The American Society of Internal Medicine (ASIM) is pleased to provide the following testimony to the Practicing Physicians Advisory Council (PPAC) on the Impact of the Clinical Laboratory Improvement Amendments (CLIA) on physicians, and the Medicare Choices demonstration project. ASIM also strongly supports the comments attached on the Resource-Based Practice Expense (RBPE) project (see attachment 1).

CLINICAL LABORATORY IMPROVEMENT ACT (CLIA) IMPACT ON PHYSICIANS

Background

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) were enacted following several publicized reports about commercial laboratories that inaccurately analyzed PAP smears resulting in the deaths of several women from undetected cervical cancer. After holding several hearings, Congress passed legislation to extend the scope of the CLIA '66 law that addressed testing done by independent and hospital labs to include any testing of human specimens for the diagnosis, prevention or treatment of disease or health problems, regardless of site. CLIA was signed into public law (PL 100-578) on October 31, 1988.

Although CLIA was based on the best of intentions—to protect patients from harm due to inaccurate lab testing—it is now clear that the law has imposed an excessive regulatory burden on physicians’ laboratories, resulting in reduced access, with no discernable benefit to the public. In fact, CLIA has increased the cost of obtaining laboratory services for Medicare beneficiaries as many physician-owned labs have closed and patients are forced to spend their own time and money to travel further for these services.

As of February 1996, the Health Care Financing Administration (HCFA) had inspected 9,708—or about half—of accredited laboratories during the second cycle of lab inspections. Very few quality problems have been uncovered. Less than one percent or only 48 out of the more than 18,000 labs surveyed had deficiencies that posed an immediate risk to the health and safety of the public.

CLIA’s Impact on Physicians and Their Patients

The CLIA regulations have resulted in significantly higher costs for those physicians performing clinical laboratory testing in their offices. The fees and paperwork requirements are especially burdensome for small office laboratories that provide a few tests needed for immediate diagnosis, examination or treatment of patients. Many physicians have closed their office laboratories or stopped providing tests in the moderate-complexity and high-complexity categories. As a result, patients are being sent to outside laboratories for routine tests that were done quickly and efficiently in the physician's office prior to CLIA. A recent study by Commission on Office Laboratory Accreditation (COLA) determined that compliance with quality measures constitutes only seventeen percent of the overall cost of complying with CLIA, indicating that too much is being spent on aspects of the laboratory that do not directly contribute to patient care.

A survey commissioned by the Texas Medical Society in 1994 found that thirty-one percent of physicians who had an office lab before CLIA indicated that they had reduced their test menu as a result of the CLIA regulations. Twenty-seven percent of the physicians who had an office lab before the enactment of the CLIA law had closed their labs. ASIM's Medical Laboratory Evaluation (MLE) proficiency testing program found that almost fifty 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—particularly the inspection and paperwork requirements. A survey released in October 1995, conducted by seven state medical associations under the direction of the AMA, reported that sixty-three percent of the practices surveyed dropped some or all of their tests due to CLIA regulations. Of the laboratories that dropped tests, more than fifty percent reported that their patients now face access problems. The study showed that POLs rank the administrative cost of CLIA as its most burdensome aspect followed by inspection and on-site survey regulations. ASIM is particularly concerned that fourteen of the nineteen laboratory tests that are commonly performed by ASIM members were dropped by more than forty percent of the respondents for reasons related to CLIA. The results of these surveys are consistent with HCFA registration data. HCFA originally estimated that ten to twenty percent of all physician office labs would register for a Certificate of Waiver. Instead, over fifty percent of physician office laboratories have done so, indicating that thousands of physicians have discontinued moderate-complexity and high-complexity testing in their offices.

Reduced availability of office testing has a direct impact on patients. 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 for drawing specimens, a potential hardship for weak, distressed, or elderly patients and for those who rely on public transportation.

ASIM has long had the policy of working with this and the previous administration to make sure that the CLIA regulations are reasonable, workable and cost-effective for physician office labs. The Society recognizes that HCFA has taken steps to modify the CLIA program in response to the concerns of the physician community, such as the creation of the provider-performed microscopy (PPM) category, the development of the Alternate Quality Assessment Survey (AQAS) form and the agency's decision to conduct announced, rather than unannounced, inspections of physician office laboratories (POLs). Although ASIM prefers a complete exemption from CLIA for POLs, we welcome the administration’s recent steps to modify the CLIA program’s regulations to ensure that they are reasonable, workable and cost-effective for POLs. Until Congress enacts legislation to exempt POLs form CLIA—or at least to substantially ease the burden on POLs--ASIM believes that it is essential that HCFA provide further administrative relief from excessive CLIA regulations. Our specific recommendations are presented below.

**Recommendations to Improve CLIA**

ASIM recommends that the following changes be implemented in the CLIA program:

1. **Approve more tests for the waived category.** HCFA and the Centers for Disease Control and Prevention (CDC) should waive all CLIA requirements for physician office laboratories performing specific routine tests that are needed for the immediate diagnosis, examination and treatment of the patient. Tests in this category would include common screening tests, simple automated tests, basic microscopic tests and a few routine cultures. **Attachment 2** lists tests that internists’ commonly perform that ASIM believes could go into the waived category if they are performed under the supervision of or in collaboration with a physician or other individual as designated by the Secretary.

2. **Reduce the red tape and fees for the new AQAS form.** The AQAS form for laboratories that have successfully passed their last on-site survey permits approved laboratories to fill out a self-assessment questionnaire in lieu of an in-office laboratory inspection. Unfortunately, in its current state, the form is too long and requires the submission of detailed materials that are not necessary to validate that a laboratory is continuing to meet a high standard of quality. The form does not adequately reward participants for exceptional performance as the in-office paper survey demands as much time, if not more, to complete as an on-site inspection. Specifically, ASIM urges HCFA to make three improvements: 1) the AQAS form should be preprinted with information HCFA has already obtained from
the laboratory; 2) HCFA should reduce the number of requests for documentation in the form; and 3) physicians who are eligible to complete the paper survey should not be expected to pay the same fee as physicians whose laboratories require an inspection by a HCFA surveyor. Preprinting the laboratory's background information on the AQAS form would decrease the time needed to complete the form and would increase the likelihood that the form would be completed in the fairly brief fifteen day period HCFA has allocated. Reducing the documentation requests makes sense because much of the information requested is not necessary for CLIA compliance, nor will it contribute to the improvement of a laboratory. Clearly, the fees for labs that complete the AQAS survey should be reduced below the current level, which is the same as for labs that are inspected on-site.

3. Eliminate routine reinspection for moderate-complexity labs. Once a laboratory passes inspection, it does not need to be reinspected every two years. We suggest that reinspection be required only if there are quality problems (e.g., the lab fails initial inspection or proficiency testing or a complaint is made). If HCFA will not agree to stop reinspection, it should extend the current two year time frame that a certificate is valid. The President’s proposed FY 1997 budget contains a provision to change the legislative language addressing the frequency of inspections. ASIM urges the administration to continue to implement this change. We do not believe that this change would require congressional approval.

4. Eliminate all fees and certification requirements for labs in the waived category. Requiring waived labs to obtain certificates to perform tests for which there are no quality standards and no federal oversight is unnecessary paperwork. Eliminating this requirement would save physicians and patients a tremendous amount of paperwork and money.

5. Revise the billing process. Because HCFA currently bills laboratories 12 months prior to the beginning of their next survey cycle and encourages its surveyors to inspect laboratories anywhere from 12 to 18 months into the survey cycle, POLs are expected to pay for an inspection that will occur, at earliest, two years later. It is our belief that laboratories should not be expected to pay their inspection fees any sooner than four months prior to the beginning of their upcoming two-year survey cycle and that a routine two-year billing procedure should be established. Such a procedure would be consistent with that used by private accrediting programs and the CLIA-exempt state programs.

6. Change HCFA's fee schedule. HCFA’s current inspection fees are dependent upon 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. Private accrediting programs base their inspection fees on the number of physicians using the laboratory and the physician’s specialty. HCFA should adopt a similar approach for its inspection fees. This approach would stop the current discrepancy whereby some surveyors count every single test run in a POL and others simply ask the laboratory personnel to estimate their numbers. At the very least, HCFA should stop counting each test in a Complete Blood Count (CBC) panel individually and instead count the panel as one test. 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 as one test would keep most POLs in a fee schedule category that is more manageable.

MEDICARE CHOICES DEMONSTRATION PROJECT

ASIM is pleased that the Health Care Financing Administration (HCFA) plans to initiate a pilot project designed to offer Medicare beneficiaries expanded choices among managed care plans. We believe that providing beneficiaries health services delivery options beyond traditional fee-for-service and Medicare health maintenance organizations (HMOs) offerings is in the best interest of the Medicare program.

In recent years, the enrollment of Medicare beneficiaries in HMOs and Competitive Medical Plans (CMPs) has grown rapidly. Currently, approximately 10 percent of beneficiaries belong to a Medicare managed care plan. In 1995, an average of 68,000 beneficiaries enrolled in risk-bearing
HMOs each month. Enrollment is increasing at an annual rate of 25 percent, and it is likely that enrollment will continue to rise swiftly as providing incentives to expand enrollment in managed care organizations (MCOs) is a lynchpin of the Medicare reform proposals that have been considered by the 104th Congress. In fact, some analysts believe that managed care will soon replace fee-for-service as the dominant form of delivering services to Medicare beneficiaries.

The Medicare Choices demonstration project is intended to assist HCFA in preparing for the expected continued increase of beneficiary enrollment in managed care plans. Beneficiaries in communities that have relatively low enrollment in managed care will be afforded the opportunity to join managed care organizations that offer more flexibility than conventional HMOs or CMPs. It will also allow for an assessment of the readiness of beneficiaries to enroll in plans that will be new to the Medicare program: provider sponsored networks (PSO), provider-owned HMOs, and preferred provider organizations (PPOs). Many of these of plans will also offer a point-of-service (POS) rider.

With increased managed care enrollment, however, there is an increased need for the federal government to exercise appropriate oversight over MCOs. Unfortunately, the federal government, despite recent efforts to make improvements, is doing an inadequate job of exercising oversight over the care provided to almost four million beneficiaries who are currently enrolled in nearly 300 managed care plans that now participate in the program. Since the current standards and enforcement methods are inadequate to protect the relatively small minority of beneficiaries enrolled in managed care, it is obvious that they will prove to be insufficient as the number and types of plans, as well as the number of enrollees, increases rapidly over the next several years.

ASIM believes that there is an urgent need for Congress and the Administration to make improvements in the standards used to evaluate Medicare MCOs. As a result, ASIM is in the process of developing a policy paper entitled, Re-Inventing Medicare Managed Care. The paper, which will be released in several weeks, will propose that HCFA implement new standards to protect Medicare beneficiaries who are enrolled in managed care plans. Issues that will be addressed in the paper include the following:

1. Providing more information to patients and physicians to help them make informed choices of plans. Existing data, such as disenrollment rates and medical expense ratios, should be routinely provided to current and prospective enrollees even as more extensive, outcome-based performance measures are being developed.

2. Providing for external oversight, by peer review organizations or other appropriate bodies, of the internal quality improvement methods employed by Medicare managed care organizations. The Physician Payment Review Commission and the General Accounting Office (GAO) both agree that HCFA’s current procedures for certifying MCOs’ internal quality improvement activities are inadequate.

3. Involving participating physicians in development of the utilization review, credentialing, and physician performance standards for all Medicare MCOs. Beneficiaries should have the confidence that MCOs’ medical policies are developed in consultation with their own doctors. Medical policies that are developed without the expertise--and support--of practicing physicians will lack credibility and may not always be in the best interests of patients enrolled in the plan.

4. Reducing the time involved in appeals of denied claims. As recommended by the GAO, Medicare’s timetable for acting on appeals of claims denied by MCOs can be streamlined. ASIM will propose changes so that the timetable for getting a final determination is shortened by as much as three months.
5. Assuring that Medicare MCOs meet standards relating to access to physician services that are at least as extensive as those required by private sector accrediting bodies.

The paper will also re-iterate ASIM’s views that HCFA’s final rule on physician incentive arrangements needs to be strengthened to provide better stop-loss coverage, to require that MCOs adjust capitation rates to reflect differences in severity of illness, and to require more uniform reporting of the potential impact of such arrangements on patient care. Given that the rule published by HCFA imposes very minimal, modest requirements on Medicare MCOs, ASIM is surprised to learn that HCFA has decided to delay implementation of the rule, possible as a precursor to withdrawing or weakening it, because of pressure from the managed care industry. As noted in the attached letter to Secretary Shalala (attachment 3), ASIM believes that restoration of the physician incentive regulations—without further delay—is a necessary first step if the administration is to meet its obligations to the public, as Congress intended when it enacted the physician incentive mandate in 1990 and again in 1993.

Given the opposition of the managed care industry to the modest set of proposals included in the physician financial incentive regulations, ASIM fully anticipates that the industry will label our forthcoming proposals for improving Medicare managed care as being “anti-managed care.” We hope that HCFA rejects the notion that requiring that MCOs meet reasonable standards of accountability is anti-managed care. ASIM fully supports giving beneficiaries the option of enrolling in managed care plans, including ones that place physicians at financial risk, provided that those plans meet reasonable federal standards to assure that access and quality are not compromised. Managed care will only have credibility with beneficiaries and physicians if they have confidence that the federal government will hold MCOs accountable for the impact of their policies on access and quality.

ASIM urges that PPAC recommend that HCFA re-instate the physician incentive regulations without further delay and consider making changes to improve the protection provided by those regulations as Congress intended. We also recommend that PPAC include as an agenda item at your next meeting a full discussion of federal oversight over Medicare MCOs. ASIM will be pleased to share with the Council our complete set of recommendations on improving Medicare MCO accountability.

**CONCLUSION**

ASIM urges that PPAC:

1. Support administrative relief from excessive CLIA requirements on POLs, including an expansion of the waived category, improvements in the AQAS survey, elimination of routine reinspection requirements for moderate complexity labs with good quality records, and development of more equitable fee schedule and billing requirements;

2. Oppose any delay in implementation of resource-based practice expenses until or unless a review of the proposed methodology, when published in 1997, conclusively shows that it is less methodologically sound than the current distorted and inequitable change-based methodology (for more detail see attachment 1);

3. Urge HCFA to re-institute the physician financial incentive regulation without further delay, with improvement to expand protection for beneficiaries with more costly and chronic medical conditions; and

4. Discuss ways to improve federal oversight of Medicare MCOs at the next PPAC meeting.
MEDICARE RESOURCE-BASED PRACTICE EXPENSE (RBPE) PROJECT

Resource-Based Practice Expenses are Needed

The American Academy of Family Physicians (AAFP), American Academy of Pediatrics (AAP), American College of Physicians (ACP), American College of Rheumatology (ACR), and American Society of Internal Medicine (ASIM) strongly urge the Practicing Physicians Advisory Council (PPAC) to recommend to the Health Care Financing Administration (HCFA) and the Congress that they stay the course and maintain the current resource-based practice expense (RBPE) implementation schedule until or unless an evaluation of the RBPE methodology—when published in 1997—conclusively shows that it will yield practice expense RVUs that are less sound than the current RVUs.

Congress—through the 1994 Social Security Amendments—directed the Health Care Financing Administration to continue physician payment reform by making the practice expense component of the Medicare Fee Schedule (MFS), accounting for overhead costs of medical practice, resource-based. This legislation was enacted to promote a more appropriate distribution of the nation’s finite health care resources and to end systematic payment disparity in the MFS by employing a more equitable and rational reimbursement methodology. Under this approach, reimbursement is based on the cost of the resources used to deliver the particular procedure or service, rather than on outdated estimates based on historical charges. Congressional mandate calls for full implementation of a resource-based practice expense methodology on January 1, 1998.

The inequality of the current charge-based methodology has long been acknowledged. The current system is biased and must be corrected. The historical-charge methodology of the practice expense component systematically overvalues many surgical procedures while evaluation and management services are undervalued. This skews the incentives in the MFS against primary care. For example, a primary care physician would have to conduct 73 new patient office visits (level 3) to equal the overhead that would be assigned to one coronary triple bypass procedure. This is particularly troubling because a considerable portion of the surgeon’s overhead is assumed by the hospital. This biased system will have been in place six years by the time this situation is scheduled to be rectified in 1998.

RBPEs Should be Implemented Within the Timeframe Established in Law

Any suggestion of a delay in implementation is unwarranted at this time. Given the unfairness of the current system, there should be no delay in implementation unless a review of the proposed methodology next year leads to a conclusion that the methodology is unsound. We know that the current system to create practice expense values is methodologically unsound, antiquated, and unfair. Therefore, it should be changed as soon as possible. Thus far, no information has been presented that supports a conclusion that sound resource-based practice expense values cannot be implemented by January 1, 1998.

Determining practice expense relative value units (RVUs) is not a new concept. The analytical framework for developing a more fair and rational resource-based methodology for determining practice expenses has been underway for almost a decade (see attached for a chronological history on the development of RBPEs). The methodology, scheduled for full implementation of January 1, 1998, will be based on years of work devoted to the development of sound RBPE relative values. Abt Associates, the contractor selected by HCFA to gather data for the RBPE project, has projected that its direct cost estimates will be available in August 1996. Expert panels advising Abt have already finished their work developing data on the direct cost of providing each service.
Abt is also surveying physician practices on indirect costs, the results of which should be available by Fall 1997. In addition, other research studies by Daniel Dunn, PhD at Harvard University, and by Greg Pope, MS, and Russell Burge, PhD, at the Policy Center for Health Economics, are available on physician practice expense costs. HCFA recently indicated that these studies, using existing data that lend themselves to prompt implementation and refinement, and producing results similar to accounting-based studies, will be available to construct methodologically sound practice expense allocations by January 1, 1998. These studies are also less susceptible to stakeholder gaming, and to skewed or inadequate response rates that may compromise the quality of data from the Abt indirect cost survey. The combined data from the Abt, Dunn, and Pope/Burge studies will provide a substantial amount of data and expert analysis for development and implementation of RBPE relative values on January 1, 1998.

HCFA intends to publish a proposed rule on the RBPE methodology and the future refinement process in Spring 1997. Concerns about the proposed methodology can be expressed at that time. It is premature to express concerns about the RBPE methodology prior to the publication of the proposed rule. Upon publication, HCFA will have an adequate opportunity to review and reply to public comments, to appoint refinement panels to advise it on specific practice expense estimates, and to use subsequent Abt survey data to validate indirect cost estimates.

In order to ensure that the Congressional deadline is met, HCFA plans to issue a final rule indicating the methodology and the practice expense relative values in Fall 1997. To address concerns over the uncertainty of the newly developed values, the RVUs implemented on January 1, 1998 could be considered “interim” values subject to further refining and updating. Therefore, any imperfections in the new practice expense values can be refined without interfering with the current implementation schedule. Utilization of a refinement process facilitated acceptance of the physician work relative values and is likely to serve the same positive function regarding practice expense relative values.

We understand that many surgical groups are arguing for a delay in implementation of resource-based practice expenses because the Abt Associates indirect practice expense survey results will not be available until Fall 1997. They suggest that without the Abt Associates survey data, HCFA will not be able to create methodologically sound RBPEs. This argument ignores the fact that direct practice expense results—which are likely to constitute the majority of practice expense RVUs--will be completed by the end of this year. It also ignores the existence of other data sources on individual practice expenses that may be more valid than the Abt Associates survey data. This argument overlooks that fact that the Abt Associates indirect survey data will be available to validate and refine interim practice expense RVUs. It assumes that the Abt Associates indirect cost survey will produce better data than extant sources—a premise that we believe is highly questionable for the reasons cited earlier. Most importantly, if the argument for a delay is accepted by Congress it will mean continuation of the current formula-driven methodology, which is based on inflated historical charges that have no relationship to the costs of providing physician services. The data that HCFA will likely use to create RBPEs within the timeframe mandated by Congress will clearly be methodologically more defensible—and more fair—than the current formula-driven charge-based method. Although cloaked as an argument for “better data,” we suspect that the real agenda of most of those seeking a delay is to perpetuate a methodologically indefensible system that overpays some physicians for overhead costs while underpaying many of their colleagues.

The development of a RBPE methodology is clearly necessary to correct the inequalities created by a charge-based system. Extensive research has been done to enable the development of a sound resource-based methodology to determine practice expense relative values. Data derived from these studies allows for RBPE implementation by the mandated deadline. HCFA is equipped with all of the tools necessary, including legal precedent, to fulfill its obligation as required by law. Full implementation of a resource-based practice expense methodology by January 1, 1998 is in the best
interests of the nation’s patients and physicians, alike. We strongly urge PPAC to recommend to HCFA and the Congress that they stay the course and maintain the current RBPE implementation schedule until or unless an evaluation of the RBPE methodology—when published in 1997—conclusively shows that it will yield practice expense RVUs that are less sound than the current RVUs.
ATTACHMENT 2 -- TESTS PROPOSED TO BE ADDED TO CURRENT 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