October 6, 1997

Nancy-Ann Min DeParle, Administrator-Designate
Health Care Financing Administration
Department of Health and Human Services
Room 309-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Attention: HSQ-219-GNC

Dear Ms. DeParle,

On behalf of the American Society of Internal Medicine (ASIM), representing the nation's largest medical specialty, I am writing to comment on the Health Care Financing Administration's (HCFA) proposed Clinical Laboratory Improvement Act (CLIA) program fee schedule revision notice, published in the August 29, 1997 Federal Register. Our comments will discuss the following: (1) HCFA's need to revise CLIA certificate fees; (2) the impact of the revised fee schedule on small, low- volume, multi-specialty labs; and (3) recommendations to HCFA for alternatives/modifications to the proposed fee schedule revisions.

I. HCFA's Need to Revise CLIA Certificate Fees

ASIM understands that Section 353(m) of the Public Health Service Act requires that fees be collected to recoup costs of general administration of the CLIA Program and that revisions to the fees may be necessary because the current fees, established in 1992, are no longer sufficient to support the administration of the CLIA program. According to HCFA, the CLIA program is currently running a deficit of about $13 million a year. However, we do not understand how the new proposed fees have been developed. We also maintain that information regarding the derivation of the program deficit should be a matter of public record. We have asked HCFA to provide us with an analysis of the program's current financial status and a projection of its deficit, but have not received this information as of yet. A public record of this information is necessary to allow for public review prior to any increases sought by the program.

ASIM recognizes that the CLIA program is funded by user fees and must adjust those fees from time to time in order to maintain a standard of operation that provides appropriate levels of program service and integrity. However, we are concerned about the methodology used to ascertain the costs of the program and how those costs will be shared by physician office laboratories (POLs).

II. Impact of the revised fee schedule on small, low- volume, multi-specialty labs

The proposed fee schedule represents HCFA's effort to equitably distribute the projected costs of maintaining the program over 11 categories of laboratory testing. Costs per test increase, however, in a regressive fashion with the highest volume of testing being charged only one-tenth that charged the labs billed based on the lowest volume testing.

HCFA's suggestion that this method accounts for economies of scale does not reflect the increased burden placed on smaller POLs, which have to compete with large, for-profit reference laboratories. A disproportionate share of the increases can be seen in the cost per test for those labs that perform less than 100,001 tests annually (Schedules C-G). Based on the proposed cost per test rates, this group will see its average cost of certification increase by over 300%. While HCFA's proposed fee adjustment method ties the cost of certification to the volume of testing, it gives unfair advantage to labs performing the largest testing volume.

III. ASIM Recommendations for alternatives/modifications to the proposed fee schedule revisions

ASIM makes the following recommendations to HCFA to address the budget deficit of the CLIA program:

1. Adjust the per test rate

HCFA must reconsider the cost allocation of the per test rate. ASIM suggests that HCFA set a price ceiling lower than the proposed $0.027 biennial rate for Schedule C and D labs (such as $0.02, or lower) and redistribute the cost differential to the high volume testing labs. This would reduce the burden on small, multi-specialty labs while still allowing HCFA to meet its targeted revenue. If the per test rate is not adjusted, then the per test fee would be more than ten times higher for certain small, low-volume labs than for high volume labs. Such a cost differential is unacceptable.

2. Adjust the reinspection schedule for compliant labs

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. ASIM recommends 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). To reflect the increased cost of the certificate, HCFA should extend the current two year time-frame that a certificate is valid to three years.

3. Increase the use of the Alternate Quality Assessment Survey (AQAS)

Finally, ASIM recommends that HCFA increase the use of the Alternate Quality Assessment Survey (AQAS) (a paper survey option used instead of an in-person inspection for labs that perform consistently well), especially in light of the decreasing number of labs cited for condition level deficiencies. Physicians who are eligible to complete the paper survey should pay a substantially lower fee than physicians whose laboratories require an inspection. ASIM also agrees with a recent Practicing Physicians Advisory Council (PPAC) recommendation that a "successful" survey should be the criteria that qualifies a lab for the AQAS form rather than a "perfect" survey.

ASIM appreciates the opportunity to comment on the CLIA program fee schedule revision notice. If you have any questions regarding ASIM's comments, please contact ASIM's Health Policy Analyst, Chris A. Washington, at (202) 466-0285 or <cwashington@asim.org>.

Thank you for full consideration of these comments.

Sincerely,

Alan Nelson, MD
Executive Vice President