

DEPARTMENT OF HEALTH AND SOCIAL SERVICES
DIVISION OF MEDICAID AND MEDICAL ASSISTANCE
Statutory Authority: 31 Delaware Code, Section 512 (31 Del.C. §512)

FINAL

ORDER

Chronic Renal Disease Program

Nature of the Proceedings:

Delaware Health and Social Services ("Department") / Division of Medicaid and Medical Assistance (DMMA) initiated proceedings to amend the Division of Social Services Manual (DSSM) to clarify, update, and eliminate rules used to determine eligibility for the Chronic Renal Disease Program. The Department's proceedings to amend its regulations were initiated pursuant to 29 **Delaware Code** Section 10114 and its authority as prescribed by 31 **Delaware Code** Section 512.

The Department published its notice of proposed regulation changes pursuant to 29 **Delaware Code** Section 10115 in the December 2005 *Delaware Register of Regulations*, requiring written materials and suggestions from the public concerning the proposed regulations to be produced by December 31, 2005 at which time the Department would receive information, factual evidence and public comment to the said proposed changes to the regulations.

Summary of Proposed Changes

Statutory Authority

Title 29, Chapter 79, Subchapter II, Sections 7932 – 7935, *The Chronic Renal Diseases Program*

Background

The Delaware Legislature established the Chronic Renal Disease Program (CRDP) effective 1970 by enacting Title 29, Chapter 79, Subchapter 11, Sections 7932-7935. The purpose of this program is to provide assistance to state residents diagnosed with End Stage Renal Disease (ESRD). The CRDP is not federally funded. CRDP is 100% State funded. Since there are limited funds available, the CRDP should only be utilized as a program of last resort. All third party resources (Medicare, Medicaid, Veteran's Benefits, and Private Insurance) must be considered before CRDP funds are utilized.

The mission of the CRDP is to "improve the quality of life for Delawareans with ESRD by promoting health and well-being, fostering self-sufficiency, and protecting a vulnerable population."

The Chronic Renal Disease Advisory Board is composed of 11 members who are appointed by the Secretary of Delaware Health and Social Services. The role of this Advisory Board is to consult with the Secretary in the administration of the Chronic Renal Disease Program, as needed. Board members represent hospitals and medical centers, which establish dialysis centers, voluntary agencies interested in kidney diseases, related public agencies, physicians licensed to practice medicine and the general public.

Summary of Proposed Changes

DSSM 50100.3, 50400, 50700 and 50700.2: The proposal updates the transportation provider information; clarifies the application process; clarifies eligibility standards; and, eliminates the resource test.

Summary of Comments Received with Agency Response and Explanation of Changes

The Delaware Developmental Disabilities Council (DDDC) and the State Council for Persons with Disabilities (SCPD) offered the following observations summarized below. DMMA has considered each comment and responds as follows:

DMMA describes this program in the "Background" section of the regulations. It was started in 1970. It is

entirely State funded. DMMA asserts that it is intended as a “program of last resort”. We attach a copy of the enabling legislation, Title 29 **Del.C.** §§7932-7935. The statute indicates that the CRDP is intended to serve persons suffering from chronic renal diseases who require lifesaving care and treatment but who are unable to pay for such services on a continuing basis.” Title 29 **Del.C.** §7932. This provision does authorize imposition of financial eligibility standards as a condition of eligibility for the program. Concomitantly, DHSS, with the advice of the Renal Disease Advisory Committee, is authorized to develop eligibility standards.

First, there is a “typo” in §50100.3. In the second paragraph, the word “my” should be “may”.

Agency Response: The “typo” is noted. However, this sentence is stricken in the final order regulation.

Second, the “Transportation” section (§50100.3) is revised. It retains the current 3 contexts for funding (mileage reimbursement; DART tickets; private transportation) while deleting specific criteria for implementing them. The rationale is that this represents an “update”. It is difficult to assess the impact of the revision. On the one hand, it may maximize flexibility by allowing DMMA to implement the funding authorization in conformity with office practice and policy. On the other hand, if non-regulatory standards do not exist, the lack of specific criteria will predictably lead to indecision, misunderstandings, and appeals. If the current provisions are outdated, it would be preferable to either update them with some specific criteria or ensure that non-regulatory standards exist.

Agency Response: Section §50100.3 is revised to include the specific criteria requested.

Third, the elimination of a financial resource test (§50700.2) merits endorsement.

Agency Response: Thank you for the endorsement.

Fourth, the income standard would benefit from revision as follows.

A. Section 50700 recites that a participant’s income must be below 300% of the Federal Poverty Level (FPL). If not clarified elsewhere, it would be preferable to clarify if this term simply refers to “gross income” or, alternatively, to “countable income” which incorporates some customary deductions. If “income” is defined in another standard, it may be prudent to at least include a cross reference or regulatory note here.

Agency Response: Cross reference sections have been included, as requested.

B. The adoption of an income standard based on the Federal Poverty Level (PDL) standard is an acceptable administrative approach to establishing a financial eligibility benchmark, which increases with inflation. However, the application of the PDL is generally dependent on family size. For example, the PDL for a family of four will be higher than the PDL for a family of two. Unfortunately, the regulation runs afoul of this approach with the following recital: “Applicants with a legally married spouse will be considered a household of two.” This is accurate only if there are no dependents. Obviously, if a couple have 6 children, using a PDL for a household of 2 may unnecessarily exclude a financially needy individual from the program. Moreover, this standard literally includes the income of a separated spouse who is not part of the household. For example, there could be a “legally married” but separated couple in which the father pays spousal or child support to a mother. Under the regulation, the mother’s income would be counted towards the father’s eligibility for the CRDP. Indeed, the support could theoretically be “double counted” (father’s earnings; mother’s support). It would be preferable to delete the sentence altogether.

Agency Response: DMMA notes that the acronym “PDL” should be “FPL” in the comment written above. In response to this comment, DMMA intentionally limited the household size to two in order to simplify the eligibility process. Since DMMA eliminated the resource test, it is hoped that clients who are most in need will receive the services. Should DMMA find that it is denying a disproportionate number of clients then the issue may be revisited.

C. DMMA proposes to delete an existing authorization to consider extenuating factors in considering financial eligibility. [§50700, last paragraph, 5 bullets]. While it is appropriate to exclude some references (e.g. to resources), the deletion does eliminate flexibility. For example, if an applicant’s income equals 300% of the FPL, but the applicant has extraordinary household expenses, the new regulation would preclude eligibility. This complete elimination of consideration of other financial circumstances, in favor of a no-exceptions 300% FPL standard, may result in deflection of some needy individuals from the program. A compromise approach would be to add the following exception to §50700:

Applicants with countable income between 300 - 400% of the FPL may be determined eligible if the CRDP worker confirms that extraordinary household expenses realistically preclude access to alternative sources of renal disease treatment.

Agency Response: The new regulation does eliminate the flexibility to consider extraordinary household expenses. DMMA feels there should be consistency among the standards and application of the rules. DMMA hopes to automate the Chronic Renal Disease Program (CRDP) as the other medical assistance programs. To design a computer system with the flexibility you describe would be extremely difficult and costly. Again, should we find that DMMA is denying a high number of applicants; we may consider additional disregards in the future.

Findings of Fact:

The Department finds that the proposed changes as set forth in the December 2005 *Register of Regulations* should be adopted.

THEREFORE, IT IS ORDERED, that the proposed regulation to amend the Division of Social Services Manual to clarify, update, and eliminate rules used to determine eligibility for the Chronic Renal Disease Program is adopted and shall be final effective April 10, 2006.

Vincent P. Meconi, Secretary, DHSS, 3/15/06

DMMA FINAL ORDER REGULATION #06-05

Revisions:

50000 Chronic Renal Disease Program

The Delaware Legislature established the Chronic Renal Disease Program (CRDP) effective 1970 by enacting Title 29, Chapter 79, Subchapter 11, Sections 7932-7935. The purpose of this program is to provide assistance to state residents diagnosed with End Stage Renal Disease (ESRD). The CRDP is not federally funded. CRDP is 100% State funded. Since there are limited funds available, the CRDP should only be utilized as a program of last resort. All third party resources (Medicare, Medicaid, Veteran's Benefits, and Private Insurance) must be considered before CRDP funds are utilized.

The mission of the CRDP is to "improve the quality of life for Delawareans with ESRD by promoting health and well-being, fostering self-sufficiency, and protecting a vulnerable population."

The Chronic Renal Disease Advisory Board is composed of 11 members who are appointed by the Secretary of Delaware Health and Social Services. The role of this Advisory Board is to consult with the Secretary in the administration of the Chronic Renal Disease Program, as needed. Board members represent hospitals and medical centers, which establish dialysis centers, voluntary agencies interested in kidney diseases, related public agencies, physicians licensed to practice medicine and the general public.

50100 Services Provided by CRDP

Services provided by the CRDP can consist of payment for medications, nutritional supplements, transportation, and payment of Medicare Part D costs. Electronic Data Systems (EDS) is the CRDP's fiscal agent. They are responsible for processing all eligible CRDP claims.

9 DE Reg. 774 (11/01/05)

50100.1 Medications

The CRDP has the ability to fund prescription medications, over-the-counter medications (OTC's) or both. Services covered include generic and brand name prescription drugs that have been approved as safe and effective by the Federal Food and Drug Administration as well as cost effective over-the-counter drugs prescribed by a practitioner. Prescription drugs covered under CRDP are restricted to products manufactured by pharmaceutical companies that agree to provide manufacturer rebates.

Reimbursement for medications will be made only for client's authorized by the CRDP. Client's eligibility for the medication benefit is based upon the outcome of their medical and financial assessment.

Prescription medications potentially will be funded if prescribed by a physician for eligible clients. Refills may be authorized in compliance with appropriate pharmacy laws.

Reimbursements for OTC products for eligible clients are those, which the physician/practitioner has provided written or verbal authorization to the pharmacist. These products must be for the client's personal use

only. There will be no reimbursement for OTC products that are not prescribed by a physician/practitioner. Supplies such as mouthwash, toothpaste, shampoo, etc. will not be reimbursed.

At point of sale, the pharmacist will determine electronically if CRDP will fund the requested product. In order for the pharmacy to receive CRDP payment, they must have a Delaware Medicaid provider number.

Note: All third party resources must be used before CRDP funds are utilized.

9 DE Reg. 774 (11/01/05)

50100.2 Nutritional Supplements

Nutritional supplements will only be funded by the CRDP if the client is diagnosed with ESRD, is on dialysis or has received a kidney transplant, and, exhibits signs and symptoms of malnutrition as determined by documentation of specific laboratory values. Additionally, the only nutritional supplements funded by the CRDP are those currently on the formulary as dictated by First Data Bank.

Other criteria that must be met include:

- it is reasonable and necessary part of the client's treatment plan;
- ordered by a physician or certified nurse practitioner as indicated by completion of a Medical Necessity Form;
- not furnished for the convenience of the client, client's family, attending practitioner, or other practitioner or supplier;
- necessary and consistent with generally accepted professional medical standards;
- monitored and assessed regularly by the attending practitioner to determine effectiveness and necessity.

The CRDP will fund oral nutritional supplements for a durational period of 6 months or less as needed. The durational period is dependent upon the client's medical and financial situation. If the client will need the supplement past the authorized durational period, the practitioner must submit another Certificate of Medical Necessity Form. Upon submission CRDP will redetermine eligibility. Claims submitted without prior approval, or exceeding the authorized durational period may be denied.

50100.3 Transportation

~~The CRDP may reimburse for transportation to and from the dialysis unit, transplant hospital, or in exceptional cases, related medical appointments. Once determined eligible, all types of reimbursable transportation will be explored for cost effectiveness.~~

- ~~• The types of transportation funded by CRDP are:~~
- ~~• Mileage Reimbursement – the CRDP may reimburse the client, client's spouse, caregiver, or anyone who consistently transports clients. Round trip mileage must be greater than 10 miles to be eligible.~~
- ~~• Delaware Authority for Regional Transit (DART) tickets – the CRDP will purchase DART tickets for client use. A monthly supply of DART tickets is sent to the dialysis social worker for distribution. These tickets are replaced monthly based on the previous month's usage.~~
- ~~• Private Transportation Companies – The CRDP may contract with private transportation companies. Transportation may be supplied via company vehicle or by a volunteer who is trained by the Transportation Company.~~

[Transportation services for eligible CRDP clients are arranged by the Division of Medicaid & Medical Assistance (DMMA) Transportation Broker. Transportation may be provided to and from the dialysis unit, transplant hospital, or in exceptional cases, related medical appointments. DMMA's transportation broker will explore all types of reimbursable transportation for cost effectiveness.

The types of transportation that may be provided are:

Mileage Reimbursement – mileage reimbursement may be provided to the client, client's spouse, caregiver, or anyone who consistently transports clients. There is no restriction on the minimum amount of miles to be eligible.

Delaware Authority for Regional Transit (DART) tickets - DART tickets will be purchased for client use. A monthly supply of DART tickets is sent to the dialysis social worker for distribution. These tickets are replaced monthly based on the previous month's usage.

Private Transportation Companies - private transportation companies may provide transportation if they have a contract with DMMA's transportation broker.

Volunteer – a volunteer trained by DMMA’s transportation broker may provide transportation utilizing a company vehicle.]

50100.4 Medicare Part D Costs

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) established the Medicare Prescription Drug Program, also known as Medicare Part D, making prescription drug coverage available to individuals who are entitled to receive Medicare benefits under Part A or Part B, beginning on January 1, 2006.

The MMA provides for a Low Income Subsidy (LIS) for individuals with limited income and resources. The LIS is assistance provided by the Centers for Medicare and Medicaid Services to pay Medicare Part D costs for eligible individuals. The LIS will provide payment assistance with the monthly premium, the yearly deductible, and the coverage gap. The LIS will also provide payment assistance for co-payments after an individual with income below 135% of the Federal Poverty Level reaches a total of \$5100 in drug expenses.

The CRDP will provide coverage for Medicare Part D costs including monthly premiums, yearly deductible, drug costs that fall into the Part D coverage gap, and co-payments. If an individual is eligible for the LIS, this assistance will be primary to CRDP assistance.

50200 Services Not Provided by CRDP

The CRDP will not pay health insurance premiums (except Medicare Part D premiums); nor will the program pay for medical, hospital, or ancillary services, medical supplies, or transportation not directly related to the care of End State Renal Disease (ESRD).

50300 Referral Process

The CRDP can receive referrals from many sources. Client, family, caretaker, physicians and/or other professionals may initiate the referral process by calling the CRDP office. Dieticians and dialysis social workers may begin the referral process by calling or by mailing/faxing a completed referral form to the CRDP office. Once the referral has been received, the client or referral source will be contacted to set up an appointment to complete the CRDP assessment.

50400 Application Process

Applicants must be medically and financially eligible to receive coverage. The client or his representative must complete and sign a CRPD an application form in person or via the telephone. and mail or fax to the DMMA office. The date the application is received in the DMMA office is the first possible date that benefits may start. The individual must also provide the requested verifications necessary to determine eligibility.

CRPD will consider applications without regard to race, color, age, sex, disability, religion, national origin, or political belief, as per Title VI of the Civil Rights Act of 1964.

Filing an application gives the applicant the right to receive a written determination of eligibility and the right to appeal the written determination.

At time of application and/or redetermination, each individual must be informed that they are responsible for notifying the CRDP worker of all changes in their circumstances, which could potentially affect their eligibility for the CRDP.

50450 Disposition of Applications

Each applicant's case record must include facts to support the eligibility decision. Each application will be determined eligible or ineligible, unless:

- a. there is an entry in the case record that the applicant voluntarily withdrew the application
- b.. there is a supporting entry in the case record that the applicant has died; or
- c. there is a supporting entry in the case record that the applicant cannot be located.

Certain factors of eligibility must be verified. If all information requested is not received, eligibility cannot be determined or redetermined. This may result in denial of the application or the termination of eligibility. Verifications received and/or provided may reveal a new eligibility issue not previously realized and this may require additional verifications. Failure to provide additional requested verifications may result in denial or termination of eligibility.

All applicants will receive a notice of action taken on the applications.

Eligibility for CRDP will be redetermined on an annual basis.

50500 Technical Eligibility

Only persons who are residents of the State of Delaware shall be eligible for services. Additionally, the individual must be an U.S. citizen or a lawfully admitted alien.

An individual who is entitled to receive Medicare benefits under Part A or Part B must enroll in Part D in order to be eligible for CRDP. The individual must provide proof of Medicare Part D enrollment. Exception: Medicare eligible individuals who have creditable coverage are not required to enroll in Part D as a condition of eligibility. Coverage is creditable if the actuarial value of the coverage equals or exceeds the actuarial value of the standard prescription drug coverage under Part D.

An individual must apply for the LIS if potentially eligible. The individual must provide a copy of the LIS denial or approval notice.

Individuals may be found eligible for CRDP pending their Medicare Part D enrollment and application for LIS for a period of no longer than 90 days from the date of application for CRDP. Current recipients will be notified about the Medicare Part D enrollment requirement and the LIS requirement. They will be given a deadline date by which they must meet this requirement.

50600 Medical Eligibility

The client must be diagnosed with ESRD, receive dialysis or have had a renal transplant.

50700 Financial Eligibility

CRDP staff determines financial eligibility. The amount of assistance received from the CRDP is dependent upon the applicant's financial situation. Applicant's/client's **[gross countable]** income and resources need to must be below 300% of the Federal Poverty Level (FPL). **[See DSSM 20200 for Income.]** Applicants/clients with income and resources above 300% of the FPL may be eligible for an annual medication cost deduction from the applicant's/client's annual income and resources. If, after this deduction, income and resources are below 300% of the FPL, the individual may be eligible. Applicants with a legally married spouse will be considered a household of two [unless the couple is separated and maintains two separate residences for at least 12 months prior to application.]

~~Additional factors that may be considered for eligibility include, but are not limited to:~~

- ~~• Number of household members financially dependent on applicant/client~~
- ~~• Cost of certain medications~~
- ~~• Household expenses~~
- ~~• Income/resources of applicant/client~~
- ~~• Income/resources of any household member that contributes to household expenses.~~

50700.1 Income

Income is the total amount of money authorized and received for the applicant's benefit. Income includes anything received by the individual in cash or in kind, that can be used to meet needs for food, clothing or shelter. Gross income is used to determine eligibility. Some examples of income include, but are not limited to the following: Social Security, Railroad Retirement, pensions, wages, rental income, etc.

50700.2 Resources

~~Resources are items that can be converted to cash to be used for food, clothing or shelter. Some examples of resources include, but are not limited to the following: bank accounts, stocks, bonds, certificates of deposit, money market funds, retirement funds, etc.~~

~~If the individual has the right, authority or power to liquidate his or her share of the property, it is a resource. In addition, the individual must have:~~

- ~~• Some form of ownership interest in the property;~~
- ~~• A legal right to access the property;~~
- ~~• The legal ability to use the property for his/her own support and maintenance.~~

~~There is no resource test.~~

50800 Resident of a Long Term Care Facility

An individual who has been admitted to a nursing facility for placement other than rehabilitation will not be

eligible for or continue to be eligible for CRDP services. If the individual is discharged from the nursing facility, they may reapply for CRDP services.

50900 Fair Hearings

A fair hearing is an administrative hearing held in accordance with the principles of due process. An opportunity for a fair hearing will be provided, subject to the provisions in policy at DSSM sections 5000-5607.

51000.1 Waiting List Policy General Statement

The applicant must meet certain medical and financial criteria in order to be eligible for benefits from the Chronic Renal Disease Program. (For eligibility criteria see DSSM sections 50600 and 50700) A waiting list will be maintained according to the need of each client/potential client, with those with most critical needs served first.

Referrals are prioritized on the waiting list according to medical/financial need.

The number of clients served by the CRDP program is limited by the amount of available funds. If the CRDP budget has been depleted prior to the end of the fiscal year, clients on the CRDP waiting list will be processed for CRDP benefits at the beginning of next fiscal year.

51000.2 Medical Criteria

Within 24 hours of referral receipt, medical eligibility specific to the individual's need will be determined. The order of priority will be medications/supplements and transportation services.

51000.3 Financial Criteria

Within 24 hours of referral receipt, financial eligibility and specific need will be determined. Clients, who have a documented medical need and appear to be financially eligible for CRDP, with limited income and no insurance, will be given highest priority.

The order of priority will be clients with limited income and no insurance coverage, minimal insurance coverage, or insurance copays.

9 DE Reg. 774 (11/01/05)

9 DE Reg. 1558 (04/01/06) (Final)