

DISTRICT OF COLUMBIA DEPARTMENT OF HEALTH

NOTICE OF EMERGENCY AND PROPOSED RULEMAKING

The Director of the Department of Health, 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(b)), Reorganization Plan No. 4 of 1996, and Mayor's Order 97-42, entitled "Establishment of the District of Columbia Department of Health," dated February 18, 1997, hereby gives notice of the adoption, on an emergency basis, of a new Chapter 64 of Title 29 of the District of Columbia Municipal Regulations (DCMR) entitled "Medicaid Section 1115 Health Care Reform Demonstration" (HIV/AIDS Demonstration Project) under Section 1115 of the Social Security Act.

These proposed rules establish program requirements for the HIV/AIDS Demonstration Project to expand access to costly but highly effective anti-retroviral drug therapy for individuals diagnosed with Human Immunodeficiency Virus (HIV) and to increase access to Medicaid benefits for the District's HIV-identified population.

Many citizens in the District of Columbia who are diagnosed as HIV positive need access to Highly Active Anti-Retroviral Therapy. However, a large number of low-income D.C. residents with HIV are uninsured, under-insured, or simply cannot afford Highly Active Anti-Retroviral Therapy, which costs approximately \$12,000 annually. The District, therefore plans to expand Medicaid health benefit access for its low-income residents who have HIV.

The emergency rulemaking was adopted on April 7, 2004 and shall become effective one day after the publication of the emergency rules in the *D.C. Register*. The emergency rules will expire 120 days from the date of effectiveness or upon publication of Final Rulemaking in the *D.C. Register*, whichever occurs first.

The Director also gives notice of the intent to take final rulemaking action to adopt these proposed rules in not less than thirty (30) days from the date of publication of this notice in the *D.C. Register*.

Title 29 DCMR is be amended by adding the following new Chapter 64 which shall read as follows:

MEDICAID SECTION 1115 HEALTH CARE REFORM DEMONSTRATION PROJECT**CHAPTER 64 MEDICAID SECTION 1115 HEALTH CARE REFORM DEMONSTRATION PROJECT****6400 GENERAL PROVISIONS**

- 6400.1 The purpose of this Chapter is to establish standards governing the administration of the Medicaid Section 1115 Health Care Reform Demonstration for individuals with HIV (the "Demonstration Project"), as authorized under §1115 of the Social Security Act.
- 6400.2 The Demonstration Project term shall be from March 19, 2004 until August 31, 2009
- 6400.3 The Demonstration Project shall not be construed as an entitlement and may be terminated at any time by the United States Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), or by the District of Columbia.

6401 ELIGIBILITY REQUIREMENTS

- 6401.1 Each individual eligible to receive services shall meet all of the following requirements:
- (a) Is a District of Columbia resident:
 - (b) Has a gross income at or below one hundred percent (100%) of the Federal Poverty Level (FPL);
 - (c) Has resource limits of \$2,600 for an individual and \$3,000 for an individual and his/her spouse;
 - (d) Owns no property other than the home in which he or she lives and a car;
 - (e) Is not eligible for the traditional Medicaid program under Titles XIX and XXI of the Social Security Act;
 - (f) Is HIV-infected;
 - (g) Does not reside in a long-term care facility, mental health facility, or penal institution; and
 - (h) Has completed an informed consent form at the time of application.

6403 INCOME REQUIREMENTS

6403.1 Each applicant shall provide documentation of income that shall include the following:

- (a) For a gross income determination, each applicant shall provide evidence of any of the following documentation that is applicable:
 - (1) Social Security cash benefit verification;
 - (2) Unemployment compensation;
 - (3) Veteran's benefits;
 - (4) Pension check stub;
 - (5) Any other public assistance documentation; or
 - (6) Any other award letter for receipt of cash benefits.

6404 ENROLLMENT PROCESS

6404.1 Each applicant shall complete a single application that shall be signed and dated. Application forms shall be made available and submitted to the District's HIV/AIDS Administration (HAA) for review and approval.

6404.2 Each applicant shall obtain and present to HAA one (1) piece of documentation to support proof of residency within the District of Columbia. Documents needed to prove residency include the following:

- (a) Copy of a utility bill or a letter from a government agency with the applicant's District of Columbia address listed;
- (b) Voter registration card;
- (c) District of Columbia driver's license, or non-driver's identification; or
- (d) Lease or mortgage agreement.

6404.3 Each applicant shall obtain one (1) of the following signatures on the application form to verify his or her HIV status:

- (a) Physician's signature; or
- (b) Case manager's signature.

- 6404.4 Each applicant shall provide evidence of receipt of other health insurance coverage from the following sources, if applicable:
- (a) Health insurance card;
 - (b) Letter from the health insurance company;
 - (c) Consolidated Omnibus Budget Reconciliation Act of 1986 (COBRA) coverage;
 - (d) Retirement health benefit coverage;
 - (e) Medicare coverage; or
 - (f) Any other health plan.
- 6404.5 Each applicant shall complete, sign, and date an informed consent form as part of the application process during the initial enrollment. Each applicant shall certify by signing the informed consent form that each applicant understands the following:
- (a) Participation in the Demonstration Project is voluntary; and
 - (b) Enrollment in the Demonstration Project is limited, and if the programs are already full at the time of application, the applicant will be placed on a waiting list;
- 6404.6 The applicant shall complete, sign to acknowledge receipt of a copy of the form, and date the informed consent form in order to be placed on a waiting list.
- 6404.7 Each applicant shall be screened to determine if he or she is eligible for Medicaid benefits under other Medicaid eligibility groups.
- 6404.8 A recipient's eligibility shall be subject to re-determination annually. The re-determination date shall be one (1) calendar year from the date of enrollment.
- 6404.9 A recipient and the case manager, when appropriate, shall receive a notice of re-determination from the District's HIV/AIDS Administration.
- 6404.10 A recipient shall respond to a request for information or to resubmit re-determination forms within thirty (30) days from the date of notice of re-determination. The HIV/AIDS Administration may extend the thirty (30) day requirement in cases involving extraordinary circumstances.

6405 RECIPIENT PROVIDER ASSISTANCE

6405.1 A Demonstration Project recipient shall have the freedom to choose his or her Medicaid providers.

6405.2 The HIV/AIDS Administration shall provide, as necessary, to all waiver recipients a list of the following at the time of initial enrollment:

(a) List of Ryan White case management providers; or

(b) List of Ryan White HIV-experienced physician and clinic providers and Board-certified infectious disease specialists.

6406 ENROLLMENT CEILING AND WAITING LIST

6406.1 The District's Medical Assistance Administration shall establish a ceiling on the number of participants for each year of the project. If the number of applications exceeds the annual enrollment ceiling prior to the Demonstration Project implementation, then participants in the Demonstration Project shall be selected by the District's HIV/AIDS Administration on a first come, first served basis, in the order in which their applications were received.

6406.2 After the initial selection of participants in the Demonstration Project is made and the annual enrollment ceiling is established, all other applicants shall be placed on a waiting list.

6406.3 After the initial enrollment ceiling and initial waiting list are established, each subsequent applicant shall be placed on the waiting list in the order in which the application is received by the HIV/AIDS Administration.

6406.4 An applicant on a waiting list shall receive quarterly statements from the HIV/AIDS Administration with the following information:

(a) The applicant's position on the waiting list; and

(b) The projected length of time the applicant shall have to wait prior to enrollment into the HIV/AIDS Demonstration Project.

6406.5 The applicant shall be eligible to enroll in the Demonstration Project when a Notice of Action (NOA) is received from the HIV/AIDS Administration. The NOA shall be mailed both to the initially chosen applicant and to the case manager (unless the applicant expressly prohibits such communication with the case manager to the HIV/AIDS Administration).

- 6406.6 A selected applicant shall have thirty (30) days from the date of the NOA in which to confirm enrollment in the Demonstration Project to the HIV/AIDS Administration.
- 6406.7 If the confirmation for enrollment is not received by the HIV/AIDS Administration within thirty (30) days from the date of the NOA, another applicant shall be invited to enroll in the Demonstration Project.
- 6406.8 If the HIV/AIDS Administration receives the selected applicant's confirmation after thirty (30) days but before ninety (90) days from the date of the NOA, the applicant shall be moved to the top of the waiting list.
- 6406.9 A selected applicant who has not confirmed enrollment within ninety (90) days from the date of the NOA shall be required to reapply to participate in the Demonstration Project.
- 6406.10 The District of Columbia may extend the NOA time lines for confirmation for applicants in extraordinary circumstances.
- 6406.11 An applicant who has reapplied to participate in the Demonstration Project pursuant to 5206.9 may be allowed to fill a vacancy which becomes available for the following reasons:
- (a) An initial Demonstration Project recipient has disenrolled for reasons such as, relocation, death, or failure to meet program eligibility requirements at re-determination; or
 - (b) An initial Demonstration Project recipient has become eligible, due to re-determinations, for other existing Medicaid coverage through Titles XIX or XXI of the Social Security Act.

6407 PROGRAM SERVICES

- 6407.1 Each applicant determined to be eligible pursuant to the criteria set forth in Section 5201 shall be entitled to full Medicaid benefits, including but not limited to the following services:
- (a) Laboratory and diagnostic services;
 - (b) Pharmacy benefits;
 - (c) Highly active antiretroviral drug therapy (HAART);
 - (d) Hospital care;

- (e) Physicians' services;
- (f) Mental health and substance abuse services;
- (g) Medical equipment and supplies;
- (h) Transportation; and
- (i) Case management services.

6407.8 Each participant shall receive HIV prescription medications through the DOH's pharmacy network.

6407.9 Medical treatment for waiver recipients shall not include investigational or experimental therapy, drugs, or surgery.

6408 PROVIDER QUALIFICATIONS

6408.1 Each provider shall enter into a provider agreement with the DOH, Medical Assistance Administration, which shall specify the services to be provided, methods of operation, and financial and legal requirements.

6408.2 Each provider shall furnish the necessary personnel, facilities, equipment, material, and supplies to provide comprehensive Medicaid benefit package services as required pursuant to these rules. Each provider shall have a demonstrated ability to comply with all District and federal laws and rules governing participation of providers in the District of Columbia Medicaid Program, including the ability to meet all District and federal requirements for documentation, billing, and audits.

6408.3 Each provider shall comply with the requirements set forth in the District of Columbia Health Occupations Revisions Act of 1985, effective March 25, 1986 (D.C. Law 6-99; D.C. Official Code §3-1201 *et. seq.*) or comply with the licensure requirements to provide health or medical services in the jurisdiction where the services are rendered.

6408.4 All providers participating in the Demonstration Project shall be licensed to do business in the District of Columbia.

6408.5 Each provider participating in the Demonstration Project shall ensure that all staff providing services to waiver participants are qualified and properly supervised.

6408.6 Each provider shall establish and adhere to policies and procedures for selection and hiring of staff, including but not limited to requiring:

- (a) Evidence of licensure, certification, or registration required by the job being performed;
- (b) For unlicensed staff, evidence of completion of an appropriate degree, training program, or credentials;
- (c) Appropriate references and criminal background checks; and
- (d) Evidence of completion of communicable disease testing as required by District laws and rules.

6408.7 Each provider shall comply with all applicable provisions of District and Federal law and rules pertaining to Title XIX of the Social Security Act, and all District and federal law and rules applicable to the services or activity provided.

6409 CONFIDENTIALITY AND DISCLOSURE OF INFORMATION

6409.1 The District and all providers shall protect the confidentiality of all information that identifies individual Demonstration Project recipients. The District and all providers shall maintain the same standards of confidentiality for recipient information as it maintains for recipients in the Medicaid program.

6409.2 Identifying individual recipient information shall not be disclosed except for purposes directly connected with the administration of the Demonstration Project or as otherwise provided by applicable District and/or federal law and regulations.

6410 TREATMENT OF RECORDS

6410.1 Each provider shall maintain accurate records reflecting treatment, evaluation, and management services. The record for each recipient shall include, but is not limited to, the following information:

- (a) General information including the patient's name, address, date of birth, demonstration recipient identification number, telephone number, and telephone number of emergency contact person;
- (b) Medical information, including medical and social history, results of the initial physical examination, and any other follow-up exams;
- (c) A description of any tests ordered and their results;
- (d) Initial certification and annual re-certifications;

- (e) Plan of care;
- (f) A description of treatment and follow-up care, including the dates of scheduled revisits;
- (g) Recommendations for and referrals to other sources of care;
- (h) Bill of Rights and Responsibilities;
- (i) Signed and dated progress notes, which identify the services provided;
- (j) Evidence of written consent to treatment or documentation of refusal to consent to any treatment, evaluation, or management services; and
- (k) Documentation of the treatment, evaluation, and management of each determination of an emergency medical condition.

6410.2 Each provider shall allow designated personnel of the DOH, HAA, and other authorized agents of the District of Columbia government and the federal government full access to the records for audit purposes.

6410.3 All providers shall maintain for a period of six (6) years a complete copy of the recipient's treatment record.

6410.4 Each recipient's treatment record shall include written documentation of the recipient's treatment needs and services. The documentation shall be written so that it is easily understood by a lay person.

6411 PATIENT RIGHTS AND RESPONSIBILITIES

6411.1 Each provider participating in the Demonstration Project shall develop a written statement of patient rights and responsibilities consistent with the requirements of this section, which shall be given to each recipient in advance of receiving services or during the initial enrollment before the initiation of services.

6411.2 The written statement of patient rights and responsibilities shall be available for distribution to the general public.

6411.3 Each provider participating in the Demonstration Project shall develop policies that ensure that each recipient receiving services has the following rights:

- (a) To be treated with courtesy, dignity, and respect;

- (b) To control his or her own household and lifestyle;
- (c) To participate in the planning of his or her care and treatment;
- (d) To receive treatment, care, and services consistent with the plan of care and to have the plan of care modified, as necessary, for achievement of outcomes;
- (e) To receive services by competent personnel who can communicate with the patient;
- (f) To refuse all or part of any treatment, care, or service and be informed of the consequences thereof;
- (g) To be free from mental and physical abuse, neglect, and exploitation from persons providing services;
- (h) To be assured that for purposes of record confidentiality, the disclosure of the contents of the patient's records is subject to all the provisions of applicable District and federal laws and regulations;
- (i) To voice a complaint or grievance regarding treatment or care, lack of respect for personal property by persons providing services without fear of reprisal; and
- (j) To have access to his or her records.

6411.4

Each recipient shall be responsible for the following:

- (a) Treating all provider personnel with respect and dignity;
- (b) Providing accurate information when requested;
- (c) Informing provider personnel when instructions are not understood or cannot be followed;
- (d) Cooperating in making a safe environment for care within the home; and
- (e) Notifying the provider of changes in address, insurance, and other personal information.

6411.5

Each provider shall take appropriate steps to ensure that each recipient, including patients who cannot read or have a language or communication barrier, has received the information required pursuant to this section in a

format designed to make the information understandable. Each provider shall document in the recipient's treatment record the steps taken to ensure that each patient has received the information.

6412 GRIEVANCE AND APPEALS

6412.1 Each Demonstration Project recipient that is aggrieved by a decision of the District affecting that recipient's eligibility to receive a covered service through the Demonstration Project shall be entitled to a hearing before the Department of Human Services' Office of Fair Hearings as provided in D.C. Official Code §4-210.01 and 42 CFR Part 431.200.

6499 DEFINITIONS

For the purposes of this Chapter, the following terms shall have the meaning ascribed:

AIDS – acquired immune deficiency syndrome.

COBRA- Consolidated Omnibus Budget Reconciliation Act of 1986. This program administered by the United States Department of Labor and the United States Pension and Welfare Benefits Administration allows an employee who voluntarily resigns from employment or is terminated for any reason other than "gross misconduct" to continue their former employer's group health plan (both for individual and family coverage) coverage for a period up to eighteen (18) months from the effective date of employment termination or resignation.

Demonstration Project - as authorized under Section 1115 of the Social Security Act.

DOH – Department of Health.

DOH HIV Pharmacy Network - group of participating pharmacies that distribute anti-retrovirals and other HIV-related medications for the Demonstration Project, Medicaid, and the ADAP.

Enrollment ceiling – the limit on the number of recipients in the Demonstration Project.

Gross income – total pre-tax income for a household; this amount includes all income that the Income Maintenance Administration and other agencies may disregard in their eligibility determinations for other programs (including current law Medicaid).

HAART – Highly Active Anti-Retroviral Therapy. A broad category of treatment regimens for individuals with HIV usually comprised of three (3) or more anti-retroviral drugs that, in previously untreated HIV-1-infected patients, are expected to reduce plasma virus levels below the limits of detection. Most HAART regimens include drugs from at least two (2) of the three (3) classes of anti-retroviral therapy (nucleoside analog reverse transcriptase (RT) inhibitors, non-nucleoside analog RT inhibitors, and protease inhibitors).

HIV – human immunodeficiency virus. A retrovirus that causes AIDS, formerly known as HTLV-III.

Comments on the proposed rules shall be submitted in writing to Robert T. Maruca, Senior Deputy Director, Medical Assistance Administration, Department of Health, 825 North Capitol Street, N.E., 5th Floor, Washington, D.C. 20002, within thirty (30) days from the date of publication of this notice in the D.C. Register. Copies of the proposed rules may be obtained from the same address.