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

50100 Services Provided by 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 provide a standard pharmacy benefit to Chronic Renal Disease Program recipients. 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 June 2006 *Delaware Register of Regulations*, requiring written materials and suggestions from the public concerning the proposed regulations to be produced by June 30, 2006 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

Delaware Code, 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.

Purpose of the Proposed Regulation

The purpose of the proposed regulation is to provide a standard pharmacy benefit to Chronic Renal Disease Program (CRDP) recipients. Pharmaceutical charges have been offset with the implementation of Federal Medicare Part D benefits; thereby permitting the inclusion of all non-Part D covered medications as a standard benefit available to all qualified recipients.

Summary of Proposed Changes

The cost shift of medications to Medicare Part D has permitted the standardization of the pharmacy benefit to CRDP clients. The proposed changes removes the additional steps previously necessary to obtain individual authorizations for each medication required.

The anticipated benefit of expanding pharmacy access is improved health outcomes for CRDP recipients, thereby avoiding costs associated with the more serious health care issues that could occur from lack of access to medications.

The proposal amends DSSM 50100.1, Medications and 50100.2, Nutritional Supplements as follows:

1) As participation in Medicare Part D or proof of creditable coverage became a condition of CRDP eligibility, the CRDP program no longer provides primary pharmacy benefit coverage for many medications.

2) Prescription drugs will be reimbursed in accordance with current Delaware Medicaid and Medical Assistance formulary limitations and procedures.

3) Reimbursement for medications will be made only for clients currently eligible and approved for participation in CRDP.

4) Refills may be authorized in compliance with appropriate pharmacy laws, and subject to Delaware Medicaid and Medical Assistance formulary restrictions.

5) At the point of sale, the pharmacist will determine electronically if another funding source is available, and bill that vendor(s) first, and then will determine if CRDP will fund the requested product.

6) At the point of sale, the pharmacist will be alerted if program quantity limits for nutritional supplements have been exceeded and if prior authorization is needed by EDS.

7) Approval of funding nutritional supplements is subject to Division of Medicaid and Medical Assistance formulary restrictions.

8) The CRDP will fund oral nutritional supplements for a period prescribed by the physician.

SUMMARY OF COMMENTS RECEIVED WITH AGENCY RESPONSE

The Governor's Advisory Council for Exception Citizens (GACEC) and the State Council for Persons with Disabilities (SCPD) offered the following similar observations and recommendations summarized below.

DMMA has considered each comment and responds as follows:

First, the Councils have not embraced and oppose the use of a DMMA formulary in similar contexts. Due to the uniqueness of each patient and the complexity of treating mental illness and other illnesses, it is imperative that patients have access to the widest range of pharmaceutical treatments. Patient disease characteristics and clinical efficacy should be the primary factors considered by providers when selecting pharmaceutical agents to treat these illnesses. Furthermore, a one-size-fits-all approach to drugs for such conditions is unworkable since clinical effectiveness and individual tolerances vary considerably, these conditions are complex, and person with these conditions are vulnerable. We would like to reiterate its preference that physicians not be constrained in their selection of medically appropriate drugs.

Agency Response: All pharmacy programs, including federally funded programs, utilize a formulary to maintain cost neutrality. Additionally, since CRDP is a secondary payer, it is unlikely DMMA formulary restrictions will have any impact; since CRDP is supplementing payments made by the primary payer, and does not generally override the primary payer formulary. If a client requires a non-formulary prescription, there is an avenue to request an exemption.

Second, the 6-month durational cap on funding nutritional supplements has been deleted. Councils endorse this deletion.

Agency Response: DMMA appreciates the endorsement. This, in fact, relaxes earlier program requirements by requiring prior authorizations for supplements exceeding a dollar limit instead of requiring an authorization for all requests. Only if program quantity limits for nutritional supplements are exceeded, a prior authorization will be required. Once approved, the medical necessity of the nutritional supplement must be substantiated every 6 months if the quantity limit is exceeded. This will insure client usage and will require provider monitoring of client's needs on a routine basis.

Third, proposed Section 50100.1 recites that "participation in Medicare Part D or proof of creditable coverage became a condition of CRDP eligibility". No Federal or State law requires Medicare beneficiaries to enroll in Medicare Part D. Moreover, the current CRDP do not *require* Medicare beneficiaries to enroll in Medicare-D or have "creditable coverage". The regulations allow DSS to ìconsiderî third party resources but enrollment in Medicare-D is not currently an absolute requirement for eligibility in the CRDP. By analogy, many CRDP beneficiaries may be "eligible" to purchase individual health insurance policies (at considerable cost). However, they are not required to do so as a condition of eligibility for the CRDP. DSS may wish to consider amending the incorrect recital in §50100.1.

Agency Response: Eligible applicants must enroll in Medicare Part D, unless they have creditable coverage, as a condition of eligibility for CRDP. Section 50500 Technical Eligibility states, "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."

Client cost incurred for Medicare Part D premiums have been and will continue to be covered by CRDP. Section 50100 Services Provided by CRDP states, "Services provided by the CRDP can consist of payment for medications, nutritional supplements, transportation, and payment of Medicare Part D costs." Therefore this requirement should not be burdensome to the client.

Fourth, the third and fourth bullets in §50100.2 should be deleted. They are variations of portions of the existing DSS "medical necessity" regulation published at 9 **DE Reg.** 1249 (January 1, 1999). By reproducing an incomplete variation of medical necessity standards, the bullets "muddy the waters". Moreover, the second bullet already requires completion of "a Medical Necessity Form" which makes the third and fourth bullets unnecessary.

Agency Response: These bullets are not the subject of the proposed regulation. However, DMMA has determined no ambiguity. The third and fourth bullets in section 50100.2 remain valid.

No changes were made to the final regulation as a result of these comments.

FINDINGS OF FACT:

The Department finds that the proposed changes as set forth in the June 2006 *Register of Regulations* should be adopted.

THEREFORE, IT IS ORDERED, that the proposed regulation to amend the Division of Social Services Manual (DSSM) to provide a standard pharmacy benefit to Chronic Renal Disease Program recipients is adopted and shall be final effective August 10, 2006.

Vincent P. Meconi, Secretary, DHSS, 7/14/06

DMMA FINAL ORDER REGULATION #06-30
REVISIONS:

50100.1 Medications

The CRDP has the ability to fund prescription medications, over-the-counter medications (OTC's) or both. ~~Prescription drugs covered under CRDP are restricted to products manufactured by pharmaceutical companies that agree to provide manufacturer rebates.~~ As participation in Medicare Part D or proof of creditable coverage became a condition of CRDP eligibility, the CRDP program no longer provides primary pharmacy benefit coverage for many medications. As such, to improve access to prescription and OTC medications, benefits may be offered to all CRDP eligible clients, regardless of individual need review.

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 licensed practitioner. Prescription drugs will be reimbursed in accordance with current Division of Medicaid and Medical Assistance formulary limitations and procedures.

Reimbursement for medications will be made only for ~~client's authorized by the~~ clients currently eligible and approved for participation in CRDP. All third party resources must be used before CDRP funds are utilized. ~~Client's eligibility for the medication benefit is based upon the outcome of their medical and financial assessment.~~

Prescription medications ~~potentially~~ will be funded as described above if prescribed by a physician or licensed practitioner for eligible CRDP clients. Refills may be authorized in compliance with appropriate pharmacy laws~~.~~ and are subject to Division of Medicaid and Medical Assistance (DMMA) formulary restrictions. Reimbursements for OTC products for eligible clients are those, which the physician/practitioner has provided ~~written~~ a legal prescription ~~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.~~ OTCs are covered based on the DMMA policy with an exception for nutritional supplements (for additional information, refer to "DSSM 50100.2 Nutritional Supplements").

At the point of sale, the pharmacist will determine electronically if ~~CRDP~~ another funding source is available, and bill that vendor(s) first, and then will determine if CRDP will fund the requested product. In order for the pharmacy to receive CRDP payment, they must ~~have~~ be a participating Delaware Medicaid provider, with a valid provider identification number.

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

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

(Break in Continuity of Sections)

50100.2 Nutritional Supplements

Reimbursement for nutritional supplements will be made only for clients currently eligible and approved for participation in CRDP. All third party resources must be used before CRDP funds are utilized.

Nutritional supplements will be funded as described above if prescribed by a physician or licensed practitioner for eligible CRDP clients. Refills may be authorized in compliance with appropriate pharmacy laws and are subject to Division of Medicaid and Medical Assistance (DMMA) formulary restrictions. Reimbursements for nutritional supplements for eligible clients are those, which the physician/practitioner has provided a legal prescription to the pharmacist.

At the point of sale, the pharmacist will determine electronically if another funding source is available, and bill that vendor(s) first, and then will determine if CRDP will fund the requested product. In order for the pharmacy to receive CRDP payment, they must be a participating Delaware Medicaid provider, with a valid provider identification number.

At the point of sale, the pharmacist will be alerted if program quantity limits for nutritional supplements have been exceeded and if prior authorization is needed by EDS.

Prior authorization criteria for eligible clients:

~~Nutritional supplements will only be funded by the CRDP if the~~ The client ~~is~~ must be 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, approval of funding ~~the only~~ nutritional supplements is subject to Division of Medicaid and Medical Assistance formulary restrictions. ~~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~~ as prescribed by the physician or licensed practitioner. ~~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.~~

10 DE Reg. 347 (08/01/06) (Final)