August 7, 1996

David Satcher, Administrator
Public Health Service
Center for Disease Control and Prevention
Mail Stop F-11
4770 Buford Highway, NE
Atlanta, GA 30341-3724

ATTENTION: CLIA Federal Register Notice

Dear Dr. Satcher:

On behalf of the American Society of Internal Medicine (ASIM), representing the nation’s largest medical specialty, I am pleased to submit the enclosed comments on the "Notice of Specific List for Categorization of Laboratory Test Systems, Assays, and Examinations by Complexity; Notice of Additional Waived Laboratory Test Systems, Assays, and Examinations; and Notice of Announcement of Boards Approved by HHS," published in the July 8, 1996 Federal Register.<i/>

Thank you for full consideration of these comments.

Sincerely,

Alan Nelson, MD
Executive Vice President

AMERICAN SOCIETY OF INTERNAL MEDICINE

Comments on the July 8, 1996 Expanded Waived Testing Category Notice

Full Title: Notice of Specific List for Categorization of Laboratory Test Systems, Assays, and Examinations by Complexity; Notice of Additional Waived Laboratory Test Systems, Assays, and Examinations; and Notice of Announcement of Boards Approved by HHS.

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) have had a damaging effect on the number and types of tests that physicians are willing to perform in their office laboratories. In order to avoid the high cost associated with CLIA regulations, many physicians have discontinued valuable office tests in the moderate and high complexity categories, although the prompt receipt of such test results and the capability to evaluate specimens directly expedite decisions regarding appropriate
patient care. The waived testing category was created to allow physicians to continue performing common, yet simple, tests in their office laboratories for the convenience of patients. The American Society of Internal Medicine (ASIM) supports the decision by the Centers for Disease Control and Prevention (CDC) to add the following test systems to the waived category:

*HemoCue B-Glucose System
*Cholestech LDX
*Serim PyloriTek
*Quidel QuickVue In-Line One-Step Strep A Test
*Bayer Glucometer Encore+Blood Glucose Meter
*ChemTrak Accumeter
*Johnson & Johnson ADVANCED CARE Cholesterol Test
*Boehringer Mannheim Accu-Chek InstantPlus Cholesterol
*all qualitative color comparison pH testing for the analyte Body fluid (other than blood) pH
*SmithKline Gastroccult for the analyte Gastric Occult Blood

However, ASIM strongly believes that a complete exemption for physician office laboratories (POLs) from CLIA is needed to assure continued patient access to necessary testing. Although we support interim efforts to revise the CLIA rules to reduce the regulatory burden on POLs, we believe that CLIA will continue to reduce access to in-office laboratory tests without resulting in any demonstrable improvement in test accuracy. Only a complete exemption of POLs from CLIA will result in the degree of regulatory relief that is required to assure continued patient access to testing.

In the interim, ASIM asks the CDC to expand the waived category. Without a clear commitment by the Department of Health and Human Services (HHS) and the CDC to expand the waived category, CLIA will continue to force physicians to discontinue providing tests to avoid the costs and regulatory hassles associated with the moderate complexity category. If physicians no longer offer their patients the convenience of testing in their own office, then patients will be burdened with the inconvenience of having to go elsewhere for testing. Unfortunately, for many older patients and those in rural and underserved communities, traveling to a site that does offer such testing is not always an immediate option. ASIM urges the CDC to approve the following list of tests--composed of those tests that are critical to the physician’s practice of medicine and are needed during the office visit for the immediate diagnosis, evaluation and treatment of a
patient, or are common screening tests needed to monitor therapeutic patient treatment-
to the waived category:

**Common Screening Tests:**

- Any test method approved by FDA for home use
- Rapid strep antigen detection
- Antistreptolysin O (ASO) - Rheumatoid Factor (RF)
- Semi-quantitative urine colony count (paddle or bulls eye methods)
- Dipstick tests for allergen-specific IgE
- Chlamydia Antigen
- Infectious mononucleosis screen

**Simple Automated Tests:**

- CBC (hemoglobin, hematocrit, white blood cell count, red blood cell count and platelet count)
- Therapeutic drug screen
- Creatinine
- Potassium
- Glucose
- Blood urea nitrogen (BUN)
- Uric Acid
- Bilirubin
- Liver enzyme (SGOT, SGPT, GGT, CK)
• Partial thromboplastin time
• Prothrombin time
• Theophylline (using Accu-level method)

**Basic Microscopic Tests Involving Smear or Count:**

• Eosinophil stain (nasal sputum)
• KOH Preparation *
• Vaginal wet mount *
• Gram stain
• Molluscum smear
• Tzanck smear
• Fecal smears for leukocytes

**Basic Microscopic Tests Involving Observation:**

• Microscopic Urinalysis *
• Scabies
• Semen analysis--qualitative
• Pinworm *
• Prostate smears
• Synovial fluid analysis
• Post-coital test *
• Fern test *
• Microscopic examination of hair morphology
• Any microscopic examination by and individual meeting qualifications of a general supervisor

**Routine Cultures:**
• Dermatophyte test medium

• Throat culture screen for Strep A

• Fungal culture

* Currently in the Physician Performed Microscopy Procedures category

The CDC’s September 13, 1995 proposed rule to revise criteria for the waived testing category represents a modest first step in the provision of needed relief, but the administration should implement additional interim improvements until such time as Congress acts on a POL exemption. ASIM agrees with the CDC that the standards of the current waived testing category are ambiguous and require explanation. However, ASIM cautions the CDC to revise the regulations in a manner that does not increase regulatory demands on physicians. ASIM reiterates the following suggestions on the September 13, 1995 proposed rule for revising the criteria of the waived testing category:

1) Revise the cumbersome manufacturer requirements for waived tests.

Waived tests are simple laboratory examinations and procedures that "have been approved by the Food and Drug Administration (FDA) for home use, employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible, or the Secretary has determined they pose no reasonable risk of harm to the patient if performed incorrectly." The success of this category depends on participation by the test system manufacturers. Manufacturers are not likely to create test systems in this category if the approval requirements are too cumbersome. After speaking with representatives from several laboratory equipment manufacturers, ASIM believes that the extensive field studies and research method approval requirements are overly burdensome. Requiring independent field studies at a minimum of three non-laboratory sites is a rigorous demand. Furthermore, the requirements mandating that manufacturers prove the written instructions accompanying the test system are thorough enough to perform the test accurately and reliably and that additional studies must be conducted to demonstrate that no formal training is necessary to perform the test are cumbersome. Organizing such field studies are a time-consuming and costly endeavor many manufacturers are not likely to pursue. Any requirements imposed on manufacturers should be modified to encourage new participants.

Additionally, the requirement that a physician must notify both the manufacturer and the Public Health Service (PHS) of test systems not meeting performance requirements is unnecessarily burdensome. Physicians should be required to report a poor test system only once. Physicians should either report poor test systems to the manufacturer who is then responsible for complying and reporting to the PHS, or the physician should initially report a poor test system to the PHS. A physician should not be required to track and report on whether the manufacturer "solved the problem," as the proposed rule suggests.
2) Modify characteristic criteria for test system approval.

Any test cleared by the FDA for home use is automatically accepted as waived under CLIA upon submission of the test by the manufacturer to the CDC. All other tests have to be proven to be both "simple and have an insignificant risk of an erroneous error." In order to determine whether the test system could pose a reasonable risk of harm if performed incorrectly, test systems must possess certain characteristics that would make them easier to use. The CDC's list of simple and easy to use properties include "direct, unprocessed specimen," but this is not clearly defined. ASIM is concerned that this characteristic requirement may be too restrictive for this category. If an unprocessed specimen is one that has not been processed at all, the spun microhematocrit—which is currently in the waived category—would be excluded, as whole blood must first be spun before the volume of red blood cells can be measured.

3) Establish a clear time frame for approval of tests for the waived category.

The proposed rule does not offer any guarantees on how long the approval process for a new testing system will take. This process could take months, if not longer, as test systems must first be approved by the FDA and then by the CDC. Additional time will be added if the Clinical Laboratory Improvement Advisory Committee (CLIAC) exercises its prerogative to review the test system as well. A lengthy review by these agencies would result in little relief for physician office laboratories.

4) Assure continuity for all tests currently included in the waived category.

All tests that qualify for the waived category should continue to qualify for the category, even if the test system criteria and/or instructions are subsequently modified by CDC or the manufacturer. Physicians should be assured that once they purchase a test system that qualifies for the waived category, it will remain in that category. The proposed rule states that "a modified test is considered to be high complexity." Modifications made outside the control of the physician should not be permitted to affect the testing status. Purchasing a new test system can be an expensive undertaking and physicians need the security of knowing that this investment will not be in vain. It is critical that neither the CDC nor the manufacturer be permitted to alter test system criteria or a test system that would jeopardize the categorization of the test. ASIM believes that it is essential to keep the nine test types that currently comprise the waived category in this category as physicians have arranged their office laboratories accordingly. Removing any of the tests currently categorized as waived would be confusing and disruptive to the operation of POLs. Without knowledge of what tests will be classified in this category, it is difficult to anticipate the impact the proposed rule will have on patient access to care. If the number of tests in the waived category is reduced, the number of tests performed in POLs will also be reduced.

Conclusion
ASIM supports a full exemption from CLIA for physician office laboratories. In the interim, ASIM urges the CDC to expand the waived category; revise the proposed cumbersome manufacturer requirements for waived tests; modify the proposed characteristic criteria for test system approval; establish a clear time frame for approval of tests for the waived category; and assure continuity for all tests currently included in the waived category.