

DEPARTMENT OF HEALTH AND SOCIAL SERVICES
DIVISION OF MEDICAID AND MEDICAL ASSISTANCE
Statutory Authority: 31 Delaware Code, Section 512 (31 **Del.C.** §512)
16 **DE Admin. Code** 50000

PROPOSED

PUBLIC NOTICE

50000 Chronic Renal Disease Program

Executive Order 36 Review and Reform of State Agency Regulations Part 2

In compliance with the State's Administrative Procedures Act (APA - Title 29, Chapter 101 of the **Delaware Code**) and under the authority of 31 **Del. C.** §512, Delaware Health and Social Services ("Department") / Division of Medicaid and Medical Assistance (DHSS/DMMA) is proposing a periodic review of Division of Social Services Manual (DSSM), specifically, regulations promulgated three years ago or more for possible modification or elimination.

Any person who wishes to make written suggestions, compilations of data, testimony, briefs, or other written materials concerning the proposed new regulations must submit same by mail to Planning and Policy Unit, Division of Medicaid and Medical Assistance, 1901 North DuPont Highway, P.O. Box 906, New Castle, Delaware 19720-0906; by email to DHSS_DMMA_Publiccomment@Delaware.gov; or by fax to 302-255-4413 by 4:30 p.m. on July 1, 2025. Please identify in the subject line: Executive Order 36 Review and Reform of State Agency Regulations Part 2.

The action concerning the determination of whether to adopt the proposed regulation will be based upon the results of Department and Division staff analysis and the consideration of the comments and written materials filed by other interested persons.

SUMMARY OF PROPOSAL

The purpose of this notice is to advise the public that Delaware Health and Social Services (DHSS)/Division of Medicaid and Medical Assistance (DMMA) is proposing a periodic review of Division of Social Services Manual (DSSM), regarding Executive Order 36 Review and Reform of State Agency Regulations Part 2.

Statutory Authority

- State of Delaware Executive Order 36, Review and Reform of State Agency Regulations

Background

Delaware Health and Social Services (DHSS) is the principal state agency charged with providing health and other essential human services so its citizens can live healthier, more prosperous, and more productive lives.

On June 14, 2012, Governor Jack Markell signed Executive Order 36, which establishes a process for the review of certain regulations by state agencies. In Executive Order 36, "Review and Reform of State Agency Regulations", the Governor recognized the importance of a streamlined, effective, and efficient regulatory framework designed to promote economic growth and improve the efficiency of state government.

While regulations can establish clear and transparent frameworks for competition and economic activity, unnecessary and duplicative regulations can also damage market economy by imposing unnecessary costs on the private sector and citizens.

Executive Order 36 is the mechanism to achieve a more robust and effective regulatory framework. The Governor has directed the heads of all state departments and agencies to review existing significant regulations to identify those rules that can be eliminated as obsolete, unnecessary, burdensome, or counterproductive or that can be modified to be more effective, efficient, flexible, and streamlined.

While the systematic review of regulations will focus on the elimination of rules that are no longer justified or necessary, the review will also consider strengthening, complementing, or updating rules where necessary or appropriate—including, if relevant, undertaking new rulemaking.

DMMA is responsible for regulations, in whole or in part, that appear in the Delaware Administrative Code and are identified as Division of Social Services Manual (DSSM) Sections 16000, 30000, 50000, 70000, and 80000. These regulations may

be viewed online at: Delaware Social Services Manual

Summary of Proposal

Purpose

The purpose of this proposed regulation is to conduct a periodic review of Division of Social Services Manual (DSSM).

Summary of Proposed Changes

Effective August 11, 2025, the DHSS/DMMA proposes to amend DSSM promulgated three years ago or more for possible modification or elimination.

Public Notice

In accordance with the *federal* public notice requirements established in Section 1902(a)(13)(A) of the Social Security Act and 42 CFR 440.386 and the *state* public notice requirements of Title 29, Chapter 101 of the **Delaware Code**, DHSS/DMMA gives public notice and provides an open comment period for 30 days to allow all stakeholders an opportunity to provide input on the proposed regulation. Comments must be received by 4:30 p.m. on July 1, 2025.

Provider Manuals and Communications Update

Also, there may be additional provider manuals that may require updates as a result of these changes. The applicable Delaware Medical Assistance Program (DMAP) Provider Policy Specific Manuals and/or Delaware Medical Assistance Portal will be updated. Manual updates, revised pages or additions to the provider manual are issued, as required, for new policy, policy clarification, and/or revisions to the DMAP program. Provider billing guidelines or instructions to incorporate any new requirement may also be issued. A newsletter system is utilized to distribute new or revised manual material and provide other pertinent information regarding DMAP updates. DMAP updates are available on the Delaware Medical Assistance Portal website: <https://medicaid.dhss.delaware.gov/provider>

Fiscal Impact

There is no fiscal impact.

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~~ is responsible for processing all eligible CRDP claims.

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

50100.1 Medications

The CRDP ~~has the ability to~~ may fund prescription medications, over-the-counter medications (OTC's) or both. 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 & Medical Assistance formulary limitations and procedures.

Reimbursement for medications 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.

Prescription medications 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 a legal prescription to the pharmacist. 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 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.

9 DE Reg. 775 (11/01/05)

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

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:

The client 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 nutritional supplements is subject to Division of Medicaid and Medical Assistance formulary restrictions.

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 period as prescribed by the physician or licensed practitioner.

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

50100.3 Transportation

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.

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

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~~ 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, co-payments, 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.

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

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).

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

50300 Referral Process

~~A referral for the Chronic Renal Disease Program (CRDP) may be received from many sources. Client, family member, caretaker, physicians and/or Clients, family members, caretakers, physicians, or other professionals may initiate the referral process by contacting the CRDP office and requesting that to request an application be mailed or faxed. Completed applications may be returned to the office by mail or telephone, fax, via mail, in person with reasonable accommodations for those with disabilities, as defined by the Americans with Disabilities Act (ADA), and through other commonly available electronic means. Once the application has been received, the client or referral source will be contacted to set up an appointment to complete the CRDP eligibility determination.~~

11 DE Reg. 318 (09/01/07)

50400 Application Process

Applicants must be medically and financially eligible to receive coverage. The client or ~~his~~ the client's representative must complete and sign a CRPD application form ~~and mail or fax to the DMMA office. Completed applications may be submitted by telephone, fax, via mail, in person with reasonable accommodations for those with disabilities, as defined by the Americans with Disabilities Act (ADA), and through other commonly available electronic means. Once the application has been received, DMMA may contact the applicant or the referral source if additional information is required to complete the determination of eligibility.~~ The date the application is received in the DMMA office is the first possible date that benefits may start. ~~The client must complete an application in person or via the telephone. 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.

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

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~~ non-citizen.

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.

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

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 gross countable income must be below 300% of the Federal Poverty Level (FPL). See DSSM 20200 for Income. 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.

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

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~~ the applicant's need for food 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, net earnings from self-employment (NESE), rental income, etc.

50700.2 Resources

There is no resource test.

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

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.

28 DE Reg. 842 (06/01/25) (Prop.)