SUBJECT: Regulation of HIV home collection/testing kits

COMMITTEE: Public health — committee substitute recommended

VOTE: 7 ayes — Berlanga, Hirschi, Coleman, Glaze, Janek, Maxey, Rodriguez

0 nays

2 absent — Delisi, McDonald

WITNESSES: For — None

Against — None

On — Carolyn A. Parker, Ph.D., Texas AIDS Network; Dennis E. Baker, Charles E. Bell, M.D., Texas Department of Health

DIGEST: CSHB 988 would allow the sale of qualified home collection kits to obtain specimens for tests for human immunodeficiency virus (HIV) infection and would allow test results to be reported orally, including by telephone.

The bill would amend the Health and Safety Code provisions on HIV management to define as a "service provider" a kit manufacturer or person designated by the manufacturer to provide the required services. The kits would have to comply with the Texas Food, Drug and Cosmetic Act and be sold as a part of a package that included testing by a federally qualified laboratory, reporting of test results, verification of positive test results and pre-test and post-test counseling. The manufacturer would have to provide information, upon request, describing how test results and related information is stored by the service provider. Kit labels would have to explain who would have access to test results. Labels and required counseling would have to be provided in English, Spanish and any other language of a population that might be targeted for marketing.

Pre-test counseling could be provided orally or in writing. Test results would have to be reported orally to the individual tested along with counseling and referral to care and treatment. Confidentiality requirements

and reporting requirements currently in statute regarding HIV test results would apply.

The service provider would be prohibited from soliciting the purchase of additional services or products and from referring the individual to a business with which the service provider has an ownership or financial relationship.

A service provider could not use technology allowing the provider to identify the tested individual or the telephone number from which the person is calling.

CSHB 988 would encourage manufacturers of home collection kits for HIV testing to make the kits available at low cost to nonprofit organizations and would express legislative intent that the kits not affect the accessibility of anonymous testing programs established by the department of health.

The bill would take effect immediately if approved by two-thirds of the membership of each house.

SUPPORTERS SAY:

CSHB 988 would improve HIV testing rates and help prevent the spread of HIV infection by providing additional anonymous testing. AIDS, a fatal disease triggered by HIV infection, is killing men and women of all backgrounds. Anonymous testing is an important component of HIV control; sometimes positive test results, or just getting tested, creates an unfair stigma or results in job loss or denial of health coverage.

About 32,000 cases of AIDS have been reported in Texas since 1980, and about 73,000 Texans are believed to be infected with HIV. Without knowledge of their infection, infected individuals may continue risky behaviors. Home collection kits will help prevent the spread of HIV infection and encourage early medical treatment.

State and local governments can make better informed public policy and funding decisions once the true extent of HIV-infection rates are known. Prevention and early detection and treatment cost significantly less than treatment and services for serious medical conditions.

Home testing is private, popular and convenient and is not a new concept in other areas of health care; for example devices are available to monitor blood sugar and blood pressure and to test for pregnancy. The testing technology that these kits would use is the same technology used to test newborns for HIV.

New technology allows a person to send a small blood sample, identified by a private code number, to a laboratory for testing. The person could then call for results and counseling a week to 10 days later, using a toll-free number.

Recent surveys have shown that a majority of individuals of all sexual backgrounds would prefer home testing and receiving test results over the telephone than receiving tests elsewhere. Obtaining test results and counseling over the telephone could encourage testing by people uncomfortable with face-to-face discussions with a family physician or other individual about sexual and other personal behavior.

The design and marketing of home collection kits would be subject to both state and federal laws and ongoing enforcement. CSHB 988 links manufacturing, labeling and instruction standards to the Texas Food, Drug and Cosmetic Act, which in turn incorporates federal Food and Drug Act (FDA) laws and rules. A home collection kit would have to be FDA-approved before it could be sold in Texas. Violators could be penalized under both Texas and federal laws. The Texas Department of Health has ongoing enforcement activities to detect and prosecute fraudulent medical devices and false advertising.

CSHB 988 would impose counseling standards that appear to work. It is unlikely that the FDA would impose counseling standards; service providers would be subject to Texas law and be required to adopt model counseling protocols. But even the most effective post-test counseling cannot prevent all suicides and emotional suffering from the communication of positive test results.

OPPONENTS SAY:

The state should move cautiously in approving an untried HIV testing alternatives such as home kits and should provide better protection against unscrupulous marketing or poor counseling and treatment referrals. No kits

have received FDA approval, although Johnson & Johnson has submitted a prototype for review and plans to initially market the kits in Texas, California and Florida.

The federal requirements for home collection kits are not yet known because the FDA is still developing its standards for approval. Post-test counseling standards, if inadequate, could result in unnecessary suicides, suffering, fear and delayed treatment. Texans may become unduly alarmed over the nature and transmission of HIV if manufacturers are not sufficiently monitored and prohibited from using fear techniques to increase sales.

The department of health needs to implement monitoring or "spot check" programs to test whether service providers are following the law, in addition to responding to complaints.

OTHER OPPONENTS SAY:

Home collection kits, by increasing testing, may result in more HIV-positive individuals seeking state public health services than state has budgeted.

NOTES:

The committee substitute differs from the original bill in that instead of placing enforcement under the Texas Food, Drug and Cosmetic Act, it would authorize the board of health to design rules relating to labelling and marketing, create alternative measures for conflicts with federal requirements and establish criminal penalties for violations of the act.

The original bill also would have become effective September 1, 1995, required the board to establish rules by December 31, 1995, and allowed the sale of kits to begin January 1, 1996. It also had a fiscal note of about $1.7 million for the biennium.