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BILL



ANALYSIS

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House Bill 4583 (Substitute H-2 as reported without amendment)
Sponsor: Representative Roy Schmidt
House Committee: Health Policy
Senate Committee: Health Policy

Date Completed: 10-25-10

RATIONALE

The Public Health Code requires informed consent for human immunodeficiency virus (HIV) tests, as well as counseling before and after testing. The Code does not contain similar requirements for other medical tests. Some people are concerned that these specific HIV testing requirements are confusing and contribute to a stigma related to HIV and autoimmune deficiency syndrome (AIDS), which may discourage testing. It has been suggested that revising the informed consent and counseling requirements could facilitate increased testing levels and help prevent the spread of HIV.

CONTENT

The bill would amend the Public Health Code to revise informed consent provisions regarding HIV tests. Specifically, the bill would do the following:

- Allow informed consent to be written or verbal.
- Expand the information that a physician must give to a test subject before performing the test ("pretest information", under the bill).
- Delete provisions pertaining to an information pamphlet that physicians are supposed to distribute to HIV test subjects.
- Require the patient to be informed and given counseling when the results of any HIV test performed under these provisions were positive.

-- Require the results of a negative HIV test to be given to the patient through normal health care provider procedures.

Section 5133 of the Code requires a physician who orders an HIV test or a health facility that performs an HIV test to provide counseling appropriate to the test subject both before and after the test is administered. The bill would refer to information, rather than counseling.

Under the Code, a physician or other authorized individual may not order an HIV test for the purpose of diagnosing HIV infection without first receiving the written, informed consent of the test subject. Under the bill, the physician or other person also would have to give the test subject pretest information (described below). In addition, the informed consent could be written or verbal. The bill would require the physician or health facility to document the provision of informed consent, including pretest information, and whether the test subject or his or her legally authorized representative declined the offer of HIV testing. The informed consent would have to be maintained in the patient's medical records.

Currently, informed consent must include all of the following:

- An explanation of the test, including its purpose, the potential uses and limitations of the test, and the meaning of the results.
- An explanation of the test subject's rights, including the right to withdraw

consent to the test at any time before it is administered, the right to confidentiality of the test results, and the right to consent to and participate in the test anonymously.

- The person or class of people to whom the test results may be disclosed.

Under the bill, "pretest information", rather than informed consent, would have to include this information. Pretest information also would have to include an explanation of how HIV is transmitted and how it can be prevented, as well as an explanation of the circumstances under which the test subject does not have the right to decline the test. The bill also would refer to the test subject's right to confidentiality and the people to whom the test results may be disclosed under the Health Insurance Portability and Accountability Act (HIPAA).

The Code required the Department of Community Health to develop a pamphlet regarding the HIV test, and requires physicians who order HIV tests to distribute the pamphlet to each subject. The pamphlet must include the following:

- The purpose and nature of the test.
- The consequences of both taking the test and not taking it.
- The meaning of the results.
- Other information considered necessary or relevant by the Department.
- A model consent form for the signed, written informed consent.

If a test subject is given a copy of the pamphlet, the physician must include in the subject's medical records a form, signed by the test subject, indicating that he or she has received it.

The bill would delete all of these provisions related to the pamphlet and the model consent form. Also, the bill would replace other references to the pamphlet with references to "information".

The bill specifies that nothing in Section 5133 would prohibit a physician or health facility from combining a form used to obtain informed consent for HIV testing with forms used to obtain consent for general medical care or any other medical tests or procedures if the forms made clear that the subject could consent to general medical care, tests, or medical procedures without

being required to consent to HIV testing and, if applicable, that the subject could decline HIV testing at any time before the test was administered.

The bill would delete a provision allowing a health facility to develop a standard protocol for an HIV test performed upon a patient in the facility in preparation for an incision or invasive surgical procedure.

The Code's informed consent and information requirements do not apply to an HIV test performed on a patient in a health facility if he or she is informed in writing upon admission to the facility that an HIV test may be performed without the required written consent if a health professional, health facility employee, police officer, fire fighter, medical first responder, emergency medical technician (EMT), EMT specialist, or paramedic has sustained exposure to the patient's blood or other body fluids. Under the bill, the patient would have to be informed that the test could be performed without his or her right to decline, rather than without his or her written consent.

In addition, the requirements do not apply if the test subject is unable to receive and/or understand the information or to execute the signed writing consenting to the test. Under the bill, the test could be performed under these circumstances if the patient could not decline the test, rather than execute the written consent.

Currently, if the results of an HIV test performed in preparation for a surgical procedure, in response to body fluid exposure of a health professional or public safety personnel, or on a patient who is unable to understand information or give informed consent, indicate that the patient is infected with HIV, the health facility must inform the patient of the positive test results and give him or her appropriate counseling regarding HIV infection and AIDS. Under the bill, these requirements would apply to positive results of any HIV test performed under Section 5133. Also, if the results of an HIV test indicated that the patient was not HIV infected, that information would have to be given to the patient through normal health care provider procedures, including a patient visit, mail, or telephone communication.

MCL 333.5133

ARGUMENTS

(Please note: The arguments contained in this analysis originate from sources outside the Senate Fiscal Agency. The Senate Fiscal Agency neither supports nor opposes legislation.)

Supporting Argument

Because a positive HIV test has serious implications for the test subject, more extensive information and counseling are warranted than for routine tests. The way these requirements currently are fulfilled, along with the mandate for written informed consent, however, can present a barrier to testing by reinforcing the stigma associated with HIV. This is especially problematic because HIV testing reportedly is becoming part of the standard battery of medical tests.

The bill would make the testing process more efficient in several ways. Under the bill, informed consent could be given verbally, as well as on the general consent form that all patients must sign before receiving medical care. Also, health care providers could give test subjects information, rather than counseling, in conjunction with an HIV test (although individuals who tested positive still would have to be given counseling). By referring to privacy rights under HIPAA, the bill would help protect individuals from discrimination due to their HIV-positive status.

There are many different medical conditions for which testing can have serious ramifications for test subjects. The law, however, does not contain detailed provisions regarding informed consent and counseling for these conditions. Health care providers can determine the appropriate time and method of informing patients during the course of treatment; it is not necessary to spell out these circumstances in statute. Testing for HIV should not be treated differently from testing associated with other medical conditions.

The bill's changes would be in line with current recommendations from the Centers for Disease Control and Prevention (CDC). The revisions would facilitate the early detection of HIV, allowing for early treatment to slow the progression to AIDS and helping to prevent transmission.

Response: The bill would not fully incorporate the CDC recommendations, which include an opt-out approach to HIV

testing rather than an opt-in approach. The CDC recommends that the testing for HIV, like testing for other diseases, be done without separate informed consent.

In addition, the CDC advises that patients should have an opportunity to ask questions and have them answered, and that test subjects' ability to understand the information given to them be taken into account. The bill does not contain specific language regarding these matters.

Legislative Analyst: Julie Cassidy

FISCAL IMPACT

The bill would have no fiscal impact on State or local government.

Fiscal Analyst: Steve Angelotti

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This analysis was prepared by nonpartisan Senate staff for use by the Senate in its deliberations and does not constitute an official statement of legislative intent.