

DEPARTMENT OF HEALTH

NOTICE OF FINAL RULEMAKING

The Interim Director of the Department of Health, pursuant to the authority set forth under § 302(14) of the D.C. Health Occupations Revision Act of 1985, effective March 15, 1986 (D.C. Law 6-99; D.C. Official Code § 3-1203.02(14)), and Mayor's Order 98-140, dated August 20, 1998, hereby gives notice of adopting the new rule to Title 17 DCMR, chapter 48 § 4812. This rule permits chiropractors to sell and dispense vitamins, minerals and other dietary supplements at their places of business in the District of Columbia. No changes were made to this rule as published with the Notice of Proposed Rulemaking in the D.C. Register on May 7, 2004, at 51 DCR 4792. This rule will become effective upon publication of this notice in the D.C. Register.

Chapter 48 (Chiropractic) of Title 17 DCMR (Business, Occupations & Professions) (May 1990) is amended as follows:

A new section 4812 is added and reads as follows:

4812 VITAMINS AND MINERALS

- 4812.1 A chiropractor, who is licensed to practice in the District of Columbia may recommend vitamins, minerals and other dietary supplements in the care and treatment of a patient. The rationale for the recommendation and use shall be documented by the practitioner.
- 4812.2 The practitioner shall conform to standards in the practice of chiropractic in the application of vitamins, minerals, and other dietary supplements as it relates to neuro-muscular-skeletal disorders. The recommendation of vitamins minerals and other dietary supplements shall be therapeutic and not experimental.
- 4812.3 A chiropractor may sell or dispense vitamins, minerals and other dietary supplements from his or her place of business in accordance with applicable laws in the District of Columbia.
- 4812.4 A chiropractor shall not sell, dispense, recommend or suggest vitamins, minerals and dietary supplements or any combination of these products in toxic doses.

DISTRICT OF COLUMBIA DEPARTMENT OF HEALTH

NOTICE OF FINAL 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 of a new Chapter 41 of Title 29 of the District of Columbia Municipal Regulations (DCMR) entitled "Ticket to Work Demonstration Project for Individuals with HIV" under the Ticket to Work and Work Incentives Improvement Act of 1999 (Public Law 106-170).

These proposed rules establish program requirements for the Ticket to Work and Work Incentives Improvement Act (TWWIA) 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 who wish to continue employment under the TWWIA.

Many citizens in the District of Columbia who are diagnosed as HIV positive want to retain their current employment. However, a large number of low-income D.C. residents with HIV, concentrated primarily within the geographical boundaries of Wards Seven (7) and Eight (8), 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 are HIV positive.

A notice of emergency and proposed rulemaking was published in the *D.C. Register* on March 5, 2004 (51 DCR 2469). No comments on the proposed rules were received. No substantive changes have been made. However, the final rules have been changed in section 4112.1 to conform to the grievance procedure previously approved by the federal Centers for Medicare and Medicaid Services (CMS) in the project's Operational Protocol. These rules shall become effective on the date of publication of this notice in the *D.C. Register*.

Title 29 DCMR is amended by adding the following new Chapter 41, which shall read as follows:

TICKET TO WORK DEMONSTRATION PROJECT FOR INDIVIDUALS WITH HIV**CHAPTER 41 TICKET TO WORK DEMONSTRATION PROJECT FOR
INDIVIDUALS WITH HIV****4100 GENERAL PROVISIONS**

- 4100.1 The purpose of this Chapter is to establish standards governing the administration of the Ticket to Work Demonstration Project for individuals with HIV (the "Demonstration Project"), as authorized under §204 of the Ticket to Work and Work Incentives Improvement Act of 1999, approved December 17, 1999 (Public Law 106-170).
- 4100.2 The Demonstration Project term shall be from September 1, 2002, until August 31, 2008.
- 4100.3 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.
- 4100.4 The Demonstration Project shall serve approximately four hundred twenty (420) people living with HIV.

4101 ELIGIBILITY REQUIREMENTS

- 4101.1 Each individual eligible to receive services shall meet all of the following requirements:
- (a) Be a District of Columbia resident;
 - (b) Have a gross income at or below three hundred percent (300%) of the Federal Poverty Level (FPL);
 - (c) Meet the Qualified Medicare Beneficiary (QMB) resources limits set forth in 42 U.S.C. §§ 1396a(a)(10)(E)(i), 1396d(p)(1), 1396d(p)(3). The resource limits shall be \$4000 for an individual and \$6000 for his/her spouse;

- (d) Own no property other than the home in which he or she lives and a car;
- (e) Not be eligible for the traditional Medicaid program under Titles XIX and XXI of the Social Security Act;
- (f) Be HIV-infected;
- (g) Not reside in a long-term care facility, mental health facility, or penal institution;
- (h) Complete an informed consent form at the time of application; and
- (i) Meet the employment requirements as set forth in Section 4102.

4102 EMPLOYMENT REQUIREMENTS

- 4102.1 Each salaried applicant shall document employment for at least a minimum of forty (40) hours in the month preceding the enrollment process or one hundred and twenty (120) hours during the preceding three (3) months prior to the enrollment process at the minimum wage level.
- 4102.2 Each applicant who is self-employed shall qualify for the Demonstration Project by showing economic activity that generated wages in employment for at least forty (40) hours in the month preceding the enrollment process or one hundred and twenty (120) hours during the preceding three (3) months prior to the enrollment process.
- 4102.3 Each recipient shall verify continued employment at the time of the annual re-determination by submitting current documentation of income as identified in Section 4103.1.
- 4102.4.1 Each recipient shall continue to be eligible for the Demonstration Project if he/she is involuntarily unemployed until their annual recertification.

4103 INCOME REQUIREMENTS

- 4103.1 Each applicant shall provide documentation of income that shall include the following:
 - (a) For wage amounts, each applicant shall provide pay stubs for at least one (1) month or a letter from the employer stating the number of hours worked and the wages that were paid; or

(b) 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.

4104 ENROLLMENT PROCESS

4104.1 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 for review and approval.

4104.2 Each applicant shall obtain one (1) piece of documentation to support proof of residency within the Demonstration Project area as defined in Section 4101.1(a). 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.

4104.3 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.

- 4104.4 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) COBRA coverage;
 - (d) Retirement health benefit coverage;
 - (e) Medicare coverage; or
 - (f) Any other health plan.
- 4104.5 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 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;
- 4104.6 The applicant shall complete, sign to acknowledge receipt, and date the informed consent form in order to be placed on a waiting list.
- 4104.7 Each applicant shall be screened to determine if he or she is eligible for Medicaid benefits under other Medicaid eligibility groups.
- 4104.8 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.
- 4104.9 A recipient and the case manager, when appropriate, shall receive a notice of re-determination from the District's HIV/AIDS Administration.
- 4104.10 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.

4104.11 A recipient shall verify, at the time of the annual re-determination, recipient's employment in accordance with 4102.

4105 RECIPIENT PROVIDER ASSISTANCE

4105.1 A Demonstration Project recipient shall have the freedom to choose his or her Medicaid providers.

4105.2 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 physicians, clinic providers and Board-certified infectious disease specialists.

4106 ENROLLMENT CEILING AND WAITING LIST

4106.1 If the number of applications exceed 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.

4106.2 After the initial selection of the participants Demonstration Project is made and the annual enrollment ceiling is established, all other applicants shall be placed on a waiting list.

4106.3 After the initial enrollment ceiling and initial waiting list are established by the District's HIV/AIDS Administration, each subsequent applicant shall be placed on the waiting list in the order in which the application is received by the HIV/AIDS Administration.

4106.4 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 TWWIA Demonstration Project.

4106.5 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).

- 4106.6 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.
- 4106.7 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.
- 4106.8 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.
- 4106.9 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.
- 4106.10 The District of Columbia may extend the NOA time lines for confirmation for applicants in extraordinary circumstances.
- 4106.11 An applicant who has reapplied to participate in the Demonstration Project pursuant to 4106.9 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.
- 4107 **PROGRAM SERVICES**
- 4107.1 Each applicant determined to be eligible pursuant to the criteria set forth in Section 4101 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.

4107.2 Each participant shall receive HIV prescription medications through the Department of Health's pharmacy network.

4107.3 Medical treatment for waiver recipients shall not include investigational or experimental therapy, drugs, or surgery.

4108 PROVIDER QUALIFICATIONS

4108.1 Each provider shall enter into a provider agreement with the Department of Health, Medical Assistance Administration, which shall specify the services to be provided, methods of operation, and financial and legal requirements.

4108.2 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.

4108.3 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.

4108.4 Each provider shall comply with the requirements set forth in the District of Columbia Health Occupations Revision 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.

4108.5 All providers participating in the Demonstration Project shall be licensed to do business in the District of Columbia.

4108.6 Each provider participating in the Demonstration Project shall ensure that all staff providing services to waiver participants are qualified and properly supervised.

4108.7 Each provider shall establish and adhere to policies and procedures for selection and hiring of staff, including but not limited to requiring the following:

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

4108.8 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.

4109 CONFIDENTIALITY AND DISCLOSURE OF INFORMATION

4109.1 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.

4109.2 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.

4110 TREATMENT OF RECORDS

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4110.1 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 an 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.

4110.2 Each provider shall allow designated personnel of the Department of Health, the HIV/AIDS Administration, and other authorized agents of the District of Columbia government and the federal government full access to the records for audit purposes.

4110.3 All providers shall maintain for a period of six (6) years a complete copy of the recipient's treatment record.

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

4111 PATIENT RIGHTS AND RESPONSIBILITIES

- 4111.1 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.
- 4111.2 The written statement of patient rights and responsibilities shall be available for distribution to the general public.
- 4111.3 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.

4111.4

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.

4111.5

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.

4112

GRIEVANCE AND APPEALS

4112.1

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 file a written grievance with the Department of Health, Senior Deputy Director for the Medical Assistance Administration. All other recipients aggrieved by a decision shall be entitled to a hearing before the District of Columbia Office of Administrative Appeals as provided in D.C. Official Code § 4-210.01 and 42 CFR Part 431.200.

4299

DEFINITIONS

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

AIDS- acquired immune deficiency syndrome.

ADAP - AIDS Drug Assistance Program. Program that supplies anti-retrovirals and other HIV-related medications to persons with gross incomes under four hundred percent (400%) of the Federal poverty level.

CMS- Centers for Medicare and Medicaid Services, United States Department of Health and Human Services.

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 - projects funded under the Demonstration to Maintain Independence and Eligibility initiative in the Ticket to Work and Work Incentives Improvement Act of 1999.

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, 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.

TWWIA Demonstration - demonstration project funded under the Demonstration to Maintain Independence and Eligibility initiative in the *Ticket to Work and Work Incentives Improvement Act of 1999* (TWWIA) (Public Law 106-170).

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A notice of proposed rulemaking was published in the *D.C. Register* on April 16, 2004 (51 DCR 3901). No written comments were received on the proposed rules. No substantive changes have been made. These rules shall be come effective on the date of publication of this notice in the *D.C. Register*.

Amend Section 5009 (Reimbursement) of Title 29 DCMR by deleting subsection 5009.2 in its entirety and replacing it to read as follows:

5009.2 Reimbursement for personal care services shall not exceed eight (8) hours of service per day per patient. Reimbursement for services shall not exceed one thousand and forty hours (1040) hours in any twelve (12) month period, unless prior authorization is obtained from MAA.