

/\* Maryland Administrative code, part 2 \*/

## Subtitle 52 PREVENTIVE MEDICINE

### Chapter 06 Maryland AIDS Drug Assistance Program: Eligibility

#### .01 Definitions.

A. In this chapter, the following terms have the meanings indicated.

#### B. Terms Defined.

- (1) "AIDS" means a medical condition meeting the current definition for acquired immune deficiency syndrome, published in the Morbidity and Mortality Weekly Report by the Centers for Disease Control of the Department of Health and Human Services.
- (2) "Appeal" means a process by which a client obtains review of a decision, action, or failure to act on the part of the Department.
- (3) "Applicant" means an individual who has submitted an application seeking Maryland AIDS Drug Assistance Program benefits and has not yet been certified as eligible. This includes a person whose application is submitted through a representative.
- (4) "Caseload" means the number of persons who can be enrolled in MADAP.
- (5) "Certification period" means the period of time during which a recipient is certified to receive Maryland AIDS Drug Assistance Program benefits. The certification period may not exceed 184 days.
- (6) "Certify" means to determine an applicant eligible for enrollment in the Maryland AIDS Drug Assistance Program.
- (7) "Completed application" means an application form on which all requested information has been completed by both the applicant and the applicant's physician and which has been sent to and received by MADAP.
- (8) "Department" means the Department of Health and Mental Hygiene, which is the State agency designated to administer the Maryland AIDS Drug Assistance Program.
- (9) "Determination" means a decision regarding an applicant's eligibility for Maryland AIDS Drug Assistance Program benefits.
- (10) "Drug" means a drug licensed by the U.S. Food and Drug Administration and covered by the Maryland AIDS Drug Assistance Program as specified in COMAR 10.52.07.04.
- (11) "Gross income" means the total income before any type of deduction of the applicant and any member of the applicant's household.
- (12) "Hearing" means an evidentiary hearing conducted pursuant to the requirements of COMAR 10.01.04.
- (13) "Household" means the applicant and other persons sharing

the same residence with the applicant and having one of the following relationships with the applicant:

- (a) The spouse;
  - (b) The natural or adoptive parent or parents of a child younger than 18 years old;
  - (c) The natural or adopted children younger than 18 years old;
  - (d) Persons younger than 18 years old under the court ordered guardianship of an adult member of the unit, or related to an adult member of the unit by blood, marriage, or adoption.
- (14) "Maryland AIDS Drug Assistance Program" (MADAP) means the program administered by the Department of Health and Mental Hygiene providing financial assistance to qualified applicants in need of specified FDA (U.S. Food and Drug Administration) approved drugs recommended for treatment of persons with HIV infection.
- (15) "Maryland Pharmacy Assistance Program" means the program mandated by Health-General Article, Section 15-123(b), Annotated Code of Maryland.
- (16) "Medical Assistance Program" means the State program of comprehensive medical and other health-related care for indigent and medically indigent persons.
- (17) "Recipient" means a person who is certified as eligible for, and is receiving, MADAP benefits.
- (18) "Resident" means a person who is living in the State voluntarily with the intention of making it that person's home and not for a temporary purpose, and for whom any temporary absence from the State is coupled with an intent to return so as not to interrupt the continuity of the residence.

#### .02 Persons Who Are Not Eligible.

The following persons are not eligible for MADAP benefits:

- A. Persons qualified for full third-party payment for all drugs which would be made available under MADAP pursuant to COMAR 10.52.07.04 and prescribed for the individual;
- B. Persons certified eligible for Medical Assistance or Maryland Pharmacy Assistance Program;
- C. Persons whose income exceeds the financial criteria set forth in Regulation .03C of this chapter.

#### .03 Eligibility.

- A. Residency. To be eligible for MADAP, an applicant shall be a resident of Maryland.
- B. Medical Criteria. To be eligible for MADAP, an applicant shall submit written certification by a physician that the applicant has been diagnosed as having HIV infection or AIDS, and meets other specific criteria established by the Food and Drug

Administration or guidelines issued by the Secretary of the Department of Health and Human Services for receipt of drugs covered by MADAP, and that the applicant will be treated with one or more drug or drugs covered by MADAP.

C. Financial Criteria. An individual is not eligible whose projected gross annual household income for a 12-month period beginning with the month of application for MADAP benefits is expected to exceed the following limits:

Household Size	Income
1	\$29,400
2	30,000
3	31,737
4	34,203
5	36,259
6	37,986
7	40,049
8	41,791
9	45,497

.04 Priority Waiting List.

A. The Department shall determine the maximum case load for MADAP by dividing the total funds available for the year by the average annual cost per recipient.

B. When an applicant is certified eligible for MADAP, that applicant shall be enrolled in the program unless the Department has already enrolled its maximum case load.

-C. When the Department has enrolled its maximum case load for a calendar quarter, three priority waiting lists shall be established.

D. Placement of names on the priority waiting lists shall be as follows:

- (1) List 1: Individuals meeting the criteria listed in Regulation .03 of this chapter previously certified for MADAP whose initial certification period has expired;
- (2) List 2: Individuals who previously received benefits under MADAP and who currently meet the criteria listed in Regulation .03 but were decertified because they no longer met the medical criteria for program participation;
- (3) List 3: Other persons meeting the criteria listed in Regulation .03;
- (4) Names shall be placed on each waiting list in chronological order based upon the date of receipt of a completed application by MADAP;
- (5) If MADAP enrollment drops below the maximum case load during a calendar quarter and waiting lists have been established, available slots shall be filled as follows:

- (a) Individuals on List 1 shall be enrolled in chronological order before any individuals are enrolled from Lists 2 and 3,
- (b) If no individuals are on List 1, individuals on List 2 shall be enrolled in chronological order, and
- (c) If no individuals are on either List 1 or List 2, individuals on List 3 shall be enrolled in chronological order.

.05 Benefits.

- A. A person enrolled in MADAP will qualify for payment for azidothymidine or other drugs specified in COMAR 10.52.07.04.
- B. The Department may not enroll an applicant in MADAP unless sufficient funds exist within the current appropriation to provide benefits to the applicant.
- C. The Department shall issue a MADAP identification card to each person enrolled in MADAP.
- D. When an individual is certified as eligible pursuant to Regulation .03 of this chapter, but cannot be served due to the limitation described in Section B of this regulation, the Department shall place the individual's name on a waiting list according to procedures described in Regulation .04 of this chapter.

.06 Application.

- A. A person requesting MADAP benefits shall be given the opportunity to file an application.
- B. An applicant shall complete a written application on the form designated by the Department.
- C. An applicant shall have his physician complete and sign the designated area of the application to provide adequate information to allow the Department to determine the applicant's medical eligibility for MADAP benefits.
- D. An applicant shall provide the Department with copies of wage statements, tax returns, paycheck stubs, or other documentation to support information about income on the completed application form.
- E. The applicant shall mail completed application forms to the address designated on the form.
- F. Applicants are determined ineligible without prejudice when they fail to provide information sufficient for a determination of eligibility.
- G. Applicants shall sign a statement authorizing the Department to verify, from the application or any other source, qualifying information submitted to the Department by the applicant. Refusal to sign an authorization is considered failure to provide sufficient information, and applicants are determined ineligible without prejudice as in Section F of this regulation.

H. The Department shall give the applicant written notice of the final decision on his application, including the applicant's certification, placement of his name on a waiting list, or disapproval of his application, pursuant to Regulation .11E of this chapter.

1. An applicant may voluntarily withdraw his application.

.07 Obligation of Program Recipient.

A. A person receiving benefits pursuant to Regulation .05A is responsible for payment of a fee to the Department in accordance with procedures described in Section B D of this regulation.

B. Instructions for Calculating Participation Percentage and Fee.

(1) The fee is based on projected annual income of the household.

(2) Determine size of household, in accordance with Regulation .01 of this chapter.

(3) From Schedule A under Section C of this regulation, determine base income for household size.

(4) Deduct base income from gross income to determine income over base.

(5) Locate amount of income over base on Schedule B under Section D of this regulation. Read across to determine participation percentage.

(6) To calculate dollar fee, multiply participation percentage by amount of income over base.

C. Schedule A-Maryland AIDS Drug Assistance Program.

Household Size Base Income

1	\$20,000
2	22,000
3	24,000
4	26,000
5	28,000
6	30,000
7	32,000
8	34,000
9	36,000

D. Schedule B-Maryland AIDS Drug Assistance Program.

Income Over Base	Participation Percentage
Less than 1	0%
\$1-3,000	10%
3,001-6,000	15%
6,001+	20%

E. Results of the calculation described in this regulation

notwithstanding, a recipient may not be responsible for a fee in excess of the amount paid by MADAP for benefits to the recipient less the amount of insurance collections for the individual by MADAP.

F. If a monthly fee is less than \$15, the Department may waive the fee.

G. Acceptance of benefits under MADAP will be considered acknowledgment by the recipient of the recipient's responsibility for payment of the fee as described in this regulation.

H. In the event of the death of a recipient before payment of the fee, the Department will file a claim against the open estate of the deceased.

I. Collection of Fee.

(1) The Secretary shall authorize the Division of Reimbursements of the Department of Health and Mental Hygiene to collect the required fee on a monthly basis, as set forth in Section A of this regulation.

(2) The applicant shall submit to the Department information on the applicant's income, pursuant to Regulation .08 of this chapter, upon application for benefits.

(3) The Department shall issue a bill to the recipient in accordance with the principles set forth in this regulation.

(4) Payment shall be made to the Department of Health and Mental Hygiene and shall be mailed or delivered to the address indicated on the bill.

(5) The recipient may request recalculation of the recipient's required fee at the end of a month if the recipient's actual income varies significantly from the estimated income.

(6) The recipient shall submit periodically to the Department a signed statement indicating actual income received during the reporting period, at dates and times to be determined by the Department.

(7) Funds collected shall be accounted for and deposited in a special fund account of the State Treasury and used for the purchase of drugs within the Maryland AIDS Drug Assistance Program.

J. If a recipient is eligible for partial third-party payment for benefits under this Program, the recipient shall assign to the Department the rights to collect and retain any funds from the third party payer. All funds collected shall be used for the purchase of drugs within the Maryland AIDS Drug Assistance Program.

.08 Income.

A. Income to be considered in determining financial eligibility and calculation of the fee is both earned and unearned gross

income of the household.

B. For purposes of determining financial eligibility and calculation of the fee, the applicant shall project income based on what can be reasonably expected to be available, for the ~2-month period beginning with the month in which the completed application is filed with the Department.

C. Earned income includes:

- (1) Wages.
- (2) Commissions and fees.
- (3) Salaries and tips.
- (4) Profit from self-employment.
- (5) Profit from rent received from a roomer, tenant, or boarder.

When profit cannot be documented, the following apply:

- (a) When the source of payment is the rental of a room in the recipient's own residence, profit is considered 25 percent of payments when the tenant receives room and board, or 75 percent of payments when the tenant receives room only;
- (b) When the source of payment is the rental of a home or apartment, profit is considered 30 percent of the payment when the recipient pays all utilities, 35 percent when the recipient pays either heat or electric utilities, and 40 percent when the recipient pays for no utilities.

D. Unearned income includes:

- (1) Payments from unemployment insurance, Veterans' and Workers' Compensations, private insurance, Black Lung Program, railroad retirement, public assistance programs of any nature, Social Security, pensions, annuities, and other regular benefits received;
- (2) Monetary support from absent relatives, monetary support from legally responsible relatives, and income which is received on a regular basis from relatives and friends who are not legally responsible, including income received by a child as support from his natural parents or putative father;
- (3) Income from assets received as either interest, dividends, or other income from savings accounts, certificates, stocks, bonds, insurance policies, mortgages, and from real property when not included as earned income.

.09 Certification.

A. If an application for benefits is approved by the Department, the certification period for that applicant shall begin on the first day of the month in which the application is approved by the Department. If the application for benefits is initially denied, an applicant may submit a new application. The certification period for a reapplication shall begin on the first day of the month in which it is approved.

B. Recipients are certified for a 6-month period. The Department shall promptly redetermine eligibility when it receives information concerning a recipient's circumstances that may affect the recipient's eligibility. The certification period may not exceed 184 days.

C. Changes in eligibility criteria may not affect the eligibility of a recipient who was enrolled in MADAP before the effective date of those changes.

D. Applications may be accepted and benefits paid to the extent of available funding according to the provisions of this chapter. Benefits may not be paid in excess of those specifically appropriated for this program.

#### .10 Reapplication.

A. A person previously determined ineligible for MADAP benefits may make a new application at any time.

B. A person previously certified for MADAP who loses eligibility due to changes in medical condition, drug regimen, third-party coverage, or income, may reapply for MADAP benefits whenever conditions affecting that person's eligibility so warrant.

C. Reapplication Procedure.

(1) When the certification of a recipient expires, the recipient may reapply for MADAP benefits.

(2) The Department shall notify the recipient in writing 45 days before the recipient's certification expires.

(3) The application to extend MADAP benefits is the same as for the initial application.

D. Reapplications are processed and eligibility of applicants is determined according to Regulations .03 .09. A person previously determined ineligible for MADAP benefits may make a new application at any time.

#### .11 Notification and Appeals.

A. Recipients shall notify the Department within 10 working days of any of the following changes in circumstances which would affect continuing eligibility:

(1) Changes in medical condition leading to an alteration in drug regimen;

(2) Changes in availability of third-party payment for drugs covered under MADAP;

(3) Changes in income or assets, or both, which:

(a) Could result in the recipient's eligibility for either the Medical Assistance Program or the Maryland Pharmacy Assistance Program, or

(b) Would disqualify the recipient from benefits under this



program;

(4) Change in address.

B. If any of the changes reported in Section A, above, result in a recipient no longer qualifying for eligibility for the certification period under Regulation .02 or .03 of this chapter, the recipient shall be considered ineligible for MADAP benefits and the current certification shall be terminated.

C. If a recipient is determined to be ineligible before the expiration of the recipient's current certification period, the termination shall be effective the first day of the month which begins at least 15 days after the date of the notification letter sent according to Section E(3) of this regulation.

D. When the certification of a recipient is terminated, the recipient shall return the MADAP identification card to the Department.

E. The Department shall inform an applicant or recipient of the individual's legal rights and obligations and give the individual written notification of the following:

(1) The final decision on an application, which includes:

(a) Reason for finding the applicant ineligible;

(b) Approval of application and placement of the eligible applicant on a waiting list pursuant to Regulation .04 of this chapter; and

(c) Obligation of any recipient of MADAP benefits to repay the Department a fee, pursuant to Regulation .07 of this chapter.

(2) An intended action to deny, terminate, suspend, or reduce MADAP benefits. The notice shall:

(a) Be mailed at least 15 calendar days before the date on which the action becomes effective;

(b) Include a statement of the proposed action, the reasons for the action, and the regulatory citation supporting the action;

(c) Include an explanation of the right to request a hearing.

F. Hearings.

(1) An applicant/recipient who is dissatisfied with a decision, action, or inaction of the Department may request, and shall be granted, a hearing.

(2) An applicant/recipient requesting a hearing shall notify the Department on the form designated by the Department within 30 days of the date the notice of final decision or intended action was mailed by the Department.

(3) Hearings will be conducted according to COMAR 10.01.04 as they pertain to the MADAP.

(4) Notwithstanding other provisions of this regulation, the applicant/recipient, instead of appearing at the hearing, may file not later than 15 days before the hearing a written memorandum stating his or her position and intention not to

appear.

.12 Reimbursement, Liens.

A. The Department requires payment of a fee by each recipient according to Regulation .07 of this chapter.

B. In all cases where MADAP benefits have been incorrectly paid as a result of a recipient's action or inaction, the Department will seek recovery.

.13 Fraud.

Cases of suspected misrepresentation or fraud shall be investigated pursuant to Article 27, Section 230A, Annotated Code of Maryland, or any other applicable statutory provision.

.14 Confidentiality.

Unless otherwise authorized by law, all information maintained by the Department in administering MADAP shall be maintained in a confidential fashion and may not be disclosed to any individual or organization without written consent of the applicant or the applicant's guardian.

.15 Program Termination.

If monies received by the Department under Title II of the federal Ryan White C.A.R.E. Act are not available to fund MADAP, the Department may terminate this program. In the event of program termination, the Department shall pay benefits for each current recipient until the end of the recipient's certification period.

## Chapter 07 Maryland AIDS Drug Assistance Program: Service

.01 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "AIDS" means a medical condition meeting the current definition for acquired immune deficiency syndrome published in the Morbidity and Mortality Weekly Report published by the Centers for Disease Control of the Department of Health and Human Services.

(2) "Allowable cost" means the manufacturer's or wholesaler's invoice price for procuring drugs, not to exceed an upper limit established by the Department pursuant to COMAR 10.09.03.07G.

(3) "Department" means the Department of Health and Mental Hygiene.

(4) "Drug" means a drug licensed by the U.S. Food and Drug

Administration and covered by the Maryland AIDS Drug Assistance Program as specified in Regulation .04 of this chapter.

- (5) "Invoice" means a pharmacy invoice (a form issued or approved by the Department for use by providers in submitting bills for payment) or a manufacturer or wholesaler invoice (a bill issued by a manufacturer or wholesaler to the provider which indicates proof of purchase and the price paid by the provider).
- (6) "Maryland AIDS Drug Assistance Program (MADAP)" means the program administered by the Department of Health and Mental Hygiene, and providing financial assistance to qualified applicants in need of specified FDA (U.S. Food and Drug Administration) approved drugs recommended for treatment of persons with HIV infection.
- (7) "Medical Assistance Program" means the State program of comprehensive medical and other health-related care for indigent and medically indigent persons.
- (8) "Pharmacist" means an individual registered and licensed to practice pharmacy in the state where the prescription is filled.
- (9) "Pharmacy" means an establishment or institution registered and licensed to dispense legend drugs to the public in the state in which the establishment or institution is located.
- (10) "Preauthorization" means an approval required from the Department or its designee before the dispensing of the prescription.
- (11) "Prescriber" means a physician licensed to prescribe legend drugs.
- (12) "Prescription" means a written order for medication approved for coverage in the MADAP program.
- (13) "Program" means the Maryland AIDS Drug Assistance Program.
- (14) "Provider" means a pharmacy recognized by the Department to participate in the Medical Assistance Program.
- (15) "Recipient" means a person who is certified as eligible for, and is receiving, benefits under the Maryland AIDS Drug Assistance Program.

#### .02 License Requirements.

The license requirements for participation in the program are the same as those for the Medical Assistance Pharmacy Services Program according to COMAR 10.09.03.02.

#### .03 Conditions for Participation.

To participate in the program, the provider shall:

- A. Be approved by the Department for participation in the Medical Assistance Program.
- B. Accept payment by the program as payment in full for the professional services rendered and make no additional charges to

the patient or the patient's family.

C. Maintain adequate records. The provider shall maintain prescriptions for a minimum of 5 years and make them available for inspection, upon request, to the Department or its designee.

D. Include on all prescriptions sufficient information to justify the pharmacy invoice charges.

E. Provide services without regard to race, color, age, sex, national origin, marital status, physical, or mental handicap.

F. Not employ knowingly a person who has been disqualified from the program or Medical Assistance Program to compound or dispense prescriptions, unless prior written approval has been received from the Department.

G. Verify the recipient's eligibility.

H. Place no restriction on a recipient's right to select providers of the recipient's choice.

#### .04 Covered Services.

A. A recipient shall obtain a prescription for each medication the recipient obtains under the MADAP Program.

B. Prescriptions for the following are covered when ordered and signed by prescribers for recipients within the limits established by the program:

- (1) Acyclovir;
- (2) Amphotericin B;
- (3) Clotrimazole;
- (4) Didanosine;
- (5) Ethambutol;
- (6) Fluconazole;
- (7) Foscarnet;
- (8) Ganciclovir;
- (9) Isoniazid;
- (10) Ketoconazole;
- (11) Leucovorin;
- (12) Pentamidine;
- (13) Pyrazinamide;
- (14) Pyrimethamine;
- (15) Rifampin;
- (16) Interferon alpha-2a, recombinant;
- (17) Trimethoprim -sulfamethoxazole; and
- (18) Zidovudine.

#### .05 Limitations on Covered Services.

The total amount dispensed on one prescription at one time may not exceed a 34-day supply of the prescribed drug.

#### .06 Preauthorization Requirement.

- A. Providers shall obtain preauthorization from MADAP for each prescription or refill before dispensing the drug.
- B. Preauthorization may be obtained by contacting the Maryland AIDS Drug Assistance Program of the AIDS Administration.

.07 Payment Procedures.

Payments to providers under the program shall be in accordance with the procedures of the Medical Assistance Pharmacy Services Program at COMAR 10.09.03.07.

.08 Recovery and Reimbursement.

The regulations covering recovery and reimbursement are the same as those for the Medical Assistance Pharmacy Services Program according to COMAR 10.09.03.08.

.09 Cause for Suspension or Removal and Imposition of Sanctions.

A. If the Department determines that a provider or the provider's employee, or both, have failed to comply with federal or state laws and regulations, Department may initiate one or both of the following:

- (1) Suspend the provider from the program;
- (2) Withhold payment to the provider by the Program.

B. If a provider or the provider's employee is removed from Medical Assistance, the program shall take similar action.

C. The Department may consult with the State Pharmaceutical Association and the State Board of Pharmacy. The findings and recommendations of these groups shall be given consideration.

D. The Department will give the provider reasonable notice of its intentions to impose sanctions. In the written notice, the Department will establish the effective date and the reasons for the proposed action, and advise the provider of the right to appeal.

E. A provider voluntarily withdrawing from the program or removed or suspended from the program according to this regulation shall notify recipients that the provider no longer honors MADAP cards, before rendering additional services.

.10 Appeal Procedures.

The appeal procedures for the program are the same as for the Medical Assistance Pharmacy Services Program according to COMAR 10.09.03.10.

.11 Confidentiality.

Unless otherwise authorized by law, all information maintained by the Department or by any provider or prescriber in administering MADAP may be maintained in a confidential fashion and may not be

disclosed to any individual or organization without written consent of the applicant or the applicant's guardian.

.12 Program Termination.

If monies received by the Department under Title II of the federal Ryan White C.A.R.E. Act are not available to fund MADAP, the Department may terminate this program.

## Chapter 08 HIV Testing and Counseling Procedures

.01 Scope.

These regulations govern pretest and post-test counseling and requirements for written informed consent whenever HIV testing is undertaken, except:

A. In cases when an HIV test is performed on an individual solely for the purpose of determining the suitability of that individual as a prospective donor of blood, semen, or tissue, the requirements are addressed in:

(1) Health-General Article Section 18-334, Annotated Code of Maryland, and

(2) COMAR 10.10.02;

B. HIV testing undertaken under provisions of Health-General Article, Section 18-338, Annotated Code of Maryland, is not governed by these regulations; and

C. HIV testing of blood samples for research is not governed by these regulations if:

(1) All personal identifiers have been removed from the blood samples; and

(2) The research protocol has been approved by an institutional review board.

.02 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Anonymous" means that a person does not use the person's name as identification and can only be identified through use of an assigned patient identifying number.

(2) "Confidential" means that a person uses the person's name as identification and that the person's medical records contain the person's name but are protected against disclosure as provided in the Annotated Code of Maryland.

(3) "Department" means the Department of Health and Mental Hygiene.

(4) "Designated anonymous test sites" means those HIV counseling and testing sites approved by the Department as sites where

persons can use a patient identifying number rather than a name for identification.

(5) "Health care facility" means a:

- (a) Hospital or related institution as described in Health-General Article, Section 19-301, Annotated Code of Maryland;
- (b) Freestanding medical facility as defined in Health-General Article, Section 19-3A-01, Annotated Code of Maryland; or
- (c) Health maintenance organization as defined in Health-General Article, Section 19-701, Annotated Code of Maryland.

(6) "Health care practitioner" means a physician or other person authorized to order laboratory examinations under various sections of Health Occupations Article, Annotated Code of Maryland.

(7) "Health care provider" means a physician or nurse licensed under Health Occupations Article, Annotated Code of Maryland, or a designee of a health care facility.

(8) "HIV" means HIV-1, the human immunodeficiency virus that causes acquired immune deficiency syndrome.

(9) "HIV counseling" means a discussion between a physician or nurse licensed under the Health Occupations Article, or a designee of a health care facility and another person intended to impart information about HIV infection, risks, tests for HIV, and means of preventing infection.

(10) "HIV infection" means an infection with HIV.

(11) "Indeterminate HIV test result" means that:

- (a) The blood sample tested positive on an initial screening test designed to identify the presence of HIV infection; and
- (b) A confirmatory test designed to identify the presence of HIV infection did not establish either the presence or absence of HIV infection in the blood sample.

(12) "Institutional review board" means a group of individuals designated by an institution in compliance with 45 CFR Part 46, to review the use of human subjects in proposed research.

(13) "Negative HIV test result" means that the blood sample has tested negative on either a screening or a confirmatory test designed to identify the presence of HIV infection.

(14) "Partner" means sexual partner or person with whom an individual has shared hypodermic needles or other similar drug paraphernalia.

(15) "Patient identifying number" means the unique identifying number assigned to an individual who comes to a designated anonymous test site for HIV testing.

(16) "Personal identifier" means name, address, social security number, or other number or information which would identify the person from whom a blood sample was taken.

- (17) "Positive HIV test result" means that the blood sample has tested positive on both a screening and a confirmatory test designed to identify the presence of HIV infection.
- (18) "Post-test counseling" means HIV counseling of an individual after an HIV test has been performed, for the purpose of notifying the individual about the test results and imparting other relevant information.
- (19) "Pretest counseling" means HIV counseling of an individual in the physical presence of the counselor before blood is drawn for the purpose of testing for the presence of HIV infection.
- (20) "Research" means an investigation carried out according to a protocol approved by an institutional review board.
- (21) "Secretary" means the Secretary of the Department of Health and Mental Hygiene.
- (22) "Seropositive" means that a positive HIV test result has been obtained from the test of an individual's blood.
- (23) "Substitute consent" means consent given under provisions of Health-General Article, Section 20-107, Annotated Code of Maryland.

.03 Requirements for Pretest Counseling.

- A. Pretest counseling shall be conducted before blood is drawn for the purpose of HIV testing and before any HIV test is performed on any blood sample drawn for another purpose. Ensuring that pretest counseling is performed in accordance with this regulation shall be the responsibility of the health care practitioner who orders the HIV test to be performed by a laboratory.
- B. A person performing pretest counseling shall be a physician or nurse licensed under the Health Occupations Article or the designee of a health care facility.
- C. Pretest counseling shall be conducted in a manner to protect the confidentiality of the individual to be tested.
- D. Pretest counseling shall include, at a minimum, presentation followed by a discussion with the individual of the following:
- (1) That a health care provider shall obtain written, informed consent before drawing blood for, or before performing, an HIV test;
  - (2) That a health care facility or laboratory may not use refusal to consent to an HIV antibody test or a positive test result as the sole basis for denying services or treatment;
  - (3) That a person licensed under the Health Occupations Article may not refuse, withhold from, deny, or discriminate against an individual with regard to the provision of professional services for which the licensee is licensed and qualified to render because the individual is HIV positive;



- (4) That an individual may choose to be tested on either a confidential or anonymous basis, and how an anonymous site can be located;
- (5) An explanation of HIV and AIDS, including the:
  - (a) HIV infection process;
  - (b) Stages of disease, from asymptomatic HIV seropositive to AIDS;
  - (c) Primary modes of HIV transmission; and
  - (d) Means of preventing HIV transmission
- (6) Behavioral or medical indications which suggest the need for an HIV test, including specific medical indications already identified by the health care provider;
- (7) Advantages of knowing one's HIV status, including:
  - (a) If negative, the ability to protect oneself from future HIV infection; and
  - (b) If positive, the ability to avoid transmission to others and to take advantage of available treatment to prevent or delay disease progression;
- (8) Types and purpose of HIV tests used;
- (9) That a negative HIV test means either that:
  - (a) A person is not infected with HIV; or
  - (b) The test is unable to detect the presence of HIV because a person is in:
    - (i) The early stage of infection and has not yet developed detectable evidence of HIV infection, or
    - (ii) An advanced stage of HIV disease and no longer has detectable evidence of HIV infection in a person's blood;
- (10) That a patient should be retested if the HIV test result is negative and the patient has:
  - (a) Engaged in high risk behavior in the past 6 months;
  - (b) Engaged in unprotected sex in the past 6 months with an individual who has engaged in high-risk behavior; or
  - (c) Had a massive exposure to blood or a needlestick from a source known to be HIV positive;
- (11) That a positive HIV test result means the person:
  - (a) Is infected with HIV; and
  - (b) Could develop symptomatic HIV infection or AIDS;
- (12) That a person with a positive HIV test result could experience:
  - (a) Emotional discomfort; and
  - (b) If the test result becomes known in the community, discrimination in work, personal relationships, and insurance;
- (13) That a person with a positive HIV test result:
  - (a) Could have infected others since becoming infected and could infect others in the future;
  - (b) Has a responsibility to notify the person's partners of the

person's HIV-positive status, or to ask assistance of someone else in notifying those individuals;

(c) Can be assisted by the local health department and that the local health department would not reveal the person's name to the person's partners when notifying the partners;

(14) That, if a person with a positive HIV test result refuses to notify that person's partners:

(a) That person's physician may notify either the partners or the local health officer; and

(b) A local health officer, notified under the provisions of Section D(14) (a), above, shall attempt to notify the partners of the HIV positive individual;

(15) That, if a person with a positive HIV test result has signs or symptoms of HIV disease, the person's physician or other health professional licensed under the Health Occupations Article shall report that information to the local health department;

(16) For persons being counseled in designated anonymous HIV test sites:

(a) That patient identifying numbers will be used instead of names;

(b) That test results can be obtained only by returning to the clinic with the patient identifying number; and

(c) How to schedule a return appointment to obtain test results;

(17) For persons being counseled at any site other than the designated anonymous test sites:

(a) How the confidentiality of HIV test results will be safe guarded;

(b) That HIV test results and other medical information could be shared with other individuals who are providing health care to the person and need this information;

(c) That the person may be asked to sign a release granting permission to reveal HIV test results and other medical information to insurance companies, employers, etc.; and

(d) How and when to return to obtain HIV test results.

E. Pretest counseling shall include an opportunity for the person being counseled to ask the individual performing pretest counseling questions about HIV infection and other topics described in Section D(1)-(17) of this regulation, and to have those questions answered.

#### .04 Requirement to Obtain Written, Informed Consent.

A. Ensuring that written, informed consent is obtained in accordance with this regulation shall be the responsibility of the health care practitioner who orders the HIV test to be performed by the laboratory.

B. A health care provider shall obtain written, informed

consent on the form printed in Section G of this regulation before any blood is drawn for the purpose of HIV testing or before an HIV test is performed on blood obtained for another purpose, except that:

- (1) A person tested at a designated anonymous test site may indicate consent by placing that person's assigned patient identifying number on the signature line of the form;
- (2) If a person is unable to give informed consent, substitute consent may be given under Health-General Article, Section 20-107, Annotated Code of Maryland; and
- (3) In cases exempted from the requirements of this chapter, as specified in Regulation .01, it is not necessary to obtain written, informed consent on the form printed in Section G of this regulation.

C. Before obtaining a person's signature on the required form, the health care provider shall provide the person with pretest counseling according to Regulation .03. If substitute consent is to be given, the health care provider shall provide the person giving substitute consent with pretest counseling.

D. The health care provider administering the informed consent form shall read and explain the form to anyone who cannot read and understand its contents.

E. The patient shall sign the form or enter that person's patient identifying number on the signature line before the health care provider or designee draws blood for an HIV test.

F. The health care provider who performed the pretest counseling shall also sign the form.

G. Required Form.

Informed Consent and Agreement to HIV Testing

With my signature below I acknowledge that I have read (or have had read to me) and understand the following information:

Facts About HIV Testing

(HIV-i antibody or other HIV tests)

I HAVE BEEN TOLD THAT: (1) My blood will be tested for signs of an infection by the Human Immunodeficiency Virus, the virus that causes AIDS; (2) My consent to have my blood tested for HIV should be FREELY given; (3) I understand that every attempt will be made to keep the results of this test confidential, but that confidentiality cannot be guaranteed.

What a POSITIVE Test Result Means:

A. A positive HIV test means that I have the HIV infection and can spread the virus to others by having sex or by sharing needles;

B. A positive HIV test DOES NOT mean that I have AIDS-other tests are needed

C. If my test result is positive, I may experience emotional discomfort and, if my test result becomes known in the community, I may experience discrimination in work, personal relationships, and insurance.

What a NEGATIVE Result Means:

A. In most instances, a negative test means that a person is not infected;

B. However, it can take 3 to 6 months (or longer) for the HIV ANTIBODY test to become positive AFTER infection;

C. Although I have a negative test now, I can still become infected by having unprotected sex or by sharing needles.

What Will Be Done for Me if My Test is Positive:

A. I will be told what needs to be done to keep me in good health and will be given a copy of the Department of Health and Mental Hygiene's publication, "Directory of Counseling and Referral Resources for HIV Seropositive Persons", which contains information about the medical, social, psychological, or legal services that will be helpful to me;

B. I will be told how to keep from spreading my HIV infection by:

(1) Avoiding sexual intercourse, or practicing SAFER sex; (2) Not sharing drug needles-better still, getting off drugs; (3) Not donating or selling my blood, plasma, organs, or sperm; (4) Avoiding pregnancy or (if I'm a male) not causing a woman to get pregnant; and (5) Not breastfeeding, or donating breast milk;

C. If I have signs or symptoms of HIV infection, my name will be reported to a local health department to assist me in obtaining services and to help the health department understand and control the AIDS problem;

D. I know that my local health department or doctor may assist me in notifying and referring my partners for medical services-without giving my name to my partners; and

E. If I refuse to notify my partners, my doctor may either notify them or have the local health department do so. In this case, my name will not be used. Maryland law requires that, when a local health department knows of my partners, it must refer them for care, support, and treatment.

I have had a chance to have my questions about this test answered.

I hereby agree to have my blood drawn for the HIV (antibody, or \_\_\_\_\_) test.

specify

Signature      Date      Signature of Counselor  
(Form 90-2)

- A. Blood samples shall be tested by means of a screening test using a methodology accepted by the U.S. Food and Drug Administration, such as the Enzyme-Linked Immunosorbent Assay (ELISA) Test.
- B. Blood samples which test positive on a screening test shall be retested on a confirmatory test using a methodology accepted by the U.S. Food and Drug Administration, such as the Western Blot Test.
- C. If both a screening test and a confirmatory test are performed, the tests shall be performed using different test methodologies.

.06 Requirements for Notification of Test Results and Post-Test Counseling.

- A. Notification of test results shall be part of post-test counseling.
- B. Ensuring that post-test counseling is performed in accordance with this regulation shall be the responsibility of the health care practitioner who orders the HIV test to be performed by a laboratory.
- C. Post-test counseling shall be performed by a physician or physician's designee.
- D. Post-test counseling shall be performed in a manner to protect the confidentiality of test results and of the individual tested.

.07 Content of Post-Test Counseling.

- A. If the person's HIV test result is:
  - (1) Negative, post-test counseling shall include:
    - (a) Information that the test result was negative;
    - (b) Information about the meaning of a negative result, as specified in Regulation .03D(9);
    - (c) A recommendation about whether a repeat test is advisable; and
    - (d) Information about what the person can do to avoid infection with HIV in the future;
  - (2) Indeterminate, post-test counseling, performed in the physical presence of the individual tested and the counselor, shall include the following:
    - (a) Explanation of what an indeterminate test result means;
    - (b) Review of information regarding transmission of HIV and means of preventing transmission of HIV from one individual to another;
    - (c) Recommendation that the person return in 8 to 12 weeks for another HIV test;
    - (d) Recommendation that the person take precautions as if the

person's HIV test result had been positive until the person is retested and found to be truly negative;

(3) Positive, post-test counseling, performed in the physical presence of the individual tested and the counselor, shall include information:

(a) That the test result has been confirmed as positive;

(b) About the meaning of a positive test, as specified in Regulation .03D(11);

(c) About why the person should notify the person's sexual and needle-sharing partners about the person's positive test result or ask assistance of someone else in notifying the person's partners, including information about:

(i) How the local health department can assist with partner notification,

(ii) A physician's right to notify either the local health department or the person's partners if the person refuses to notify the person's partners;

(d) About how the person can keep from transmitting HIV to another person, including:

(i) Abstinence,

(ii) Safer sex techniques and use of condoms for all sexual encounters,

(iii) Never sharing hypodermic needles or other drug paraphernalia and seeking treatment for a drug addiction problem,

(iv) Never donating blood, semen, tissue, or breast milk, and

(v) For a female, not becoming pregnant;

(e) Of a medical nature which may be useful to an HIV-positive person, including:

(i) Current and future medical implications of being HIV positive,

(ii) That the person should have a complete physical examination by a physician who knows that the person is HIV positive, and

(iii) For a seropositive woman who is pregnant, how HIV infection may affect the pregnancy, fetus, or newborn, and the potential that the newborn would have HIV infection.

B. If a person's HIV test result is positive, the physician or the physician's designee shall:

(1) Offer to assist the person in notifying all of the person's sexual or needle-sharing partners that they may have been exposed to HIV;

(2) Provide the person with a copy of the Department's publication, "Directory of Counseling and Referral Resources for HIV Seropositive Persons", describing counseling and support services available to persons who are HIV positive.

.04 HIV/AIDS Prevention Education.

A. General.

(1) Acquired immune deficiency syndrome (AIDS) is a major health problem for which no cure or effective treatment has been found, and AIDS education is critical in preventing the spread of the human immunodeficiency virus (HIV) that causes AIDS.

(2) Local school systems shall provide annual instruction in AIDS to all students at least once in grades 3 to 6, 6 to 9, and 9 to 12.

(3) The local board of education shall determine the three grades between 3 and 12 at which all students are to receive instruction.

(4) Students may be excused from the instructional unit on HIV/AIDS prevention upon a written request from their parents/guardians. For those students excused from the unit, the local school shall provide other worthwhile learning activities in another health-related area. When practical, curricular materials may be made available by the school system for home instruction use by parents/guardians of students excused from HIV/AIDS prevention instruction in the school.

(5) Content and curricular topics shall be appropriate to the age, interests, and needs of students, giving particular regard to students at the early learning level.

(6) Pursuant to instructional guidelines developed by the State Department of Education and as appropriate for the age of the students, curricular topics shall include:

(a) The definition and description of HIV/AIDS;

(b) Symptoms and complications associated with HIV/AIDS and related disorders;

(c) Means by which HIV is transmitted;

(d) Diagnosis and treatment of AIDS;

(e) Methods for prevention of the spread of HIV/AIDS; and

(f) Information on the available research concerning HIV/AIDS.

B. Curriculum Development and Review.

(1) The local school system shall maintain a curriculum in HIV/AIDS prevention education in consultation with the local health department and may use resources available from the State Department of Health and Mental Hygiene and the State Department of Education.

(2) The local school system shall use an existing committee or appoint a committee comprised of educators, representatives of the community including parents/guardians of students enrolled in a public school program, and the local health department, which shall examine all instructional materials proposed for use in HIV/AIDS prevention education curriculum. Recommendations from this committee shall be submitted to the local superintendent of

schools and the local board of education for final action. All aspects of the curriculum shall be reviewed by the committee at least annually to assure that it is accurate and current.

C. Training and Awareness Programs.

(1) Teacher Training. School staff selected to teach HIV/AIDS prevention curricular topics in the classroom shall receive in-service education before initiating instruction with students, and annually after that. The content of the in-service education program shall be designed in consultation with the local health department.

(2) Staff Awareness Program. Personnel employed by the local school system shall be provided annually with information or an awareness program about HIV/AIDS and its prevention. The information or awareness program shall be developed in consultation with the local health department.

(3) Parent Awareness Program. The local school system shall make an effort to provide information about HIV/AIDS to the parents/guardians of students enrolled in public school programs. The information or awareness program shall be developed in consultation with the local health department.

.05 Curriculum Guides.

Consistent with Education Article, Section 4-110, Annotated Code of Maryland, each of the local school systems shall provide comprehensive health education curriculum guides for the early, middle, and high schools under its jurisdiction.

.06 Student Participation.

The student shall have the opportunity to participate in the comprehensive health education program required by this chapter.

.07 Certification Procedures.

By September 1, 1993, and each 5 years after that, the local superintendent of schools shall certify to the State Superintendent of Schools that the comprehensive program of health education meets, at a minimum, the requirements set forth in Regulation .01 of this chapter.