

MEMORANDUM

DATE: January 10, 1997

TO: Clinical Laboratory Technology Advisory Committee (CLTAC)
cc: Karen Nickel, Ph.D.
Alice Brydon
Jerry Hurst
Walter Prober, M.D.

FROM: James Ottosen, Chair
Subcommittee on Over-the-Counter Testing Devices

RE: CLTAC Position Paper on Emergency Regulations R48-96E (Over-the-Counter Human Immunodeficiency Virus (HIV) Tests)

Attached is a draft of CLTAC comments on the above-referenced emergency regulations prepared by the Subcommittee on Over-the-Counter Testing Devices. Please review this paper and be prepared to discuss and vote on acceptance, modification, etc. during a one-hour conference call scheduled for:

Date: Tuesday, January 14, 1997

Time: 11:00AM

Call-In Number is: (510) 704-7800

Access Code is: 6340

The emergency regulations (R-48-96E) were distributed at the November 15 CLTAC meeting. Our comments must be submitted by January 21.

Clinical Laboratory Technology Advisory Committee
to the
Department of Health Services
POSITION PAPER ON R-48-96E

The following comments on R-48-96E (Over-the-Counter Human Immunodeficiency Virus (HIV) Tests) represents the views of the Clinical Laboratory Technology Advisory Committee to the Department of Health Services of the State of California.

While the committee understands the need for testing authorized by these regulations, the members have several concerns regarding the interpretation, application and implementation of these regulations for HIV testing. The stated intent of Business and Professions Code, Section 1246.5 is to authorize individuals to request selected specified tests without a physician's order. These tests will be performed by a qualified laboratory and the individual will receive the results of such tests directly. Currently, the tests specified in law are limited to occult blood, pregnancy, cholesterol and glucose. The Department of Health Services is authorized in Section 1246.5 to add tests if these tests are approved by the Federal Food and Drug Administration (FDA) for sale to the public without a prescription as an over-the-counter test kit.

The committee recognizes the rationale for the current law is to allow individuals to perform the tests on themselves or to request testing in a licensed laboratory. We believe these same individuals should also be allowed to request a California licensed laboratory to perform HIV testing and provide the results directly to the patient with appropriate counseling.

The specific concerns of the committee are the following:

1. The current over-the-counter HIV kits that are FDA approved are specimen collection kits and NOT test kits. Therefore, these kits do not qualify for inclusion in the Business and Professions Code, Section 1246.5 list because the testing cannot be performed by the individual.
2. If the kits are added to the list of tests requested by an individual, then these individuals should be permitted to also request performance of HIV testing on themselves, without a physician's order at a laboratory licensed by the State of California to perform HIV testing. Under these regulations, the only laboratory approved for self-referral testing is the one to which the purchaser of the test collection kit must mail the completed collection materials. This

laboratory may not be located in California and may not be currently licensed by DHS or authorized to perform HIV testing on California specimens.

3. We are concerned that small business in the State WILL be affected by the regulations. With this testing being performed in an out-of-state laboratory, we estimate the potential for a loss of revenue to be in excess of 100 million dollars to California laboratories. We do not believe this is in the best interest of California patients or the California laboratory industry.

The committee recommends the following:

The Department of Health Services should continue to apply the law as written which states that any test included in the list under Business and Professions Code, Section 1246.5 meet the criterion that the test can be performed by the individual for his/her personal use as an over-the-counter test rather than a collection kit only. Therefore, we recommend that the Department NOT include the currently FDA approved HIV collection kits in the Business and Professions Code, Section 1246.5 list of tests.

Further, should the Department decide to add HIV test kits to the list of self-ordered tests, we recommend that (1) the Department clarify the requirements for self-ordering of HIV tests and this testing be allowed at a laboratory licensed by California to perform HIV testing, (2) the Department clarify the mechanisms necessary to assure the confidential transmission of results to the individual, and (3) require individuals with positive or indeterminate results to seek counseling.

OVER-THE-COUNTER HIV SUBCOMMITTEE MEMBERS

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