# Department of Legislative Services

Maryland General Assembly
2015 Session

## FISCAL AND POLICY NOTE
**Revised**

House Bill 978 (Delegate Lam, *et al.*)
Health and Government Operations Education, Health, and Environmental Affairs

**HIV Testing - Informed Consent and Pretest Requirements - Modification**

This bill amends the requirements for obtaining informed consent from an individual before testing for the human immunodeficiency virus (HIV) and switches consent procedures from "opt-in" to "opt-out" testing. The bill also amends pretest counseling procedures.

The bill takes effect July 1, 2015.

## Fiscal Summary

**State Effect:** No material fiscal impact. The Department of Health and Mental Hygiene (DHMH) can update regulations and implement the bill's requirements with existing resources. Revenues are not affected.

**Local Effect:** No material fiscal impact. Local health departments can likely implement the bill's requirements and provide the required pretest counseling with existing resources. Revenues are not affected.

**Small Business Effect:** Minimal.

## Analysis

**Bill Summary:** Before testing an individual for HIV, a health care provider must (1) inform the individual either verbally or in writing, that the health care provider is going to test for HIV unless the individual refuses; (2) provide verbal or written information or show a video that contains an explanation of HIV infection and the meaning of positive and negative test results; (3) offer the individual an opportunity to ask questions and decline

HIV testing; and (4) document the individual's decision in the medical record if the individual *refuses* HIV testing.

Consent for HIV testing must be included in a patient's general informed consent for medical care in the same category as other screening and diagnostic tests. A health care provider may not be required to obtain consent for HIV testing using a separate consent form (unless otherwise specified by statute).

Health care providers must also provide easily understood informational materials to individuals who receive HIV testing. The informational materials must be available in the languages of the populations commonly encountered by the health care provider. Health care providers (not just physicians or their designees) who obtain a result from an HIV test have to notify the individual from whom the sample was obtained of the result and take additional actions if the test is positive.

The bill establishes that an individual's refusal to undergo an HIV test (or a positive test result) may not be used as the sole basis by an institution or laboratory to deny services or treatment.

**Current Law:** Before obtaining a fluid or tissue sample from the body of an individual to test for the presence of HIV, a health care provider (a physician, nurse, or designee of a facility) must obtain written informed consent from the individual after informing him or her that an HIV test will be administered and advising the individual of the right to refuse the HIV test without penalty. Further, a health care provider must document informed consent in the medical record and provide the individual with pretest counseling as developed by regulation by DHMH. If the testing occurs at a non-health care facility, the informed consent must be in writing and signed by the individual on a DHMH-approved form. The consent document must be distinct and separate from all other consent forms.

Pretest counseling may be provided in writing, verbally, by video or any combination of these formats as appropriate based on the individual's informational needs and testing history.

Refusal to consent to the HIV test or a positive test result cannot be used as the sole basis by an institution or laboratory to deny services or treatment. Substitute consent can be given if the individual is unable to give informed consent.

A physician or physician's designee who obtains a result from an HIV antibody test has to notify the individual from whom the sample was obtained of the result. If the test is positive, the physician (or designee) has to provide a referral for treatment and services; counsel the individual to inform all sexual and needle-sharing partners of the individual's positive HIV status; offer to assist in notifying the individual's partners or refer the

individual to the local health officer to do so; and, if necessary, take appropriate action to comply with the requirement that partners be notified even if the individual refuses to do so. Local health officers have to make available to all health care providers in their jurisdiction information on referral resources for an individual with an HIV positive status, including counseling, testing, needs assessment, treatment, and support services.

**Background:** Chapter 183 of 2007 required the AIDS Administration to convene a workgroup to review and make recommendations regarding the U.S. Centers for Disease Control and Prevention (CDC) guidelines regarding HIV/AIDS, including pre- and post-test counseling and written informed consent. The workgroup also had to review and consider best practices and research and data regarding treatment for HIV/AIDS and report on any recommendations by January 1, 2008. The bill reflects several of the workgroup's recommendations.

The workgroup published the required report in December 2007. The workgroup drew several conclusions and made recommendations relating to both informed consent and pre- and post-HIV test counseling. The report concluded that (1) the consent process should provide information about the purpose of HIV testing and provide individuals with an opportunity to make informed decisions about testing; (2) documentation of the provider-patient information exchange should occur, but a requirement for a separate HIV testing consent form is unnecessary; and (3) pre- and post-HIV test counseling requirements should be streamlined and flexible to accommodate a variety of health care settings.

CDC recommends "opt-out" testing, meaning that individuals in health care settings are tested for the presence of HIV after being informed that the test will take place unless they refuse testing. The report noted that Maryland law diverges from the CDC recommendation and requires "opt-in" testing, meaning individuals must affirmatively consent to testing before it takes place.

Chapters 222 and 223 of 2008 adopted some of the workgroup's recommendations, but not all recommendations were addressed, including the discrepancy between Maryland law and the CDC recommendation to allow "opt-out" testing. Chapters 222 and 223 offered more flexibility for methods of conducting the pretest counseling and the form of informed consent in health care facilities.

## Additional Information

**Prior Introductions:** None.

**Cross File:** None.

**Information Source(s):** Department of Health and Mental Hygiene, Maryland Association of County Health Officers, U.S. Centers for Disease Control and Prevention, Department of Legislative Services

**Fiscal Note History:** First Reader - March 8, 2015
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