) When a physician has failed to prescribe or order the service or level of service for which continuation or reinstatement is requested; or

(vii) If TennCare had not paid for the service for which continuation or reinstatement is requested prior to the appeal.

Subparagraph (h) of paragraph (4) of rule 1200-13-13-.11 Appeal of Adverse Actions Affecting TennCare Services or Benefits is deleted in its entirety and replaced with a new subparagraph (h) which shall read as follows:

(h) Expedited appeals.

1. Expedited appeals of any action involving time-sensitive care must be resolved within thirty-one (31) days, or forty-five (45) days when additional time is required to obtain an enrollee's medical records, from the date the appeal is received. If the appeal is not resolved within these timeframes, the appeal shall not be automatically resolved in favor of the enrollee, provided the appeal is resolved within ninety days (90) from the date the appeal is received.

2. Care will only qualify as time-sensitive if the enrollee's treating physician determines that if the enrollee does not receive the care within ninety (90) days:

   (i) They will be at risk of serious health problems or death.

   (ii) The delay will cause serious problems with their heart, lungs, or other parts of their body, or

   (iii) They will need to go to the hospital.

3. MCCs shall complete reconsideration of expedited appeals within five (5) days, or within fourteen (14) days when additional time is required to obtain an enrollee's medical records, after receiving notification of the appeal. If the MCC does not complete reconsideration within these timeframes, the appeal shall not automatically be resolved in favor of the enrollee, provided the appeal is resolved within ninety (90) days from the date the appeal is received.

Paragraph (5) of rule 1200-13-13-.11 Appeal of Adverse Actions Affecting TennCare Services or Benefits is deleted in its entirety and replaced with a new paragraph (5) which shall read as follows:

(5) Special Provisions Pertaining to Pharmacy

(a) When a provider with prescribing authority prescribes a medication for an enrollee, and the prescription is presented at a pharmacy that participates in the enrollee's MCC, the enrollee is entitled to:

1. The drug as prescribed, if the drug is on the MCC's formulary and does not require prior authorization.

2. The drug as prescribed, if the prescribing provider has obtained prior authorization.

3. An alternative medication, if the pharmacist consults the prescribing provider when the enrollee presents the prescription to be filled, and the provider prescribes a substituted drug; or

4. Subject to the provisions of rule 1200-13-13-.11(1)(d), if the pharmacist is unable to obtain the prescribing physicians approval to substitute a drug or authorization for the original prescription, the pharmacist will dispense a seventy-two (72) hour interim supply of the medication in an

emergency situation and shall not impose any cost sharing obligations upon the enrollee for this supply. Such supply shall count towards the enrollee's applicable pharmacy benefit limit and the pharmacist shall not dispense this supply if the supply would otherwise exceed these limits. In the event that a prescribing physician obtains prior authorization or changes the drug to an alternative that does not require prior authorization, the remainder of the drug shall not count towards the enrollee's applicable pharmacy benefit limit if the enrollee receives the prescription drug within fourteen (14) days of dispensing the seventy-two (72) hour interim supply.

(b) A pharmacist shall dispense a seventy-two (72) hour interim supply of the prescribed drug, as mandated by the preceding paragraph, provided that:

1. The medication is not classified by the FDA as Less Than Effective (LTE) and DESI drugs or any drugs considered to be Identical, Related and Similar (IRS) to DESI or LTE drugs or any medication for which no federal financial participation (FFP) is available. The exclusion of drugs for which no FFP is available extends to all TennCare enrollees regardless of the enrollee's age; or

2. The medication is not a drug in one of the non-covered TennCare therapeutic categories that include:

   (i) agents for weight loss or weight gain;

   (ii) agents to promote fertility or to treat impotence;

   (iii) agents for cosmetic purposes or hair growth;

   (iv) agents for the symptomatic relief of coughs and colds;

   (v) agents to promote smoking cessation;

   (vi) prescription vitamins and mineral products except prenatal vitamins and fluoride preparations;

   (vii) nonprescription drugs;

   (viii) covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee; or

   (ix) barbiturates or benzodiazepines.

3. Use of the medication has not been determined to be medically contraindicated because of the patient's medical condition or possible adverse drug interaction; or

4. If the prescription is for a total quantity less than a seventy-two (72) hour supply, the pharmacist must provide a supply up to the amount prescribed.

5. In some circumstances, it is not feasible for the pharmacist to dispense a seventy-two (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 be limited to, inhalers, eye drops, ear drops, injections, topicals (creams, ointments, sprays), 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 a seventy-two (72) hour supply of a prescription would otherwise be required and when, as described above, it is not feasible for the pharmacist to dispense a seventy-two (72) hour supply, it is the responsibility of the MCC to provide coverage for either the seventy-two (72) hour supply or the usual dispensing amount, whichever is greater.

6. The Bureau of TennCare shall establish a tolerance level for early refills of prescriptions. Such established tolerance level may be more stringent for narcotic substances. Notwithstanding the requirements of this subsection, if an enrollee requests a refill of a prescription prior to the tolerance level for early refills established by the Bureau, the pharmacy will deny this request as a service which is non-covered until the applicable tolerance period has lapsed, and will not provide a seventy-two (72) hour supply of the prescribed drug.

Paragraph (7) of rule 1200-13-13-.11 Appeal of Adverse Actions Affecting TennCare Services or Benefits is deleted in its entirety and replaced with a new paragraph (7) which shall read as follows:

(7) Time Requirements and Corrective Action.

(a) MCCs must act upon a request for prior authorization within fourteen (14) days as provided in rule 1200-13-13-.11(1)(b)2. Failure by the MCCs to meet these deadlines shall not result in an automatic authorization of the requested service.

(b) MCCs must complete reconsideration of non-expedited appeals within fourteen (14) days. MCCs must complete reconsideration of expedited appeals involving time sensitive care within five (5) days, which shall be extended to fourteen (14) days if additional time is required to obtain an enrollee's medical records. Failure by the MCCs to meet these deadlines shall not result in an immediate resolution of the appeal in favor of the enrollee.

(c) All standard appeals, including, if not previously resolved in favor of the enrollee, a hearing before an impartial hearing officer, shall be resolved within ninety (90) days of receipt of the enrollee's request for an appeal. All expedited appeals involving time-sensitive care shall be resolved within thirty-one (31) days of receipt of the request for appeal, unless extended to forty-five days when additional time is required to obtain an enrollee's medical records. Calculation of

the ninety (90) day, thirty-one (31) day or forty-five (45) day deadline may be adjusted so that TennCare is not charged with any delays attributable to the enrollee. However, no delay may be attributed to an enrollee's request for a continuance of the hearing, if s/he received less than three (3) weeks' notice of the hearing, in the case of a standard appeal, or less than one (1) week's notice, in the case of an expedited appeal involving time-sensitive care. An enrollee may only be charged with the amount of delay occasioned by his/her acts or omissions, and any other delays shall be deemed to be the responsibility of TennCare.

(d) Failure to meet the ninety (90) day deadline, as applicable, shall result in automatic TennCare coverage of the services at issue pending a decision by the impartial hearing officer, subject to the provisions of subparagraphs (7)(e) and (f) below, and to provisions relating to medical contraindication rule 1200-13-13-.11 (8). 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 required time frames. In the event that the appeal is ultimately decided against the enrollee, s/he shall not be liable for the cost of services provided during the period required to resolve of the appeal. Notwithstanding, upon resolving an appeal against an enrollee, TennCare may immediately implement such decision, thereby reducing, suspending, terminating the provision or payment of the service.

(e) When, under the provisions of rule 1200-13-13-.11(7)(d), a failure to comply with the time frames would require the immediate provision of a disputed service, TennCare may 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 not be based upon a finding that the service is not medically necessary. Rather, it may only be made with regard to a service that:

1. Is subject to an exclusion that has been reviewed and approved by the federal Center for Medicare and Medicaid Services (CMS) and incorporated into a properly promulgated state regulation, or

2. Which, under Title XIX of the Social Security Act, is never federally reimbursable in any Medicaid program.

(f) Except upon a showing by an MCC of good cause requiring a longer period of time, within five (5) days of a decision in favor of an enrollee at any stage of the appeal process, the MCC take corrective action to implement the decision. Corrective action to implement the decision includes:

1. The enrollee's receipt of the services at issue, or acceptance and receipt of alternative services; or

2. Reimbursement for the enrollee's cost of services, if the enrollee has already received the services at her own cost; or

3. If the enrollee has already received the service, but has not paid the provider, ensuring that the enrollee is not billed for the service and ensuring that the enrollee's care is not jeopardized by non-payment.

In the event that a decision in favor of an enrollee is modified or overturned within ninety (90) days from receipt of such appeal, TennCare shall possess the authority to immediately implement such decision, thereby reducing, suspending, or terminating the provision or payment of the service in dispute.

(g) In no circumstance will a directive be issued by the TennCare Solutions Unit or an impartial hearing officer to provide a service to an enrollee if, when the appeal is resolved, the service is no longer covered by TennCare for the enrollee. A directive also will not be issued by TennCare Solutions Unit if the service cannot reasonably be provided to the enrollee before the date when the service is no longer covered by TennCare for the enrollee and such appeal will proceed to a hearing.

Rule 1200-13-13-.13 Member Abuse and Overutilization of the TennCare Program is deleted in its entirety and replaced with a new rule 1200-13-13-.13 which shall read as follows:

1200-13-13-.13 MEMBERS ABUSE AND OVERUTILIZATION OF THE TENNCARE PROGRAM.

(1) The TennCare Bureau and the MCCs shall possess the authority to restrict or lock-in TennCare enrollees to a specified and limited number of pharmacy providers if the TennCare Bureau or the MCCs has determined that the enrollee has abused the TennCare Pharmacy Program. Such abuse includes, but shall not be limited to the following:

(a) Forging or altering prescription drugs;

(b) Selling TennCare paid prescription drugs;

(c) Filing to control pharmacy overutilization activity while on lock-in status; or

(d) Visiting multiple prescribers or pharmacies to obtain controlled substances.

(2) All pharmacy lock-in programs established by the TennCare Bureau or the MCCs must contain at least the following elements:

(a) Criteria for selection of abusive or overutilizing enrollees - Pharmacy lock-in program must demonstrate, in detail, how the program will identify lock-in candidates.

(b) Methods of evaluation of potential lock-in candidates - Pharmacy lock-in programs must describe how the program will review lock-in candidates to ensure appropriate patterns of health care utilization are not misconstrued as abusive or overutilization.

(c) Lock-in status - Pharmacy lock-in programs must describe the exact process used to notify the lock-in enrollee, notify the lock-in pharmacy and physician

providers, coordinate the lock-in activities with the appropriate case managers, when appropriate, and continually review the enrollee's utilization patterns.

(d) Prior approval status - Pharmacy lock-in programs may include placing an enrollee in a prior approval status in which some or all prescriptions such as controlled substances, require prior authorization. The program must describe the exact process used to notify the enrollee of prior approval status, notify the pharmacy of the enrollee's prior approval status, coordinate the prior approval status activities with the appropriate case managers, when appropriate, and continually review the enrollee's utilization patterns.

(e) Emergency Services - Pharmacy lock-in programs must describe, in detail, how pharmacy services will be delivered to enrollees on lock-in or prior approval status in the event of an emergency.

(3) Pharmacy lock-in program procedures shall include:

(a) Prior to imposing lock-in status upon a TennCare enrollee, the TennCare Bureau or the MCC shall provide appropriate notice to TennCare enrollees, informing enrollees that they may only use one pharmacy provider and of their right to appeal this action.

(b) If the enrollee fails to appeal this lock-in or the appeal of the lock-in is not resolved in his/her favor, the enrollee will only receive coverage for his/her prescription drugs at the lock-in pharmacy.

(c) If the enrollee attempts to fill a prescription at any pharmacy other than his/her lock-in pharmacy, the PBM will deny coverage for the prescription and the enrollee will be entitled to notice and appeal rights as described in rule 1200-13-13-.11.

(d) The MCC shall monitor and evaluate the TennCare enrollee subject to the lock-in in accordance with the criteria identified in paragraph (2) above.

Statutory Authority: T.C.A. 4-5-209, 71-5-105, 71-5-109, 71-5-134, Executive Order No. 23.

The Public Necessity rules set out herein were properly filed in the Department of State on the 29th day of December, 2005, and will be effective from the date of filing for a period of 165 days. The Public Necessity rules remain in effect through the 12th day of June, 2006.