DEPARTMENT OF HEALTH CARE FINANCE

NOTICE OF FINAL RULEMAKING

The Director of the Department of Health Care Finance, pursuant to the authority set forth in An Act to enable the District of Columbia to receive federal financial assistance under Title XIX of the Social Security Act for a medical assistance program, and for other purposes, approved December 27, 1967 (81 Stat. 774; D.C. Official Code § 1-307.02 (2012 Repl. & 2014 Supp.)) and Section 6(6) of the Department of Health Care Finance Establishment Act of 2007, effective February 27, 2008 (D.C. Law 17-109; D.C. Official Code § 7-771.05(6) (2012 Repl.)), hereby gives notice of the adoption, of a new Section 937 (Transplantation Services) under Chapter 9 (Medicaid Program) of Title 29 (Public Welfare) of the District of Columbia Municipal Regulations (DCMR).

The final rulemaking is being promulgated to: (1) establish standards governing Medicaid reimbursement of transplantation services; (2) identify the types of transplantation services available under the Medicaid program; (3) authorize Medicaid coverage for two new transplantation procedures—lung and autologous hematopoietic stem cell transplantation; and (4) establish provider participation standards. Expanding coverage of transplantation services will allow the District's Medicaid program to focus on the patient's severity of illness, needed resources and risk of mortality. This will ensure that District residents have continued access to quality transplantation services.

The State Plan Amendment (SPA), which authorized the creation of this rulemaking, was approved by the Council through the Medical Assistance Program Emergency Amendment Act of 2014, signed July 14, 2014 (D.C. Act 20-377; 61 DCR 007598 (August 1, 2014)); and subsequently approved by the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) with an effective date of October 1, 2014. A Notice of Emergency and Proposed Rulemaking was published in the *D.C. Register* on December 5, 2014 at 61 DCR 012509. No comments were received. No substantive changes have been made. The Director adopted these rules as final on January 8, 2015 and they shall become effective on the date of publication of this notice in the *D.C. Register*.

A new Section 937 of Chapter 9, MEDICAID PROGRAM, of Title 29, PUBLIC WELFARE, DCMR, entitled ORGAN TRANSPLANT SERVICES, is added to read as follows:

937 ORGAN TRANSPLANT SERVICES

937.1 The purpose of this section is to establish standards governing Medicaid reimbursement of transplantation services, identify types of transplantation services offered under the Medicaid program, authorize Medicaid coverage for two new transplantation procedures—lung and autologous hematopoietic stem cell transplantation; and to establish conditions of participation for Medicaid-enrolled providers.

937.2 Medicaid reimbursement shall be provided for transplantation services performed on a person who is currently enrolled in the District's Medicaid program and continues to be eligible throughout the period of hospitalization and follow-up treatment.

937.3 In order to qualify for reimbursement of transplantation services, the following criteria shall be used:

(a) The recipient is or has been diagnosed and recommended by his/her physician(s) for an organ or stem cell transplantation as the medically necessary treatment for the patient's survival;

(b) There is a reasonable expectation by the physician that the recipient possesses sufficient mental capacity and awareness to undergo the mental and physical rigors of post-transplantation rehabilitation, with adherence to the long-term medical regimen that may be required;

(c) There is a reasonable expectation that the recipient shall recover sufficiently to resume physical and social activities of daily living;

(d) Alternative medical and surgical therapies that might be expected to yield both short and long term survival have been tried or considered and determined not sufficient to prevent progressive deterioration and death; and

(e) The recipient is diagnosed as having no other system disease, major organ disease, or condition considered likely to complicate, limit, or preclude expected recuperation and rehabilitation after transplantation.

937.4 The types of transplants eligible for reimbursement under the Medicaid program are the following:

(a) Liver transplantation;

(b) Heart transplantation;

(c) Lung transplantation;

(d) Kidney transplantation;

(e) Allogeneic stem cell transplantation; and

(f) Autologous hematopoietic stem cell transplantation.

937.5 In order to receive Medicaid reimbursement, transplantation services shall be performed by a transplant program or center.

937.6 In order to be eligible for Medicaid reimbursement of transplant services, transplant centers shall meet the following requirements:

(a) Be located in a Medicare-enrolled hospital;

(b) Be certified and is a member in good standing by the Organ Procurement and Transplantation Network (OPTN) for the specific organ/organs being transplanted consistent with 42 C.F.R §§ 482.72, 482.74, and 482.76;

(c) If located in the District, maintain the applicable Certificate of Need (CON) issued by the State Health Planning and Developmental Agency (SHPDA) in accordance with D.C. Official Code § 44-406;

(d) If located outside of the District of Columbia, maintain any requirements of that particular state or jurisdiction for transplant program/centers; and

(e) Be enrolled in the D.C. Medicaid program.

937.7 All transplantation procedures shall be "prior authorized" by the Department of Health Care Finance, or its designee, and performed in accordance with the clinical standards established under the State Plan for Medical Assistance consistent with 42 C.F.R § 441.35.

937.8 Standards governing Medicaid reimbursement of liver transplantation are as follows:

(a) Diagnosis/clinical conditions which shall include but are not limited to cirrhosis with hepatic decompensation, primary biliary cirrhosis (PBC), primary sclerosing cholangitis (PSC), fulminant hepatic failure, cirrhosis with hepatocellular carcinoma (HCC); and

(b) D.C. Medicaid beneficiaries with hepatocellular carcinoma (HCC) initially staged outside of the Milan Criteria or "downstaged" to within the Milan Criteria by locoregional therapy(ies) shall not be eligible for liver transplantation services.

937.9 In order to be eligible for Medicaid reimbursement for heart transplantation services, each recipient shall have a diagnosis/clinical condition that include end-stage heart disease.

937.10 Standards governing Medicaid reimbursement of lung transplantation are as follows:

(a) Diagnosis/clinical conditions which shall include chronic, irreversible, progressively disabling, end-stage lung disease who is failing medical therapy, or for whom no effective medical therapy exists; and

(b) The recipient has been diagnosed with one or more of the following conditions:

(1) Alpha-1 antitrypsin deficiency;

(2) Bilateral bronchiectasis;

(3) Bronchiolitis obliterans;

(4) Bronchopulmonary dysplasia;

(5) Chronic obstructive pulmonary disease;

(6) Cystic fibrosis;

(7) Eisenmenger's syndrome;

(8) Emphysema;

(9) Idiopathic pulmonary fibrosis;

(10) Lymphangiomyomatosis;

(11) Primary pulmonary hypertension;

(12) Pulmonary fibrosis;

(13) Pulmonary hypertension due to cardiac disease;

(14) Recurrent pulmonary embolism;

(15) Sarcoidosis; or

(16) Scleroderma.

937.11 Standards governing Medicaid reimbursement of lung transplants for recipients with a contraindication are as follows:

(a) A recipient with a contraindication shall be considered to be a poor candidate for a lung transplant under the Medicaid Program, but shall not be automatically denied coverage if based on the assessment of the patient's total clinical condition and co-morbidities, it is determined by

their treating physician that the patient's condition would not compromise a successful transplant outcome; and

(b) Contraindications for lung transplant shall include but are not limited to the following:

(1) Malignancy in the last two (2) years, with the exception of cutaneous squamous and basal cell tumors; in general, a five (5) year disease-free interval is prudent;

(2) Untreatable advanced dysfunction of another major organ system (*e.g.*, heart, liver, or kidney), including coronary artery disease not amenable to percutaneous intervention or bypass grafting, or associated with significant impairment of left ventricular function;

(3) Non-curable chronic extrapulmonary infection including chronic active viral hepatitis B, hepatitis C, and human immunodeficiency virus;

(4) Significant chest wall/spinal deformity;

(5) Documented nonadherence or inability to follow through with medical therapy or office follow-up, or both;

(6) Untreatable psychiatric or psychologic condition associated with the inability to cooperate or comply with medical therapy;

(7) Absence of a consistent or reliable social support system;

(8) Substance addiction (*e.g.*, alcohol, tobacco, or narcotics) that is either active or within the last six (6) months;

(9) Critical or unstable clinical condition (*e.g.*, shock, mechanical ventilation or extra-corporeal membrane oxygenation);

(10) Severely limited functional status with poor rehabilitation potential;

(11) Colonization with highly resistant or highly virulent bacteria, fungi, or mycobacteria;

(12) Severe obesity defined as a body mass index (BMI) exceeding thirty (30) kg/m^2; or

(13) Mechanical ventilation.

937.12 Standards governing Medicaid reimbursement of kidney transplants are as follows:

(a) The recipient must have:

(1) A diagnosis/clinical condition which shall include stage 4 or stage 5 renal disease on chronic dialysis and have a glomerular filtration rate less than or equal to twenty (20) mL/min/1.73 m^2 ; or

(2) A diagnosis of End-Stage Renal Disease (ESRD).

(b) The standards under § 937.12(a) shall be documented by one or more of the following:

(1) The recipient shall be receiving chronic dialysis and have a Glomerular Filtration Rate (GFR) less than or equal to (≤) 20 mL/min/1.73 m^2; or

(2) The recipient shall have stage IV chronic kidney disease with all of the following:

(i) Written documentation from the United Network for Organ Sharing (UNOS) that the recipient has been officially activated on the wait-list as "ACTIVE";

(ii) Clinical documentation that the recipient's renal failure is rapidly progressing.

937.13 Reimbursement for kidney transplants shall not include recipients diagnosed with one or more of the following conditions:

(a) Reversible renal failure;

(b) Active infection including hepatitis, cytomegalovirus, Epstein-Barr virus and Human immunodeficiency virus infections;

(c) Anatomic anomaly that precludes kidney transplantation;

(d) Cancer (except for localized non-melanoma skin cancer);

(e) Advanced or uncorrectable coronary artery disease or congestive heart failure;

(f) Advanced or severe pulmonary disease;

(g) Cerebrovascular disease;

(h) Severe peripheral vascular disease or claudication;

(i) Other organ system failure.

937.14 Standards governing Medicaid reimbursement of allogeneic stem cell transplantation standards are as follows:

(a) Diagnosis/clinical conditions include, but are not limited to, Acute Myelogenous Leukemia (AML), Acute lymphocytic leukemia (ALL), Myelodysplastic syndrome (MDS), Chronic Myelogenous Leukemia (CML), Non-Hodgkin's lymphoma (NHL), Chronic lymphocytic leukemia (CLL); and

(b) The recipient shall not be diagnosed with multiple myeloma.

937.15 Standards governing Medicaid reimbursement of autologous hematopoietic stem cell transplantation standards are as follows:

(a) Diagnosis/clinical conditions include, but are not limited to, Acute Myelogenous Leukemia (AML), Non-Hodgkins' Lymphoma (NHL), Hodgkin's Lymphoma (HL), Multiple Myeloma (MM), recurrent neuroblastoma with localized brain recurrence after surgical resection (RN); and

(b) The recipient shall not be diagnosed with one or more of the following conditions:

(1) Acute leukemia not in remission;

(2) Chronic granulocytic leukemia;

(3) Solid tumors (other than neuroblastoma); or

(4) Tandem transplantation (multiple rounds of hematopoietic stem cell transplantation) for recipients with multiple myeloma.

937.99 DEFINITIONS

For purposes of this section, the following terms shall have the meanings ascribed:

Allogeneic stem cell transplantation – A procedure in which the transplanted stem cells come from a donor whose tissue type closely matches the recipient's.

Autologous hematopoietic stem cell transplantation - A procedure in which the recipient's healthy stem cells are harvested and transplanted into the recipient.

Contraindication - A specific situation in which a drug, procedure, or surgery is typically not to be used because it may be harmful to the patient.

Department of Health Care Finance – The single state agency responsible for the administration of the District of Columbia's Medicaid program.

Period of hospitalization - The total period of time that the person is receiving medical services related to the transplantation procedure.

Prior authorization- The process of obtaining authorization from the Department of Health Care Finance before the beneficiary receives services.

Recipient - The Medicaid-enrolled person who is receiving transplantation services.