UPDATED INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

The intention of Health and Safety (H&S) Code Section 120885 (Chapter 23, Statutes of 1985) was to assure that safe blood and blood components were available for transfusion, and that testing would be provided for the probable causative agent of acquired immune deficiency syndrome (AIDS) as a function separate from blood donation. The uncodified Section 5 of the statute stated that no laboratory should provide human immunodeficiency virus (HIV) antibody testing without approval by the California Department of Public Health (Department), formerly the California Department of Health Services. Under authority of H&S Code 1603.1(f), H&S Code 100275 and Business and Professions (B&P) Code 1224, the Department set standards for approval of laboratories testing for HIV antibodies. These standards continue to this day.

The current standards for HIV screening tests differ substantially from existing comparable federal regulations regarding proficiency testing. Federal regulations at 42 Code of Federal Regulations (CFR) 493.803 state that, “each laboratory performing non-waived testing must successfully participate in a proficiency testing program approved by the Center for Medicare & Medicaid Services (CMS).” There is no requirement in federal regulations that laboratories performing waived testing successfully participate in a proficiency testing program (1). Although implied in current regulations at Title 17 California Code of Regulations (CCR) Section 1230, amendments are proposed to clarify that waived HIV screening tests are not subject to proficiency testing requirements.

Because of changing technology and standards imposed since enactment of these regulations, the Department is proposing to amend Title 17 CCR Section 1230.

Specifically, the changes to Title 17 CCR 1230 would:

1. Repeal the requirement that all laboratories be approved by the Department before testing for HIV antibodies.

2. Repeal the requirement that all laboratories performing HIV antibody screening submit monthly reports to the Department on number of tests performed and results.

3. Repeal the requirement that all laboratories, blood banks, public health laboratories, and serology laboratories be licensed or registered by the Department because this is redundant and unnecessary.

4. Amend the requirements for use of a federal Food and Drug Administration (FDA) approved HIV screening kit.

5. Amend the requirements for confirmation of screened positive HIV results.

6. Repeal the requirement that all HIV screening facilities participate in proficiency testing as this is redundant and unnecessary.

7. Add quality assurance procedures for laboratories performing waived HIV tests.

8. Amend the requirement that all indeterminate HIV results be re-tested.

9. Repeal the requirement that all HIV-testing laboratories maintain confidential records as this is redundant and unnecessary.

10. Amend the statement that approval for laboratories performing HIV screening be denied or terminated for failure to comply with these standards to specify that sanctions shall be imposed for failure to comply.

AUTHORITY: Sections 208, 1603.1(h), 100275 and 131200 of the Health and Safety Code and Section 1224 of the Business and Professions Code.

REFERENCE: Section 5, Chapter 23 Statutes of 1985, Sections 1206, 1206.5, 1209, 1220, 1241, 1244, 1265, 1281, 1288.5 and 1300 Business and Professions Code, and Sections 1603.1,1632, 101160, 131051, 131052, Health and Safety Code.