October 28, 1996

Bruce Vladeck, Ph.D., Administrator
Health Care Financing Administration
Department of Health and Human Services
Room 309-G Hubert Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201
Attn.: BPD-846-PN

Dear Dr. Vladeck:

I am writing on behalf of the American Society of Internal Medicine (ASIM), representing the nation's largest medical specialty. We understand that HCFA is currently considering ways to ensure appropriate funding levels for the CLIA program, and that the option of increasing CLIA fees for physician office laboratories is a distinct possibility. ASIM is concerned that such a policy will create further hardships for physician office laboratories (POLs), particularly small POLs and those in rural areas. While fee increases will have an adverse impact on POLs, the most negative outcome will be the patient's diminished ability to receive timely and convenient medical treatment.

The CLIA regulations have had a significant impact on the availability of point of care testing. According to a study conducted by the Texas Medical Society in 1994, 27% of physicians surveyed had closed their labs, and 31% had reduced their test menu as a result of CLIA. ASIM's proficiency testing program--Medical Laboratory Evaluation (MLE)--found that almost 50% percent of physicians who dropped out of its program in 1994 indicated that they no longer performed office lab testing or had reduced testing to waived or PPM categories due to the cost and hassle of complying with CLIA requirements. A study released in October 1995 by seven state medical associations, under the direction of the AMA, showed that 63% of the practices surveyed dropped some or all of their tests due to CLIA regulations. More than 50% reported that their patients now face access problems.

These data clearly show that CLIA has had an adverse impact on physicians and their patients. Many patients are being sent to outside laboratories for routine tests that were performed promptly and efficiently in the physician's office prior to CLIA. An office lab can produce accurate and reliable test results for many tests clinically indicated in common ambulatory patient encounters in under twenty minutes. Prompt receipt of such test results and the capability to evaluate specimens directly expedite decisions regarding appropriate patient care. For example, office urinalysis enables the physician to diagnose and treat a patient suspected of having a urinary tract infection immediately. Diagnosis and treatment is delayed anywhere from a few hours to several days if patients are forced to make time-consuming trips to an outside lab, a hardship for weak, distressed or elderly patients and for those who rely on public transportation.

ASIM presents the following recommendations that we believe are essential to provide further relief from excessive CLIA regulations. We believe these recommendations, if implemented, would decrease the cost of CLIA for physician office laboratories, as well as the cost incurred by the federal government in administering the CLIA program. Any reduction in the costs of administering the program should be passed on to POLs in the form of lower user fees.

Expand The Waived Category

The Centers for Disease Control and Prevention (CDC) should continue to waive routine tests that are needed for the immediate diagnosis, examination and treatment of the patient. The Practicing Physician's Advisory Council (PPAC) recently recommended expanding the number of tests in the waived category. Attached is a list of tests that ASIM believes should be in the waived category. Furthermore, HCFA should eliminate all fees and certification requirements for waived labs. Requiring waived labs to obtain certificates to perform tests for which there are no quality standards and no federal oversight is unnecessary paperwork. Expansion of the waived category should dramatically lower the costs incurred by the federal government in administering CLIA as fewer inspections would be required.

Reduce Red Tape And Fees For The Alternative Quality Assessment Survey (AQAS) Form

ASIM supports the concept of a self-assessment survey for labs in lieu of an in-office laboratory inspection, but has specific concerns regarding the AQAS form. The form is too lengthy and requires documentation that is not necessary to validate that a laboratory is continuing to meet high quality standards. ASIM urges
HCFA to have the form preprinted with information already obtained from the laboratory, and to reduce the number of requests for documentation. Most importantly, physicians who are eligible to complete the paper survey should pay a lower fee than physicians whose laboratories require an inspection. ASIM also agrees with the recent PPAC recommendation that a "successful" survey should be the criteria that qualifies a lab for the AQAS form rather than a "perfect" survey.

Eliminate Routine Reinspection For Moderate-Complexity Labs In Good Standing

ASIM believes that reinspection every other year should only be required if there are quality problems (e.g., the lab fails initial inspection, does not enroll in or fails proficiency testing or a complaint against the lab is made). The current two year time-frame that a certificate is valid should be extended. The President's proposed FY 1997 budget contains a provision to change the legislative language addressing the frequency of inspections, and ASIM urges the administration to develop a specific proposal to reduce the frequency of inspections for labs in good standing. Reductions in the number of labs being inspected is the single most important step that HCFA could take to lower the costs incurred by POLs and the federal government in assuring compliance with the CLIA standards.

Revise The Billing Process

ASIM agrees with the recent PPAC recommendation that laboratories should not be expected to pay their inspection fees any sooner than four months prior to the beginning of their two-year survey cycle. Although HCFA has committed to a routine two-year billing procedure, unfortunately, ASIM members are still experiencing difficulties with inconsistent inspections and billing. We urge HCFA to implement this change as soon as possible.

Change The Fee Schedule

HCFA's current inspection fees are based on the number of tests and the category of laboratory testing that is being performed. This formula is costly, often figured unfairly and varies by region. HCFA should adopt
the approach of private accrediting programs that base their inspection fees on the number of physicians

using the laboratory and the test specialty. At the very least, HCFA should stop counting each test in a complete blood count (CBC) panel individually. Many POLs have been assessed hefty inspection fees simply because they run many CBCs. Medicare reimburses physicians only one sum for an entire CBC panel--not each test individually. The same process should be used when counting tests for CLIA inspection purposes. Counting each CBC panel as one test would keep most POLs in a fee schedule category that is more manageable.

ASIM has long had the policy of working with the administration to ensure that the CLIA regulations are reasonable and cost-effective. The Society recognizes that HCFA has taken steps to modify the CLIA program in response to the concerns of the physician community, but believes that more needs to be done to lower the costs of administering and complying with the law's mandates--and the "user fees" that are subsequently passed on to POLs. It is important that HCFA avoid imposition of high user fees that would further reduce patient access to POLs.

Sincerely,

Alan Nelson, MD
Executive Vice President

cc: The Honorable Donna Shalala, Secretary, Department of Health and Human Services
Judy Yost, Director, Center for Laboratories
Nancy Ann Min, Director, Health and Personnel, Office of Management and Budget
Christopher Jennings, Special Assistant to the President for Health Policy Development