



2009 Regulations on HIV Counseling and Testing for Pregnant Women

10.18.09 HIV Counseling and Testing for Pregnant Women

Authority: Health-General Article, §§18-102, 18-338.2, and 20-102, Annotated Code of Maryland

.01 Scope.

A. Except as provided in §§B—E of this regulation, this chapter governs counseling and requirements for informed consent when HIV testing is performed on pregnant women.

B. If 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 for counseling and written informed consent are addressed in:

- (1) Health-General Article, §18-334, Annotated Code of Maryland; and
- (2) COMAR 10.50.01.

C. If an HIV test is performed on an individual as a result of a court order issued under the provisions of Criminal Procedure Article, §§11-107—11-117, Annotated Code of Maryland:

- (1) The requirements for counseling are addressed in COMAR 10.52.10; and
- (2) The provisions in this chapter regarding informed consent do not apply.

D. HIV testing undertaken under Health-General Article, §§18-336, 18-338, 18.338.1, and 18-338.3, Annotated Code of Maryland, is not governed by this chapter.

E. HIV testing of specimens for research is not governed by this chapter if:

- (1) All personal identifiers have been removed from the specimen;
- (2) The specimen cannot be linked to the individual from whom the specimen was taken;
- (3) The test result cannot be linked to the individual from whom the specimen was taken; and
- (4) The research protocol has been approved by an institutional review board.

F. This chapter pertains to all pregnant women for whom a diagnostic test for the presence of HIV infection is conducted, including minors.

.02 Definitions.

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

B. Terms Defined.

- (1) “Counseling” means providing education on:

- (a) The effect of a positive HIV test result on the pregnant woman and the fetus concerning the risk of transmission of HIV to the fetus;

(b) Recognized methods of reducing the risk of transmission of HIV to the fetus during pregnancy, including the use of pharmaceuticals known to reduce the risk of transmission of HIV to the fetus; and

(c) The topics set forth in COMAR 10.18.08.06B(3).

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

(3) "Health care facility" means a facility or office where health or medical care is provided to patients by a health care provider, including:

(a) A hospital as defined in Health-General Article, §19-301, Annotated Code of Maryland;

(b) A facility operated by the Department or a health officer; and

(c) The office of a health care provider.

(4) "Health care provider" means a:

(a) Physician;

(b) Nurse; or

(c) Designee of a health care facility.

(5) "HIV" means the human immunodeficiency virus that causes acquired immune deficiency syndrome (AIDS).

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

(7) "Informed consent" means the voluntary permission by the individual to be tested for HIV, after the individual receives counseling as specified in Regulation .03 of this chapter.

(8) "Perinatal HIV authorization form" means the consent form developed by the Department to be signed by a pregnant woman authorizing testing for HIV.

(9) "Prenatal care" means obstetric and gynecologic service performed as part of a prenatal care program, including:

(a) Screening;

(b) Physical examination;

(c) Laboratory and diagnostic testing procedures and interpretation; and

(d) Counseling.

.03 Patient Counseling.

A. A health care provider who orders an HIV test to be performed by a laboratory shall ensure that:

(1) HIV counseling is conducted:

(a) Verbally;

(b) In writing;

(c) By video; or

(d) By any combination of §A(1)(a)—(c) of this regulation depending on the testing history and information needs of the individual being tested; and

(2) Voluntary informed consent is obtained from the pregnant woman to be tested for HIV before:

(a) A specimen is obtained for the purpose of HIV testing; or

(b) An HIV test is performed on a specimen obtained for another purpose.

B. An individual performing counseling shall:

(1) Be a health care provider;

(2) Conduct counseling in a manner to protect the confidentiality of the pregnant woman to be tested;

(3) Inform and discuss with the pregnant woman, during the counseling that:

(a) The pregnant woman is not required to consent to an HIV test;

(b) HIV can be transmitted through various methods and the pregnant woman can engage in behavior that reduces her likelihood of becoming infected;

(c) A health care provider, health care facility, or laboratory may not use refusal to consent to an HIV test or a positive test result as the basis for denying prenatal care; and

(d) There are medications to reduce the transmission of HIV from mother to child; and

(4) Provide education on and discuss with the pregnant woman:

(a) The effect of a positive HIV test result on the pregnant woman and the fetus concerning the risk of transmission of HIV to the fetus; and

(b) Recognized methods of reducing the risk of transmission of HIV to the fetus, including the use of pharmaceuticals during pregnancy known to reduce the risk of transmission of HIV to the fetus.

.04 Requirements to Obtain Informed Consent.

A. Before obtaining a specimen to test for HIV, a health care provider shall obtain the pregnant woman's voluntary informed consent to have an HIV test performed.

B. If the pregnant woman to be tested for the presence of HIV declines HIV testing, the health care provider shall document the declination in the woman's medical record.

.05 Requirements for HIV Tests.

A. A health care provider who orders an HIV test shall order the use of a test designed to confirm in a sample the presence of HIV.

B. Before administering a test for the presence of HIV, a health care provider shall notify the pregnant woman that she:

(1) Will be tested for HIV as a part of the routine prenatal blood tests unless she declines to be tested; and

(2) Has the right to refuse the test for HIV infection without penalty.

C. A health care provider shall offer a pregnant woman under the health care provider's care an HIV test in the third trimester of pregnancy if the woman's HIV status is unknown.

D. A health care provider may routinely offer a repeat HIV testing in the third trimester to all pregnant women if:

- (1) The provider is offering care at a health care facility in areas of HIV prevalence; and
- (2) The pregnant woman is at high risk of contracting HIV.

E. A health care provider who provides labor and delivery services to a pregnant woman shall offer:

- (1) A rapid HIV test to a pregnant woman with unknown or undocumented HIV status during labor and delivery; and
- (2) Antiretroviral prophylaxis prior to receiving the results of the confirmatory test if a rapid HIV test performed during labor and delivery is positive.

.06 Confidentiality of Test Results.

A. Except as otherwise provided in §B of this regulation, an individual, pursuant to Health-General Article, §18-338.2, Annotated Code of Maryland:

- (1) Shall keep the record of an HIV test performed under this chapter confidential; and
- (2) May not provide the record of an HIV test performed under this chapter:
 - (a) Under a discovery request; or
 - (b) For admission into evidence in any criminal, civil, or administrative action.

B. If the identity or any other information that could readily be associated with the identity of the pregnant woman is not disclosed, a person may introduce the results of an HIV test performed under this chapter into evidence in a criminal, civil, or administrative action, including the adjudication of a workers' compensation claim.

.07 Notification of Test Results.

A. A health care provider or a health care facility that orders an HIV test shall notify the pregnant woman who was tested for HIV of the test results.

B. In addition to what is required in Regulation .03B of this chapter, if the test result is positive, the health care provider who ordered the test shall:

- (1) Refer the individual who tests positive for HIV infection to appropriate HIV-specific health care and HIV case management services;
- (2) Counsel the individual to inform partners at risk for contracting HIV of the individual's positive HIV status;
- (3) Offer to assist in notifying partners in accordance with Health-General Article, §18-337, Annotated Code of Maryland or refer the individual to the local health officer to assist the individual with notifying the individual's sexual and needle-sharing partners;
- (4) Provide information regarding transmission of HIV and means of preventing transmission of HIV from one individual to another; and
- (5) Provide medical information that may be useful to an individual who is HIV positive, including:

(a) How HIV infection may affect a pregnancy, fetus, or newborn, the potential that the newborn would have HIV infection, and recognized methods of reducing the risk of transmission of HIV to the fetus; and

(b) That the individual should have a medical evaluation completed by a physician or a physician's designee who specializes in the treatment of HIV positive pregnant individuals.

.08 Immunity.

A health care provider or a health care facility acting in good faith to provide the counseling required under Regulation .03 of this chapter may not be held liable in any cause of action related to a woman's decision to consent or not to consent to have an HIV test.

For more information, visit: http://dhmh.state.md.us/AIDS/HIV_index.html or <http://www.healthymaryland.org/hiv-and-aids.php>.