Clinical Laboratory Improvement Amendments of 1988
Waiver History
October 1988 – October 2014

Date	Description of Federal Register Publication or Historical Event
10/31/88	Clinical Laboratory Improvement Amendments (CLIA) of 1988 was enacted. Waived tests were defined as simple laboratory examinations and procedures which, as determined by the Secretary, have an insignificant risk of an erroneous result, including those which-- (1) have been approved by the Food and Drug Administration (FDA) for home use; (2) employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or (3) the Secretary has determined pose no reasonable risk of harm to the patient if the test is performed incorrectly. In addition, the law specified that waived tests are exempt from the CLIA health and safety standards, including personnel, patient test management, quality control, proficiency testing, quality assurance and routine inspections requirements.
2/28/92	Regulations (final rule with comment) were published listing eight types of tests or examinations that met the statutory waiver criteria: (1) dipstick or tablet reagent urinalysis (non-automated) for bilirubin, glucose, hemoglobin, ketone, leukocytes, nitrite, pH, protein, specific gravity, and urobilinogen; (2) fecal occult blood; (3) ovulation tests--visual color comparison tests for human luteinizing hormone; (4) urine pregnancy tests--visual color comparison tests; (5) erythrocyte sedimentation rate--non-automated; (6) hemoglobin--copper sulfate--non-automated; (7) blood glucose by glucose monitoring devices cleared by the FDA specifically for home use; and (8) spun microhematocrit.
1/19/93	A final rule was published adding to the list of waived tests: hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout.
2/18/93	Approximately 1,100 of the comments received to the 2/28/92 regulations concerned the determination of waived test status, specifically the subjectiveness of the criteria for waiver and the failure of tests to be granted waiver. The Centers for Disease Control and Prevention (CDC) sought advice from the CLIAC and on 2/17-18/93. CLIAC recommended that CDC clarify the criteria and process for waiver and establish a moratorium on considering tests for waiver approval until the criteria were better defined. CDC established the moratorium, as recommended, while developing guidelines and a proposed rule to revise the CLIA requirements for waiver approvals. CDC used the determination of "simple" and "not prone to error" as a mechanism to meet the statutory requirement that waived tests "have an insignificant risk of an erroneous result" and required waived testing to be capable of performing accurately under all testing conditions and in all test settings.

12/19/94	The waiver moratorium was lifted, and an interim waiver review process was established by CDC. CDC notified manufacturers of moderate complexity test systems that it would consider any moderate complexity test system that met the statutory waiver criteria and for which the manufacturer or producer applied for waiver in accordance with the draft guidelines containing waiver criteria a process for reviewing waiver requests.
9/13/95	A proposed rule was published clarifying the statutory criteria for determining which tests could be waived and to provide for automatic waiver of FDA-approved home use tests. The rule also proposed that all previously waived tests be reevaluated using the clarifications to the waiver criteria in the regulation.
11/21/97	Congress enacted the Food and Drug Administration Modernization Act of 1997 (FDAMA) revising the CLIA law to make it clear that tests approved by the FDA for home use automatically qualify for CLIA waiver. In addition, Congress added "by the user" to the waiver provision related to simplicity and accuracy of methodologies, i.e., "employ methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible." (emphasis added). The waiver section of the CLIA statute now reads: Waived tests "are laboratory examinations and procedures that have been approved by the Food and Drug Administration for home use or that, as determined by the Secretary, are simple laboratory examinations and procedures that have an insignificant risk of an erroneous result, including those that- (A) employ methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible, or (B) the Secretary has determined pose no unreasonable risk of harm to the patient if performed incorrectly." According to the legislative history from House Report 105-310 to associated bill H.R. 1411 under section 21, "Modernization of regulation," the intent of the "by the user" clarifying language was to focus the waiver criteria on verifying test performance by the user and eliminating the potential for operator error in performing the test. The history also stated that, without this clarification, interpretations of "erroneous result" and "accurate" could include the inherent clinical sensitivity and specificity of a test system, which would be inappropriate since those parameters were under the purview of the FDA. The history concluded by stating that this change was intended only to specify the focus of the criterion and "not meant in any way to change the acceptable level of user error."
5/12/98	A citizen petition was filed by the Partners for Public Health and Government requesting CDC and the Health Care Financing Administration (HCFA) – now the Centers for Medicare and Medicaid Services (CMS) - to enter into negotiated rulemaking to develop waiver regulations.
2/27/99	An interagency agreement was signed by CDC, HCFA, and FDA, transferring the responsibility for categorizing the complexity of commercially marketed laboratory tests and evaluating requests for waiver from CDC to FDA.
12/30/99	A Federal Register notice announced the transfer of responsibility for the categorization (including waiver determinations) of commercially marketed in vitro diagnostic (IVD) tests under CLIA'88 from CDC to the FDA. The transfer of test categorization was completed January 2000 and the transfer of the responsibility for waiver determinations was completed February 2000.

8/14-15/00	FDA held a public workshop to obtain comments on the criteria and process used to determine whether a test could be waived. Presentations were made by 29 individuals representing government, industry, professional laboratory organizations, and academic institutions and some provided written comments.
1/23/01	FDA posted draft guidance for waiver, "Guidance for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Criteria for Waiver; Draft Guidance for Industry and FDA," on its website and sent a copy to CDC for distribution at the upcoming CLIAC meeting.
09/07/05	FDA published a notice announcing the availability of the updated draft guidance entitled "Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications" to recommend an approach for submission of waiver applications by manufacturers. This draft guidance replaced the previous draft guidance entitled "Guidance for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Criteria for Waiver."
01/30/08	FDA published a notice announcing the availability of the final guidance entitled "Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices." The guidance described recommendations for device manufacturers seeking to submit applications to FDA for waiver approval.