DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED RULES

1) Heading of the Part: African-American HIV/AIDS Response Code

2) Code Citation: 77 Ill. Adm. Code 691

3) Section Numbers: Proposed Action:

691.100	New
691.200	New
691.300	New
691.400	New
691.500	New
691.600	New
691.700	New
691.800	New
691.900	New
691.1000	New
691.1100	New
691.1200	New
691.1300	New
691.1400	New

4) Statutory Authority:

Implementing and authorized by the African-American HIV/AIDS Response Act [410 ILCS 303] and Sections 2310-10 and 2310-580 of the Civil Administrative Code of Illinois [20 ILCS 2310/2310-10 and 2310-580].

5) A Complete Description of the Subjects and Issues Involved:

This proposed rulemaking will enable the Illinois Department of Public Health to implement the provisions of P.A. 094-0797, the African-American HIV/AIDS Response Act. In 2006, the African-American HIV/AIDS Response Act was amended to add grant provisions and a special state fund – the African-American Response Fund – to provide an appropriation for implementing the Act. The proposed rulemaking will establish an administrative process for awarding grants for programs to prevent the transmission of HIV/AIDS and develop other programs and activities consistent with the purposes of this Act, the creation of community-based HIV/AIDS service delivery systems, and the administration of the Act.

6) Published studies or reports, and sources of underlying data, used to compose this rulemaking;

CDC Guidelines for National Human Immunodeficiency Virus Case Surveillance, Including Monitoring for Human Immunodeficiency Virus Infection and Acquired Immunodeficiency Syndrome, Centers for Disease Control and Prevention (CDC). Morbidity and Mortality Weekly Report (MMWR), December 10, 1999; vol. 48, no. RR-13.

Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings, Centers for Disease Control and Prevention (CDC), Morbidity and Mortality Weekly Report (MMWR), Vol. 55, No. RR-14, September 22, 2006, Atlanta, Georgia 30333.

Advancing HIV Prevention: New Strategies for a Changing Epidemic – United States 2003, Centers for Disease Control and Prevention (CDC), Morbidity and Mortality Weekly Report (MMWR), Vol. 52, No. 15, April 18, 2003, Atlanta, Georgia 30333.

7) Will this proposed amendment replace an emergency rule currently in effect? No

8) Does this rulemaking contain an automatic repeal date? No

9) Does this proposed amendment contain incorporations by reference? Yes

10) Are there any other proposed amendments pending on this Part? No

11) Statement of Statewide Policy Objectives:

This rulemaking does not create or expand any state mandates on units of local government.

12) Time, Place, and Manner in which interested persons may comment on this proposed rulemaking:

Written or e-mail comments may be submitted within 45 days after this issue of the Illinois Register to:

Susan Meister
Division of Legal Services
Illinois Department of Public Health
535 West Jefferson, Fifth Floor
Springfield, Illinois 62761

217-782-2043
(E-mail: rules@idph.state.il.us)

13) Initial Regulatory Flexibility Analysis:

A) Types of small businesses, small municipalities and not for profit corporations affected:

Community-based organizations providing health services to persons with HIV/AIDS.

B) Reporting, bookkeeping or other procedures required for compliance:

There are no new requirements for reporting, bookkeeping or other procedures required for compliance.

C) Types of Professional skills necessary for compliance:

None

14) Regulatory Agenda on which this rulemaking was summarized: January 2007

The full text of the Proposed Amendment(s) begins on the next page:

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED RULES

TITLE 77: PUBLIC HEALTH
CHAPTER I: DEPARTMENT OF PUBLIC HEALTH
SUBCHAPTER k: COMMUNICABLE DISEASE CONTROL AND IMMUNIZATIONS

PART 691
AFRICAN-AMERICAN HIV/AIDS RESPONSE CODE

SUBPART A: GENERAL PROVISIONS

Section
691.100 Definitions
691.200 Incorporated and Referenced Materials

SUBPART B: AFRICAN-AMERICAN HIV/AIDS RESPONSE ACT GRANTS

Section
691.300 Eligibility for Grant Award
691.400 Grant Requirements
691.500 Application Procedures
691.600 Review of Applications
691.700 Use of Grant Funds
691.800 Termination of Grant Award
691.900 Denial, Suspension or Revocation of Grant Award
691.1000 Grant Funds Recovery
691.1100 Hearings

SUBPART C: HIV TESTING AND TRAINING PROTOCOLS

Section
691.1200 Training Requirements for HIV Test Counseling
691.1300 HIV Testing Protocols

SUBPART D: REMOVAL AND PROPER DISPOSAL OF HAZARDOUS WASTE

Section
691.1400 Removal and Proper Disposal of Hazardous Waste

AUTHORITY: Implementing and authorized by the African-American HIV/AIDS Response Act [410 ILCS 303] and Sections 2310-10 and 2310-580 of the Civil Administrative

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED RULES

Code of Illinois [20 ILCS 2310/2310-10 and 2310-580].

SOURCE: Adopted at 31 Ill. Reg. _____, effective _____

SUBPART A: GENERAL PROVISIONS

Section 691.100 Definitions

For the purpose of this Part, the following shall be the accepted definitions of the terms used herein:

"Act" means the African-American HIV/AIDS Response Act [410 ILCS 303].

"AIDS" means acquired immunodeficiency syndrome. (Section 3(b) of the AIDS Confidentiality Act)

"African-American Community-based organization" means an organization that it is in good standing with the State of Illinois and:

Has a Board of Directors, of which the majority of the members are African-American;

Provides services to individuals or families who are or have been impacted by HIV;

Is physically located in the community to be served;

Provides HIV/AIDS services in communities that are primarily populated by individuals and families that identify themselves as African-American; and

Has been in existence for at least one year.

"Department" means the Illinois Department of Public Health.

"Director" means Director of the Illinois Department of Public Health.

"Fund" means the African-American HIV/AIDS Response Fund as established by the Act.

"Funding Period" means the time (usually twelve months coinciding with the Department's fiscal year) during which money is to be spent by award recipients.

"High-risk community" means a community that has a high prevalence of HIV defined as equal to or greater than one percent of the population of the community.

*"High-traffic facility" means a high-traffic facility as defined by the State agency operating the facility. (*Section 15 of the Act)

"HIV" means the Human Immunodeficiency Virus or any other identified causative agent of AIDS. (Section 3(c) of the AIDS Confidentiality Act)

"Potentially infectious medical waste" (PIMW) means waste generated in connection with:

Diagnosis, treatment (i.e. provision of medical services), or immunization of human beings or animals;

Research pertaining to the provision of medical services; or

Production or testing of biological waste.

"Rapid HIV Antibody Test" means a federal Food and Drug Administration-approved screening test to detect antibodies to HIV, which can be collected and processed within a short interval of time (under 60 minutes).

"State agency" means any department of State Government created under Section 5-15 of the Departments of Government Law of the Civil Administrative Code of Illinois or the Office of the Secretary of State (Section 15 of the Act)

"Test" or "HIV Test" means a test to determine the presence of the antibody or antigen to HIV, or of HIV infection. (Section 3(g) of the AIDS Confidentiality Act)

Section 691.200 Incorporated and Referenced Materials

The following materials are incorporated or referenced in this Part:

a) Illinois Statutes

1) African-American HIV/AIDS Response Act [410 ILCS 303]

2) AIDS Confidentiality Act [410 ILCS 305]

3) HIV/AIDS Registry Act [410 ILCS 310]

4) Communicable Disease Prevention Act [410 ILCS 315]

4) The Civil Administrative Code of Illinois [20 ILCS 2310]

5) Environmental Protection Act [415 ILCS 5]

6) Illinois Grant Funds Recovery Act [30 ILCS 705]

b) State of Illinois Administrative Rules

1) HIV/AIDS Confidentiality and Testing Code (77 Ill. Adm. Code 697)

2) Control of Sexually Transmitted Diseases Code (77 Ill. Adm. Code 693)

3) Rules of Practice and Procedure in Administrative Hearings (77 Ill. Adm. Code 100)

c) Federal Guidelines

1) CDC Guidelines for National Human Immunodeficiency Virus Case Surveillance, Including Monitoring for Human Immunodeficiency Virus Infection and Acquired Immunodeficiency Syndrome, Centers for Disease Control and Prevention (CDC). Morbidity and Mortality Weekly Report (MMWR), December 10, 1999; vol. 48, no. RR-13.

2) Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings, Centers for Disease Control and Prevention (CDC), Morbidity and Mortality Weekly Report (MMWR), Vol. 55, No. RR-14, September 22, 2006, Atlanta, Georgia 30333.

3) Advancing HIV Prevention: New Strategies for a Changing Epidemic –

United States 2003, Centers for Disease Control and Prevention (CDC), Morbidity and Mortality Weekly Report (MMWR), Vol. 52, No. 15, April 18, 2003, Atlanta, Georgia 30333.

4) OMB Circular A-87, Cost Principles for State, Local and Indian Tribal Governments, May 10, 2004, Washington D.C. 20503

d) All incorporations by reference of federal guidelines refer to the guidelines on the date specified and do not include any amendments or editions subsequent to the date specified.

SUBPART B: AFRICAN-AMERICAN HIV/AIDS RESPONSE ACT GRANTS

Section 691.300 Eligibility for Grant Award

In order to be eligible to receive a grant from the Fund, the applicant must meet all of the following criteria:

a) Be in good standing with the State of Illinois;

b) Have a Board of Directors, of which the majority of members are African-American;

c) Provide services to individuals or families impacted by HIV.

d) Be physically located within the community to be served.

e) Provide HIV/AIDS services, including, but not limited to, HIV prevention, case management and treatment services, in communities primarily populated by individuals and families that identify themselves as African-American.

f) Be in existence for at minimum one year prior to applying for a grant award.

Section 691.400 Grant Requirements

a) Grant recipients must comply with all applicable provisions of the African-American HIV/AIDS Response Act, AIDS Confidentiality Act, HIV/AIDS Registry Act, Communicable Disease Prevention Act, Environmental Protection Act, HIV/AIDS Confidentiality and Testing Code (77 Ill. Adm. Code 697), Control of Sexually Transmitted Diseases Code (77 Ill. Adm. Code 693) and as

provided by the guidelines of the Centers of Disease Control and Prevention for HIV prevention, testing and surveillance (see Section 691.200).

b) Grant shall be awarded for *programs to prevent the transmission of HIV and other programs and activities consistent with the purposes of this Act, including, but not limited to, preventing and treating HIV/AIDS,* and *the creation of an HIV/AIDS service delivery system.* (Section 27 of the Act)

c) The grant *funds shall provide resources for communities in Illinois to create an HIV/AIDS service delivery system that reduces the disparity of HIV infection and AIDS cases between African-Americans and other population groups in Illinois that may be impacted by the disease*. (Section 27 of the Act)

d) Grant recipients shall address the following objectives:

1) *Developing, implementing and maintaining a comprehensive, culturally sensitive HIV Prevention Plan targeting community that are identified as high-risk in terms of the impact of the disease on African Americans.* (Section 27 of the Act) The HIV Prevention Plan shall be reviewed and revised annually.

2) *Developing, implementing and maintaining a stable HIV/AIDS service delivery infrastructure in Illinois communities that will meet the needs of African-Americans statewide.* (Section 27 of the Act)

3) *Developing, implementing, and maintaining a statewide HIV/AIDS testing program.* (Section 27 of the Act)

4) *Providing funding for HIV/AIDS social and scientific research to improve prevention and treatment.* (Section 27 of the Act)

5) *Providing comprehensive technical and other assistance to African-American community service organizations that are involved in HIV/AIDS prevention and treatment.* (Section 27 of the Act)

6) *Developing, implementing and maintaining an infrastructure for African-American community service organization to make them less dependent on government resources; and*

7) *Creating and maintaining at least 17 one-stop shopping HIV/AIDS facilities across the State.* (Section 27 of the Act)

Section 691.500 Application Procedures

The Department will provide written application instructions and forms to potential applicants.

a) Applications may be submitted to the Department at the following address:

African-American Response Act Grant
Illinois Department of Public Health
HIV/AIDS Program
525 W. Jefferson St., 1st Floor
Springfield, IL 62761-0001

b) All applications shall be submitted on the form prescribed by the Department and shall include, at minimum, the following:

1) Name of the primary contact for the applicant, address, e-mail, and telephone, fax and teletypewriter (TTY) numbers, in available;

2) Name of the African-American Community-based organization for which the application is being submitted, and the address, telephone, fax and teletypewriter (TTY) numbers, in available;

3) Federal Tax Identification number;

4) Resume or curriculum vitae of the principal investigator;

5) One-page non-technical abstract that describes the scope of the project for which funding is being sought;

6) List of Board of Directors members, position, term, and race;

7) Certificate of Good Standing from the Office of the Secretary of State;

8) Description and location of high-risk community to be served;

9) Work plan for the funding period, including a list of objectives, as described in Section 691.400, and an approximate timetable for completion;

10) Detailed budget for the funding period, documenting sufficient resources to complete the objectives address in the work plan. The budget shall be by line item category and shall provide sufficient detail to justify the use of grant funds to support project activities. The applicant shall indicate the amount of the total funding requested from the Department and sources of other funding available to support the project objectives, if applicable. Grant recipients shall limit administrative costs included in the project budget to no more than ten percent of total funds requested;

11) The signature of the organization official authorized to certify the application; and

12) Description of evaluation methods to measure progress in achieving objectives and a plan for monitoring the overall the overall project.

Section 691.600 Review of Applications

a) The Department will accept applications for grant award beginning March 1 through April 30 of each year. Funding will be awarded for the subsequent fiscal year. Applications for grant award shall be made annually and are not renewable.

b) Applications will be reviewed by the Department for compliance with the requirements of this Part. During the course of its review, the Department may contact the applicant for additional information if the information provided is incomplete, inconsistent or unclear.

c) Applicants whom the Department determines to be not eligible for grant funds will be notified in writing of this decision.

d) Distribution of grants is dependent on available funding. Available grant funds will be distributed based on the applicant's application and compliance with Sections 691.400 and 691.500.

e) Applicants must submit a new application each State fiscal year in order to be considered for funding. Applications are only applicable to the State fiscal year in which the applications were received.

Section 691.700 Use of Grant Funds

a) Grant awards will be issued in an amount not less than $25,000. Funds shall be used only for the direct cost of administering, operating and maintaining a project or service in accordance with the requirements of Section 691.400. The grant funds may not be used for organizational or community-based overhead costs, indirect costs, legal fees or levies. Grant funds shall be used as provided by the guidelines of OMB Circular A-87 for allowable expenditures (see Section 691.200). The following direct costs are examples of those that may be incurred when specified in the grant application budget.

1) Personal services costs, including gross salaries and employer paid fringe benefits for full-time and part-time employees of the program being funded.

2) Contractual services costs, including, but not limited to, medical services and printing of educational materials.

3) Supplies/commodities as required in the operation of the program or provision of services that are directly related to its operation, which may include medical supplies and equipment supplies costing less than $100; and

4) Equipment directly related to the operation of the project. (Equipment is defined as items costing over $100 each, with a useful life of more than one year. Equipment costs shall include all freight and installation costs.) Purchase of equipment items, other than those included in the approved budget, require prior written approval from the Department.

5) Payments to the grantee shall be made on a reimbursement basis. Grantees may request up to three months funding to be paid upon execution of the grant award. These requests shall be made at the time of application for grant award and will be reviewed and approved by the Department. Grantees shall provide the Department with a detailed accounting of how funding was expended.

6) The grantee shall use the Reimbursement Certification Form provided by the Department or a reasonable facsimile thereof, to request reimbursement for expenditures.

7) The grantee shall document actual expenditures incurred for the purchase of goods and services necessary for conducting program activities or services.

8) To be reimbursable, expenditures must be in accordance with the terms of the

grant award and the program budget on file with the Department and must meet the following general criteria:

A) Be necessary and reasonable for proper and efficient administration of the program and not be a general expense required to carry out the overall responsibilities of the agency.

B) Be authorized or not prohibited under federal, state or local laws or regulations.

C) Follow the application of generally accepted accounting principles appropriate to the project being funded.

D) Not be allocable to or included as a cost of any other state or federally financed program in either the current or a prior period.

4) The grantee shall submit requests for reimbursement monthly throughout the period of the grant. The final request for reimbursement shall be submitted within 30 calendar days after the end of the funding period.

Section 691.800 Termination of Grant Award

a) Except as otherwise provided in this Section, the grant agreement may be terminated by either party upon 30 calendar days written notice to the other party, as specified in the grant agreement.

b) The grant agreement may be terminated immediately, without penalty of further payment required, if the General Assembly fails to appropriate or otherwise make available sufficient funds for the award, or if sufficient funds are not available in the Fund.

c) The Department may immediately suspend funding or terminate the grant agreement of any grantee that has substantially failed or continually failed to comply with the Act, this Part, or the grant agreement.

Section 691.900 Suspension, Revocation or Termination of Grant Award

a) The Director may suspend or revoke the grant agreement of a grantee when finding substantial or continued failure to comply with the Act, this Part or the grant agreement. Except as provided in Subsection (b), the Director shall provide

notice and an opportunity for the grant applicant or grantee to request a hearing before executing the denial, suspension, or revocation.

b) If the Director finds that the public interest, health, safety, or welfare requires emergency action, then the Director may immediately order summary suspension of a grant agreement pending proceedings for revocation. The Director's order shall be written and shall include the reasons for the findings. The proceedings shall be promptly instituted and promptly determined.

c) The notice of denial shall be made by regular mail. The notice of suspension or revocation shall be made by certified mail or personal service. These notices shall state the reasons for the proposed action and shall provide the opportunity to request a hearing. If a written hearing request is not received within 10 business days after receipt of the notice, then the right to a hearing is deemed waived.

d) A denial or termination due to the General Assembly's failure to appropriate funds is not subject to this Section.

Section 691.1000 Grant Funds Recovery

Grants made under this Part are subject to the Illinois Grant Funds Recovery Act. If a provision of this Part conflicts with a provision of the Illinois Grant Funds Recovery Act, then the provision of the Illinois Grant Funds Recovery Act controls.

Section 691.1100 Hearings

The Department's Rules of Practice and Procedure in Administrative Hearings apply to the proceedings conducted under this Part. Where the terms "license" and "licensing" are used in those rules, the definitions of those terms shall be expanded to include a grant applicant, a grantee awarded funds, and a grant agreement executed under this Part.

SUBPART C: TRAINING AND HIV TESTING PROTOCOLS

Section 691.1200 Training Requirements for HIV Test Counseling

HIV counseling and testing services shall be administered by persons who have completed a course of training provided or approved by the Department. Persons providing HIV counseling and testing services shall comply with the provisions of the HIV/AIDS Confidentiality Act.

Section 691.1300 HIV Testing Protocols

a) HIV antibody testing shall be completed in accordance with 77 Ill. Adm. Code 697.100 (AIDS Confidentiality and Testing Code).

b) All persons seeking counseling and HIV testing at an HIV testing site operated by a Department funded African-American Community-based organization shall be offered a rapid HIV Antibody Test. If the HIV test counselor determines that rapid HIV antibody testing is not appropriate at the time of testing, the person shall be offered the option of another HIV antibody test.

c) A patient record shall be created for each person tested at a HIV testing site operated by a Department funded African-American Community-based organization. All patient records shall be maintained in accordance with the provisions of the HIV/AIDS Confidentiality Act.

d) No person may be subjected to an HIV antibody test unless written informed consent is first obtained from the test subject or the test subject's legally authorized representative in accordance with 77 Ill. Adm. Code 697 (AIDS Confidentiality and Testing Code).

e) The HIV Counseling and Testing Centers shall provide counseling to the test subject prior to performing the test. The counseling shall include, but not necessarily be limited to, information about:

1) HIV infection and HIV transmission;

2) The difference between confidential and anonymous HIV testing; information about the meaning of the test and test results, such as the purpose, potential uses, and limitations of the test and test results and the statutory rights to anonymous testing and to confidentiality; and information about the availability of supplemental testing;

3) The availability of referrals for further information, or counseling; and

4) Methods for prevention of transmission of HIV.

f) Department funded African-American Community-based organizations shall report all positive HIV test results to the appropriate local health authority in accordance with 77 Ill. Adm. Code 693.30 (Control of Sexually Transmissible Disease Code).

SUBPART D: REMOVAL AND PROPER DISPOSAL OF HAZARDOUS WASTE

Section 691.1400 Removal and Proper Disposal of Hazardous Waste

All Potentially Infectious Medical Waste (PIMW) generated through HIV testing shall be handled and disposed of in a safe and responsible manner. Department funded African-American Community-based organizations should contact the local health authority or local waste removal company for the correct disposal method for PIMW. The PIMW shall be placed in containers that are:

a) Rigid;

b) Leak-resistant;

c) Impervious to moisture;

d) Sufficiently strong to prevent tearing or bursting under normal conditions of use and handling;

e) Sealed to prevent leakage during transport;

f) Puncture resistant for packaging sharps and sharps with residual fluids; and

g) Break-resistant and tightly lidded or stoppered for packaging fluids