

**Maryland General Assembly
Department of Legislative Services**

**Proposed Regulation
Department of Health and Mental Hygiene
(DLS Control No. 15-376)**

Overview and Legal and Fiscal Impact

These regulations amend COMAR 10.18.08 to update processes and requirements related to HIV testing by health care providers and in nonclinical settings.

The regulations present no legal issues of concern.

There is no material fiscal impact on State or local agencies.

Regulations of COMAR Affected

Department of Health and Mental Hygiene:

Human Immunodeficiency Virus (HIV) Infection and Acquired Immunodeficiency Syndrome (AIDS): HIV Counseling and Testing Procedures: COMAR 10.18.08.01-.11

Legal Analysis

Summary of Regulations

The regulations amend COMAR 10.18.08 to update processes and requirements related to HIV testing by health care providers and in nonclinical settings.

Regulation .01 adds a new section that provides that it is not necessary to obtain written informed consent for HIV testing on the form approved by the Secretary of Health and Mental Hygiene in cases exempt from the requirements for consent.

Regulation .02 adds defined terms, including “applicant” and “non-clinical settings”. The regulation also alters existing defined terms and definitions. For example, the term “health care facility” is altered to include the Department of Public Safety and Correctional Services. Finally, the term “HIV counseling” and the related definition are being repealed.

Regulations .03 and .04 make changes to reflect the new defined terms. Also, they remove the specific information, such as a description of the assessed need for HIV testing services at the proposed location, that was required to be included in an application for approval to become a designated anonymous testing site or a designated confidential testing site.

Regulation .05 specifies that the time frames which relate to a request for reconsideration of a denial under Regulation .03 or .04 refer to calendar days.

Regulation .06 governs consent and pretest requirements for HIV testing by health care providers. The regulation requires that general medical consent is required to be obtained only once during a patient visit and is sufficient to perform HIV testing. A health care provider who is obtaining consent for HIV testing is required to obtain consent as part of a patient's general consent for medical care in the same category as other screening and diagnostic tests. The health care provider also is required to document all declinations of an HIV test in the medical record of the patient. The regulation also specifies that the general informed consent for medical care may specify that an HIV test will be performed. Also, except as provided under Regulation .07, the health care provider may not be required to obtain consent for HIV testing on a separate consent form and pretesting information must be provided to the patient to be tested before each specimen is tested. Finally, the regulation requires a health care provider providing pretest information to (1) provide HIV specific information verbally, in writing, by video, or any combination of those methods; (2) provide HIV information in a manner that protects the confidentiality of the patient being tested; (3) provide minimum information, such as what different test results mean, using layman's terms; and (4) make necessary accommodation with respect to language or disability to ensure that the patient being tested understands the information presented.

Regulation .07 governs consent and pretest requirements for HIV testing in nonclinical settings. The regulation requires that, for HIV tests administered in nonclinical settings, the individual administering the test must (1) use the HIV informed consent form approved by the Secretary to document the informed consents; (2) read and explain the HIV informed consent form, through an interpreter if necessary, to anyone who cannot read or understand the form's contents; and (3) obtain voluntary written informed consent from the individual before an HIV test is performed on a specimen. Also, an individual tested at a designated anonymous nonclinical test site is allowed to indicate consent by placing their assigned code on the signature line of the form approved by the Secretary. Pretest information must be provided to the individual being tested before each specimen is tested. Finally, the individual providing pretest information must (1) provide HIV specific information verbally, in writing, by video, or any combination of those methods; (2) provide HIV information in a manner that protects the confidentiality of the patient being tested; (3) provide minimum information, such as what different test results mean and the primary modes of HIV transmission, using layman's terms; (4) include an opportunity for the individual being tested to ask questions about HIV infection and other topics described in the regulations and have the questions answered and decline HIV testing; and (5) make necessary accommodation with respect to language or disability to ensure that the patient being tested understands the information presented.

Regulation .08 governs post-test requirements for HIV testing by health care providers. The regulation requires that, if a patient's test result is negative, the individual providing the testing provide post-test information that includes that the result was negative and a review of the meaning of a negative result. If a patient's test result is indeterminate, the individual providing the testing must provide post-test information to and in the presence of the patient tested that includes (1) that the test result was indeterminate; (2) a review of the meaning of an indeterminate test result; (3) a recommendation that the patient return in a medically appropriate timeframe for another test; and

(4) a recommendation that the patient take precautions as if the patient's test result had been positive until the patient is retested. Finally, if a patient's test result is positive, the individual providing the testing shall provide post-test information to and in the presence of the patient tested that includes that the result was positive, a review of the meaning of a positive result, and information regarding the patient's responsibility to notify all known sexual and needle sharing partners of possible exposure or to request assistance from the local health department. Also, the health care provider must (1) ensure that the patient is linked to an appropriate source of HIV medical care and supportive services; (2) if necessary, provide the patient with information about mental health services for HIV infected individuals; and (3) offer to assist the patient in notifying their partners that they may have been exposed to HIV and provide testing to their partners, or request that the local health officer conduct an investigation to ensure partner notification has been completed.

Regulation .09 governs post-test requirements for HIV testing in non-clinical settings. The regulation requires that, if a patient's test result is negative, the individual providing the testing provide post-test information that includes that the result was negative, a review of the meaning of a negative result, and a recommendation about whether a repeat test is advisable based on potential recent exposures and the type of technology used. If a patient's test result is indeterminate, the individual providing the testing must provide post-test information to and in the presence of the patient tested that includes (1) that the test result was indeterminate; (2) a review of the meaning of an indeterminate test result; (3) a recommendation that the patient return in a medically appropriate timeframe for another test; (4) a review of information regarding transmission of HIV and means of preventing transmission of HIV; and (5) a recommendation that the patient take precautions as if the patient's test result had been positive until the patient is retested. Finally, if a patient's test result is positive, the individual providing the testing shall provide post-test information to and in the presence of the patient tested that includes (1) that the result was positive; (2) a review of the meaning of a positive result; (3) a review of information regarding transmission of HIV and means of preventing transmission of HIV; (4) that the individual should have a medical evaluation by a physician or physician's designee who knows that the individual is HIV positive and should receive ongoing health care appropriate for an HIV seropositive individual; and (5) if the individual is a female, a discussion of HIV transmission from mother to child in case of an unconfirmed pregnancy. Also, the health care provider must (1) ensure that the patient is linked to an appropriate source of HIV medical care and supportive services, including evaluation and treatment for tuberculosis, hepatitis, pregnancy, and sexually transmitted infections; (2) if necessary, provide the patient with information about mental health services for HIV infected individuals; and (3) offer to assist the patient in notifying their partners that they may have been exposed to HIV and provide testing to their partners, or request that the local health officer conduct an investigation to ensure partner notification has been completed.

All of the regulations amend language to reflect changes in defined terms and other terminology.

Legal Issues

The regulations present no legal issues of concern.

Statutory Authority and Legislative Intent

The Department of Health and Mental Hygiene cites §§ 2-104(b) and (i), 2-105(a) and (b), 18-102, 18-336, and 18-338.3 of the Health – General Article as statutory authority for the regulations. Section 2-104(b) authorizes the Secretary to adopt rules and regulations to carry out the provisions of law that are within the jurisdiction of the Secretary. Section 2-105(a) requires the Secretary to establish general policy for, and adopt standards to promote and guide the development of, the physical and mental hygiene services of the State. Section 2-105(b) provides that the Secretary is responsible for the health interests of the people of the State and is required to supervise generally the administration of the health laws of the State. Section 18-102 governs infections and contagious diseases. More specifically, § 18-102(a)(2) requires the Secretary to adopt rules and regulations necessary to prevent the spread of an infectious or contagious diseases or other diseases that endanger public health in the State. Section 18-336 governs HIV testing in the State.

The relevant cited authority is correct and complete. The regulations comply with the legislative intent of the law.

Technical Corrections and Special Notes

The department was contacted regarding two issues with the regulations. First, Regulation .07A requires that an individual administering an HIV test in a nonclinical setting either defer testing or refer an individual to a health care setting for testing if the individual is unable to give consent. However, § 18-336(e) of the Health – General Article allows for surrogate consent under § 5-605 of the Health – General Article and surrogate consent was included in Regulation .06 for individuals who are being tested by health care providers. The statute does not make a distinction between surrogate consent for testing by a health care provider and testing in a non-clinical setting. In light of the discrepancy, the department decided to remove the surrogate consent provisions in Regulation .06. Second, an individual providing pretest information in a non-clinical setting is required under Regulation .07 to include an opportunity for the individual being tested to ask questions, have the questions answered, and decline HIV testing. However, a health care provider who is providing HIV testing is not required to include this opportunity under Regulation .06 even though it is required under § 18-336(b)(1)(iii) of the Health – General Article. The department will be adding these requirements to Regulation .06. The above summary of the regulations reflects these changes.

Fiscal Analysis

There is no material fiscal impact on State or local agencies.

Agency Estimate of Projected Fiscal Impact

The department advises that the regulations have no fiscal impact on State agencies. The Department of Legislative Services concurs and notes that, in part, the regulations implement House Bill 978 of 2015 (enacted as Chapter 112), which amended the requirements for obtaining

informed consent from an individual prior to HIV testing, switched consent procedures from “opt-in” to “opt-out” testing, and altered pretest counseling procedures. The fiscal and policy note for House Bill 978 indicated that the department could implement the bill’s requirements with existing resources.

The department advises that the regulations have minimal fiscal impact on local health departments. The department indicates that procedural changes promulgated in the regulations streamline pre- and post-testing requirements for HIV and may result in minimal reductions in expenditures for local health departments. The Department of Legislative Services concurs and again notes that, in part, the regulations implement House Bill 978 of 2015. The fiscal and policy note for House Bill 978 indicated that local health departments could likely implement the bill’s requirements and provide the required pretest counseling with existing resources.

Impact on Budget

There is no impact on the State operating or capital budget.

Agency Estimate of Projected Small Business Impact

The department advises that the regulations have minimal fiscal impact on small businesses in the State. The department notes that the regulations streamline pre- and post-testing requirements for HIV and may result in minimal reductions in expenditures for any small businesses that provide testing services. The Department of Legislative Services concurs and notes that this impact has already been accounted for in the fiscal and policy note for House Bill 978 of 2015, which indicated a minimal small business effect.

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