

**RULES
OF
THE TENNESSEE DEPARTMENT OF HEALTH AND ENVIRONMENT
BUREAU OF HEALTH SERVICES
HEALTH PROMOTION/DISEASE CONTROL**

**CHAPTER 1200—11—1
RENAL DISEASE**

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1200-11-1-.01 STATEMENT OF PURPOSE

- (1) The Renal Disease Program provides assistance to individuals suffering from end stage renal disease or who are at risk of developing end stage renal disease.

Authority: T.C.A. §§68—35—103 and 4—5—202. Administrative History: Original rule certified June 7, 1974. Repeal and new rule filed October 9, 1985; effective January 14, 1986. Amendment filed May 10, 1995; effective September 28, 1995. Repeal and new rule filed September 17, 1998; effective January 28, 1999.

1200-11-1-.02 DEFINITIONS

- (1) Unless otherwise specifically indicated by the context, for the purpose of these rules and regulations, the terms used herein are defined as follows:
- (a) Commissioner - The Commissioner of the Tennessee Department of Health or the Commissioner's designee.
 - (b) Department - The Tennessee Department of Health.
 - (c) End Stage Renal Disease (ESRD)- Kidney function is permanently impaired to the point that the kidney will no longer sustain life.
 - (d) Family- For the purpose of the Renal Disease Program, a family is defined as follows:
 - 1. two or more persons related by birth, marriage or adoption who reside together.a household includes more than one family, the guidelines are applied separately to each family.);
 - 2. a child under 18 years of age and his/her non-parent custodians when financial responsibility has been assigned to them by the court; or
 - 3. parents of a patient under 18 years of age when the patient has been voluntarily placed outside the parent's home.
 - (e) Legend Drug - A pharmaceutical which requires a physician's prescription before being dispensed.
 - (f) Renal Dialysis - Any mechanical means of removing impurities from the blood.

(Rule 1200-11-1-.02, continued)

- (g) Resident of Tennessee - A person who has established a permanent residence in Tennessee. The test for such residence is (1) an intention to stay in a place, (2) coupled with some objective indication consistent with that intent, such as a Tennessee driver's license.
- (h) Routine Renal Drugs - Any number of pharmaceuticals which are needed to treat a patient's end stage renal disease or its complications.

Authority: T.C.A. §68—35—103 and 4—5—202. **Administrative History:** Original rule certified June 7, 1974. Amendment filed January 27, 1976; effective February 26, 1976. Repeal and new rule filed October 9, 1985; effective January 14, 1986. Amendment filed January 29, 1992; effective April 29, 1992. Repeal and new rule filed September 17, 1998; effective January 28, 1999.

1200-11-1-.03 ELIGIBILITY REQUIREMENTS

- (1) Any resident of Tennessee with the presence of end stage renal failure which currently requires chronic dialysis or has necessitated a kidney transplant within the past twelve (12) months is eligible to apply for program services.
- (2) To receive program services, the applicant must meet the following criteria.
 - (a) The applicant must submit a completed, properly signed and dated application provided by the Department. If the applicant is legally incompetent to consent to medical treatment because of age or mental condition, said application shall be completed and signed by the applicant's parent or legal guardian.
 - (b) The applicant must meet the medical criteria established in these Rules and must meet the financial criteria at the time of application and/or recertification.
- (3) The following is a list of medical criteria to be used in determining diagnostic eligibility for the program.
 - (a) End stage renal disease shall be determined by the chemical/medical criteria established by the Health Care Finance Administration and available through Renal Network 8, which includes Tennessee; or
 - (b) If the criteria in 1200-11-1-.03 (3)(a) are not met, a detailed explanation of the uremic symptoms leading to a diagnosis of ESRD must be submitted with the application; or
 - (c) Following successful kidney transplantation, a patient will be considered to continue to meet the requirements of 12-11-.03 (3) (a)-(b).
- (4) Eligibility for special coverage of Cyclosporine over and above the patient's monthly drug cap will be determined separate from, and in addition to, program eligibility. The patient must not be eligible for any other third party coverage for the medication other than Medicare.
- (5) Individuals will be financially eligible for the Renal Disease Program if the family's gross income is at or below 200% of the federal poverty level for the number in family. When a family has more than one (1) individual with ESRD, one person may be added to the total number of family members when determining eligibility. All participants in the Renal Disease Program must be financially recertified annually.

The Department shall determine the family income of the applicant as a family according to the following.

(Rule 1200-11-1-.03, continued)

- (a) Income shall include:
 - 1. wages, salaries and/or commissions;
 - 2. income from rental property or equipment;
 - 3. profits from self-employment enterprises, including farms;
 - 4. alimony and/or child support;
 - 5. inheritances;
 - 6. pensions and benefits; and
 - 7. public assistance grants.
- (b) After the income of the family is determined, any verified medical payments, including medical or health insurance premiums made by the family for any family member during the previous twelve (12) months, shall be prorated over twelve months and deducted from the gross monthly income.
- (c) Verified child support or alimony paid to another household shall be deducted from the gross monthly income.
- (6) All applicants to, or participants in, the Renal Disease Program who have no third party insurance coverage must apply for Medicare and TennCare coverage and provide proof of acceptance or denial to the Renal Disease Program. Denial of coverage by Medicare or TennCare will not prevent the individual from participation in the Renal Disease Program, so long as program eligibility requirements are met. Once accepted for TennCare coverage, Renal Disease Program participants must meet all TennCare eligibility requirements in order to maintain eligibility for the Renal Disease Program.
- (7) Applicants will be denied participation in the Renal Disease Program if they are diagnostically ineligible, financially ineligible, or fail to apply for TennCare and Medicare coverage.
- (8) Once a patient has been certified for services, the certification extends for twelve months regardless of changes in family income.
- (9) The Commissioner may prioritize acceptance into the program according to medical need (as defined in these rules), pharmaceutical requirements, and available program dollars. As vacancies occur each month, those applicants without TennCare or private third party coverage with pharmacy benefits will be given first preference in chronological order of the receipt of the application to fill those vacancies until all slots are filled for the month. Once capitated authorized funding has been exhausted, there will be no more funding.

Authority: T.C.A. §68—35—103 and 4—5—202. **Administrative History:** Original rule certified June 7, 1974. Amendment filed January 17, 1975; effective February 16, 1975. Repeal and new rule filed October 9, 1985; effective January 14, 1986. Repeal and new rule filed September 17, 1998; effective January 28, 1999.

1200-11-1-.04 COVERED SERVICES

- (1) The Department will assist in the payment for services rendered to eligible renal patients insofar as budget funds will allow. The Department may place a cap on enrollment in the program and/or a cap on expenditures per participant, when the budgetary limits are reached.

(Rule 1200-11-1-.04, continued)

- (2) Covered services may include:
 - (a) Legend and over-the-counter drugs required for the treatment of end stage renal disease which are included in the program's formulary and not covered by a participant's third party insurer. For TennCare recipients, legend drugs will be covered by TennCare.
 - (b) In-center dialysis services for patients who do not have health insurance and are ineligible for TennCare during the waiting period before Medicare eligibility begins following the onset of dialysis.
 - (c) Medicare insurance premiums for eligible program participants including both "Part A" and "Part B" premiums, as determined by the U.S. Department of Health and Human Services.
 - (d) Acute Dental services to relieve pain and suffering. Any more extensive rehabilitative work or dentures would have to be approved by the Commissioner and the decision made on the exceptional nature of the need for these services and the availability of funds.
 - (e) Case management and other services provided by the Renal Disease Intervention Program.
 - (f) Out-of-state dialysis services for participants. The Renal Disease Program pays Medicare coinsurance for participants to travel out of state. Most out-of-state dialysis units will not accept patients unless they have full coverage.

Authority: T.C.A. §§68—35—103 and 4—5—202. **Administrative History:** Original rule certified June 7, 1974. Amendment filed January 27, 1976; effective February 26, 1976. Repeal and new rule filed October 9, 1985; effective January 14, 1986. Amendment filed June 8, 1989; effective July 14, 1989. Amendment filed January 29, 1992; effective April 29, 1992. Amendment filed May 10, 1995; effective September 28, 1995. Repeal and new rule filed September 17, 1998; effective January 28, 1999.

1200-11-1-.05 AUTHORIZATION AND REIMBURSEMENT FOR SERVICES

- (1) No payment shall be made for services rendered to any participant under these Rules unless and until all third party payment sources available have been exhausted.
- (2) Payment for out-of-state dialysis services must be prior approved and is limited to six (6) dialysis treatments within any twelve (12) month period.
- (3) The Department will pay one hundred percent (100%) of the Medicare allowable reimbursement rate for in-center dialysis during that portion of the Medicare waiting period before patients are eligible for Medicare benefits, if the patient does not have health insurance coverage and is not eligible for TennCare benefits. If the patient has only health insurance coverage, the amount which will be paid will be equal to the Medicare allowable reimbursement rate, less any insurance payments.
- (4) The Department will reimburse pharmacists for routine renal drugs in an amount not to exceed a set monthly cap, established by the Commissioner based upon the availability of funds. The Commissioner will establish caps for expenditures for those participants who are covered by TennCare and for those who are covered by Medicare only.
- (5) Dental services must have prior authorization and will be reimbursed based on the Schedule of Allowances of United Concordia Companies, Inc. (Blue Cross/Blue Shield of Pennsylvania).
- (6) All services provided under these Rules are to be obtained within the state, except for services provided to participants who have received prior authorization for out-of-state treatment.

(Rule 1200-11-1-.05, continued)

Authority: T.C.A. §§68—35—103 and 4—5—202. **Administrative History:** Original rule certified June 7, 1974. Amendment filed July 22, 1976; effective August 21, 1976. Amendment filed July 22, 1977; effective August 22, 1977. Repeal and new rule filed October 9, 1985; effective January 14, 1986. Amendment filed June 8, 1989; effective July 14, 1989. Amendment filed September 25, 1990; effective December 29, 1990. Amendment filed January 29, 1992; effective April 29, 1992. Amendment filed May 10, 1995; effective September 28, 1995. Repeal and new rule filed September 17, 1998; effective January 28, 1999.

1200-11-1-.06 REMOVAL FROM PROGRAM

- (1) Participants may be removed from the program when they:
 - (a) move out of state, or
 - (b) become financially ineligible, or
 - (c) fail to apply for TennCare or adhere to TennCare requirements

Authority: T.C.A. §§68—35—103 and 4—5—202. **Administrative History:** Original rule certified June 7, 1974. Repeal and new rule filed October 9, 1985; effective January 14, 1986. Repeal and new rule filed September 17, 1998; effective January 28, 1999.

1200-11-1-.07 RECONSIDERATION OF DENIAL

- (1) Applicants who are denied participation in the Renal Disease Program or participants who are removed from the program in accordance with 1200-11-1-.06 may ask in writing to the program within ten (10) calendar days of receipt of the program's written notice of denial or removal that the denial be reconsidered. If the denial is upheld, the individual may ask the Commissioner to review the decision. The request must be in writing and be sent to the Commissioner within ten (10) calendar days of receipt of the written notice that the denial was upheld after reconsideration by the program. The decision of the Commissioner may be appealed to a hearing before an Administrative Law Judge pursuant to the provisions of the U.A.P.A.

Authority: T.C.A. §§68—35—103 and 4—5—202. **Administrative History:** Original rule certified June 7, 1974. Repeal and new rule filed October 9, 1985; effective January 14, 1986. Amendment filed April 14, 1988; effective May 29, 1988. Amendment filed June 8, 1989; effective July 14, 1989. Amendment filed September 25, 1990; effective December 29, 1990. Amendment filed January 29, 1992; effective April 29, 1992. Amendment filed May 10, 1995; effective September 28, 1995. Repeal and new rule filed September 17, 1998; effective January 28, 1999.