



AMERICAN SOCIETY FOR CLINICAL LABORATORY SCIENCE

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August 14, 2000

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20850

Dear Sir/Madam:

The American Society for Clinical Laboratory Science (ASCLS) is writing in response to the FDA's request for comment on the criteria used for the categorization of specific laboratory tests as waived under the Clinical Laboratory Improvement Amendments (CLIA) of 1988. We applaud the FDA for seeking such broad input and commit to continue to work with the agency on this and other related topics.

ASCLS is the nation's oldest and largest non-registry professional association for non-physician clinical laboratory professionals. The Society's mission includes promoting high standards of practice in the workplace and ensuring professional competence, while its ultimate goal is to ensure excellent, cost-effective laboratory services for consumers of health care. Our membership of nearly 13,000 includes clinical laboratory directors, managers, administrators, supervisors, and staff at all levels of practice.

ASCLS understands that, when CLIA '88 was enacted, criteria for waived testing was created by Congress to ensure patient access to quality laboratory testing. We have always maintained that the entire intent must be implemented, i.e., patients should have ready access to quality laboratory testing. However, the criteria in the statute are very subjective. The clarification of the criteria under the Food and Drug Modernization Act of 1997 established that waived tests are:

- ❖ Laboratory examinations and procedures that have been approved by the FDA for home use **or**
- ❖ Simple laboratory examinations and procedures that employ methods so simple and accurate as to render the likelihood of erroneous results negligible, or

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- ❖ pose no reasonable risk of harm to the patient if the test is performed incorrectly.

ASCLS believes that this clarification, while reiterating Congress' original intent, is not adequate to use as a basis of test categorization. CDC and the Public Health Service have struggled with establishing requirements for waived categorization for the same reason. The process that CDC developed was formally proposed in September of 1995. In response to the proposed rule for the categorization of waived tests published by the CDC and PHS in the Federal Register at that time, ASCLS submitted comments that said, in part:

*ASCLS concurs that only direct unprocessed specimens should be used for waived tests, as any specimen manipulation by untrained personnel introduces the potential for error. We also suggest that personnel should not be allowed to manipulate controls, calibrators, or reagents. Waived tests should have self-contained reagent packs or pre-prepared reagent. Operator intervention and interpretation must be very limited as untrained personnel are not likely to have the requisite skills or to be able to recognize erroneous results. In particular, we are pleased that fail-safe mechanisms are required so that no results are produced when a system malfunction occurs. The field testing requirements (number of samples, levels and sites coupled with testing done by laboratorians and lay users) appear to be rigid enough to ensure that the test system generates consistent results regardless of the testing environment or the skills of the testing personnel. While the studies are extensive, all components included in the criteria are essential for tests in this category. ASCLS supports requiring a waived test system to be resubmitted for evaluation and review if the manufacturer makes any changes to the waived test system that could affect accuracy and reliability."*

We felt that the evaluation criteria for waived tests for diagnostic use are adequate. It is appropriate to expect a 90% specificity and sensitivity rate for diagnostic testing. The establishment of accuracy using data generated in a laboratory setting by professionals who can recognize potential pitfalls in the procedure is also appropriate. We also support the establishment of reproducibility in the hands of lay users, including relatively untrained personnel at the point of care who will be the end users of the test.

We raised concerns in 1995 and today about the inclusion of any test system cleared by FDA for home use to automatically be waived under CLIA. The guidelines that FDA uses to approve home tests are not as comprehensive as those used for all other waived tests. We realize that

FDA was not reviewing these tests for diagnostic use. However, both the CLIA '88 and the FDMA '97 allow home tests to be used for that purpose.

ASCLS believes that there is a potential for negative consequences to patient care under the current system. Data from HCFA records of CLIA certificates over the past several years show that nearly 5,000 laboratories have dropped their moderate complexity licenses and converted to waived test licenses. This is understandable since it results in exemption from required proficiency testing, inspections, and other regulations. However, it also means that protection of patients demands that the waived tests in use are indeed simple, easy to perform and produce accurate and precise test results, regardless of testing personnel expertise. The "double standard" for evaluation of accuracy and precision for home use tests vs. other waived tests becomes problematic when both are being used in the diagnostic setting. As incentives exist for manufacturers to develop technology that is categorized as waived and the route to that categorization is easier via home test criteria, the public health demands that the categorization criteria for both be sufficiently stringent to ensure reliable test results.

Since the statutory language of CLIA is unlikely to be changed, the solution to these concerns appears to be to apply the same evaluation criteria to all waived tests, whether originally intended for home use or diagnostic use. This would close the loophole for products to become waived in laboratories and health care institutions across the country without having to meet the more stringent standards developed by CDC. We encourage the FDA to incorporate the CDC waived test criteria into the home use approval mechanism so that all waived tests would meet the same standards of accuracy and precision.

ASCLS further recommends that, upon finalization of the waived categorization rule, all tests previously categorized as waived would be re-evaluated by the approved criteria. It is not likely that all tests now categorized as waived can meet the more stringent criteria described in the 1995 proposed rule. If these tests are performed on patients with virtually no regulation, it is imperative that all waived tests be held to the same standards.

Clearly defining the criteria for waived tests will likely encourage manufacturers to develop more accurate and safe technologies for waived testing, as definite market incentives exist. The growth of the current list of waived tests is, in our opinion, a testament to the ingenuity, commitment, and technological innovations of manufacturers. We congratulate all of the manufacturers who have done so much to improve the public's access to quality testing. These same manufacturers,

and many new companies, are on the brink of introducing revolutionary technology that can explode the menu of waived tests. The analytes that will be tested, chemical or infectious agents, will stretch the waived criterion of "posing no reasonable risk of harm if performed incorrectly", will determine diagnostic pathways, and will be used as a basis for a clinical decision. Therefore, we must formalize a process that ensures that the tests are simple, accurate and precise. As additional tests are categorized as waived, patient access to testing should continue to improve. Absent the perceived regulatory burden of moderate complex testing, waived testing should be performed in more physician office laboratories and other sites. However, the test characteristics and criteria must be observed so that the resulting improved access to testing truly benefits the public. If lesser standards or alternatives are allowed and test results are not reliable, then the consequences will certainly be negative.

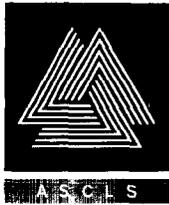
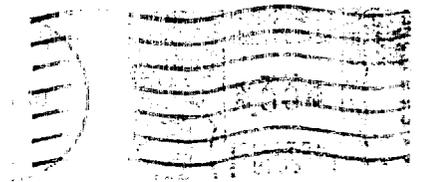
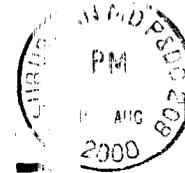
Thank you for the opportunity to submit our comments.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Cheryl R. Caskey". The signature is fluid and cursive, with a large initial "C" and "R".

Cheryl Caskey, CLS, (NCA)  
President

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