

**Procedure for the Clinical Laboratory Technology Advisory Committee Review of
New CLIA Regulations Adopted by HCFA**

Senate Bill 113 is rapidly approaching final legislative consideration and, barring unforeseen circumstances, will be enacted into law with an effective date of January 1, 1996. The Clinical Laboratory Technology Advisory Committee (CLTAC) must have a mechanism in place that will clearly outline the path newly adopted HCFA rules/regulations relating to CLIA will follow, in order to provide maximum review time by CLTAC and meet all requirements set forth in SB113. Therefore, CLTAC is recommending the following procedure. We recognize this procedure may undergo many revisions before the CLTAC and Department of Health Services (DHS) identify and correct procedural deficiencies and settle on the most effective means for review.

It is our understanding that Section 1208 Subsection (b) and (c), pages 17 and 18 of SB113, as amended July 19, 1995 (see attachment) requires the following:

1. After HCFA adopts a final rule to implement CLIA, DHS, in consultation with its multidisciplinary committee (CLTAC), shall evaluate the CLIA regulation.
2. DHS determines if the CLIA regulation is more stringent, equivalent to, or less stringent than current California law.
3. DHS publishes a notice of its determination.
4. If DHS determines the regulation is equivalent to or more stringent than California law, the CLIA regulation becomes law in 90 days.
5. If DHS determines the regulation is less stringent, DHS publishes the regulation as a comparable State regulation in a notice for rulemaking proceedings in accordance with state law. This proposed regulation that is published must then go through the public hearing process, etc. This noticed rulemaking proceeding will then result in the adoption, amendment or rejection of this comparable state regulation.

The evaluation process described above applies to all regulations adopted by HCEA as a final rule after January 1, 1994. DHS has no time limit imposed on it to determine equivalency (i.e. more stringent, equivalent to, or less stringent). Once a notice is published that a regulation has been deemed more stringent or equivalent to California law, this regulation becomes effective in 90 days by "operation of law". Those HCFA regulations deemed less stringent have no time requirement for publication.

With the above process in mind, the CLTAC is suggesting the following procedure for CLTAC review of all CLIA regulations adopted by HCFA as a final rule after January 1, 1994.

1. DHS, is responsible for identifying all final CLIA regulations adopted by HCFA between January 1, 1994 and the date of enactment of SB113 (January 1, 1996).
2. Copies of these regulations will be sent, by way of Laboratory Field Services, (LFS) to the CLTAC Chairman and two other CLTAC members (appointed by the Chairman). These should be received by CLTAC members within five working days of receipt by LFS. These three people (CLIA Review Subcommittee) shall evaluate each regulation, determine its equivalency (more stringent, equivalent to or less stringent than California law) and, by way of the Chairman, return their evaluation to the Chief of LFS within 10 days.
3. The Chairman of CLTAC and the Chief of LFS will determine if any CLIA regulation requires evaluation by the full CLTAC. It is anticipated that many regulations will be routine (housekeeping) in nature and not require CLTAC deliberation. Copies of all CLIA regulations reviewed by the CLIA Subcommittee will be sent to each CLTAC member by LFS within five days following review, along with the Subcommittee evaluation decision (more stringent, equivalent to or less stringent). Any disagreement in the evaluation decision by individual CLTAC members must be voiced to the Chairman within 5 days after receipt of the final Subcommittee/Chief's decision.
4. All CLIA regulations requiring review by the full CLTAC shall be evaluated at the quarterly CLTAC meeting or at a special meeting or by way of a phone conference call as determined by the Chairman and the Chief of LFS.
5. CLTAC shall be notified of all DHS determinations related to CLIA regulation equivalency prior to publication as required in subsection (c).
6. Any CLIA regulation adopted by HCFA as a final rule after January 1, 1996 (enactment of SB 113) will follow steps 2 through 5.

October 5, 1995

Karen Nickel, Ph.D.
Chief, Laboratory Field Services
Department of Health Services
111 Grand Avenue, 9th Floor
Oakland, California 94612

Dear Dr. Nickel:

At the September 8, 1995 Clinical Laboratory Technology Advisory Committee (CLTAC) meeting, the "Procedure for CLTAC Review of New CLIA Regulations Adopted by HCFA" was approved. Item 2 of that procedure calls for appointment of a "Subcommittee to Evaluate Newly Adopted CLIA Regulations". I am recommending the following people serve on this subcommittee:

Fred Struve, Chair
Samuel Chafin
James Ottosen
Robert Footlik

Please let me know as soon as you have confirmed these appointments.

Sincerely,



Fred Struve
Chair, CLTAC
967 Mabury Road
San Jose, California 95133

cc: S. Kimberly Belshé, Director
Neal Kohatsu, M.D., Acting Deputy Director
Michael Volz, Ph.D., Assistant Deputy Director
Sheilia Nolan, Esq., Senior Counsel
CLTAC Members