

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

Standards for the Coverage of Organ Transplant Services

**IN THE MATTER OF: REVISION OF THE REGULATION OF DELAWARE'S TITLE XIX MEDICAID STATE PLAN
ATTACHMENT 3.1-E**

NATURE OF THE PROCEEDINGS:

Delaware Health and Social Services ("Department") / Division of Medicaid and Medical Assistance (DMMA) initiated proceedings to submit a state plan amendment regarding Organ Transplants, specifically, *standards for the coverage of organ and tissue transplant services*. 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 August 2014 *Delaware Register of Regulations*, requiring written materials and suggestions from the public concerning the proposed regulations to be produced by August 31, 2014 at which time the Department would receive information, factual evidence and public comment to the said proposed changes to the regulations.

SUMMARY OF PROPOSAL

The proposed provides notice to the public that Delaware Health and Social Services/Division of Medicaid and Medical Assistance (DHSS/DMMA) intends to submit a state plan amendment to the Centers for Medicare and Medicaid Services (CMS) regarding Organ Transplants, specifically, standards for the coverage of organ and tissue transplant services.

Statutory Authority

- Section 1903(i) of the Social Security Act, *Payment to States, State Plan Requirement, Organ Transplant Procedures*
- 42 CFR 441.35, *Organ Transplants*
- State Medicaid Manual Section 4210, *Organ Transplants*
- Section 1138 of the Social Security Act, *Hospital Protocols for Organ Procurement and Standards for Organ Procurement Agencies*
- 42 CFR Subpart G, *Requirements for Certification and Designation and Conditions for Coverage: Organ Procurement Organizations*

Background

Section 9507 of the federal Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), codified as section 1903(i) of the Social Security Act, requires states, as part of the Medicaid program, to establish standards for coverage of transplantation services. Specifically, Section 1903(i)(1) requires the denial of Federal Financial Participation (FFP) for organ transplants unless the State plan provides written standards concerning the coverage of such procedures. The statute does not list the transplant procedures for which standards must be written, but the organs about which questions are most commonly asked are: cornea, kidney, heart, liver, bone marrow, pancreas and combined heart-lung. States can choose to cover no organ transplant procedures, some types of transplants and not others, or all transplants. States should specify in the written standards which organs the state covers and any special conditions or limitations which apply to them.

Standards for Coverage

If a state covers organ transplant procedures, written standards must be furnished for the coverage of these procedures which provide that:

- "similarly situated individuals are treated alike;
- "any restriction, on the facilities or practitioners which may provide such procedures, is consistent with the accessibility of high quality care to individuals eligible for the procedures under the State plan; and
- "services are reasonable in amount, duration, and scope to achieve their purpose.

Coverage for organ transplants is described in Attachment 3.1-E of the Medicaid State plan pursuant to the requirement of 42 CFR 441.35 (Organ Transplants), and meet the requirements of Section 4201 (Organ Transplants) of the

Summary of Proposal

Delaware Medicaid currently covers the following transplant procedures for eligible Medicaid recipients:

- Heart transplant
- Heart/Lung transplant
- Liver (any age) transplant
- Cornea transplant
- Bone Marrow transplant
- Pancreas transplant
- Kidney transplant

Prior authorization is required for all transplant services.

Medicaid State Plan page Attachment 3.1-E establishes standards and criteria for tissue and organ transplant services. The purpose of the proposed state plan amendment is to update standards for coverage of organ transplant services by adding "Intestinal transplant" to the list of transplant procedures to reflect long-standing practice. Also, as the current plan page is outdated, the amended state plan is reformatted to provide the information in a more useful manner as well as to update language to reflect current terms and usage, to incorporate citations, to clarify text to reflect current policy and, to reconcile state plan and provider manual policies.

The agency's proposal involves no change in the definition of those eligible to receive benefits under Medicaid, and the transplantation services benefits available to eligible recipients remains the same.

The provisions of this state plan amendment are subject to approval by the Centers for Medicare and Medicaid Services (CMS). Upon CMS approval, the applicable Delaware Medical Assistance Program (DMAP) Provider Policy Specific Manuals will be updated.

Fiscal Impact Statement

This revision imposes no increase in cost on the General Fund.

SUMMARY OF COMMENTS RECEIVED WITH AGENCY RESPONSE

No public comments were received.

FINDINGS OF FACT:

The Department finds that the proposed changes as set forth in the August 1, 2014 *Register of Regulations* should be adopted.

THEREFORE, IT IS ORDERED, that the proposed regulation to amend the Medicaid state plan regarding Organ Transplants, specifically, *standards for the coverage of organ and tissue transplant services* is adopted and shall be final effective October 10, 2014.

Rita M. Landgraf, Secretary, DHSS

DMMA FINAL ORDER REGULATION #14-39

REVISION:

Revision: HCFA-PM-87-4
MARCH 1987

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STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE: **DELAWARE**
STANDARDS FOR THE COVERAGE OF ORGAN AND TISSUE TRANSPLANT SERVICES

Coverage of Transplant Services

The following types of medically necessary organ and tissue transplantation procedures are covered as specified in the Delaware Medical Assistance Program (DMAP) Provider Specific Policy Manuals:

- Heart
- Heart/Lung
- Liver (any age)
- Pancreas
- Kidney
- Intestinal (small bowel)
- Cornea
- Bone Marrow and Peripheral Blood Stem Cell

- : Any other transplants Delaware Medicaid determine to be added to the list of medically necessary organ and tissue transplantation procedures.

Coverage is limited to transplant services that are specified in the Delaware Medical Assistance Program (DMAP) Provider Specific Policy Manuals. Additionally, the criteria for determining a recipient's clinical eligibility for transplantation are specified in the DMAP Manuals, as well. The Delaware Medical Assistance Program Provider Specific Policy Manuals, including all updates to the manuals, are available on the DMAP website at: <http://www.dmap.state.de.us/downloads/manuals.html>.

Experimental and/or Investigational Services

Services considered experimental and/or investigational are not a benefit of the Delaware Medical Assistance Program.

Transplant Criteria

Reimbursement will be made for medically necessary transplant services provided to an eligible Delaware Medicaid recipient.

Prior Authorization

All transplants require prior authorization. Specific prior authorization requirements, including the Prior Authorization Request Form, may be found in the Delaware Medical Assistance Program Provider Manuals located on: <http://www.dmap.state.de.us/downloads/manuals.html>

Standards for Coverage of Organ and Transplant Services

The following standards and criteria must be met before transplantation services are payable under the Delaware Medical Assistance Program:

Facility -The transplant facility must meet the requirements contained in Section 1138 of the Social Security Act, Hospital Protocols for Organ Procurement and Standards for Organ Procurement Agencies. The transplant facility performing the transplant must have approval for performing the surgery through the Certification of Need (CON) process and must supply supporting documentation of this.

Patient - Documentation from an appropriate attending specialist and admitting facility that all of the following conditions are met:

1. Current medical therapy has failed and will not prevent progressive disability and death;
2. The patient does not have other major systemic disease that would comprise the transplant outcome;
3. There is every reasonable expectation, upon considering all the circumstances involving the patient, that there will be strict adherence by the patient to the long-term difficult medical regimen which is required;
4. The transplant is likely to prolong life for at least two years, and to restore a range of physical and social function suited to activities of daily living;
5. The patient is not both in an irreversible terminal state (moribund) and on a life support system;
6. The patient has a diagnosis appropriate for the transplant;
7. The patient does not have multiple uncorrectable severe major system congenital anomalies.