June 9, 1998

June Gibbs Brown, Inspector General
Office of Inspector General
Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, SW
Washington, DC 20201

Re: Revised OIG Civil Monetary Penalties; OIG-25-P

Dear Ms. Brown,

On behalf of the American Society of Internal Medicine (ASIM), representing the nation’s largest medical specialty, I am writing to comment on the Office of Inspector General’s proposed rule on “Health Care Programs: Fraud and Abuse; Revised OIG Civil Money Penalties Resulting From the Health Insurance Portability and Accountability Act of 1996,” published in the March 25, 1998 Federal Register.

ASIM recognizes the responsibility of Congress, Health Care Financing Administration (HCFA) and the Department of Health and Human Services’ (HHS) Office of Inspector General (OIG) in ensuring the integrity of federally-funded health care programs. We support many of the efforts established by recent legislation to curb fraud and abuse within these programs. We would, however, caution that as appropriate as these tools may be in meeting Congressionally-mandated program goals of reducing fraudulent and abusive practices within Medicare and Medicaid, the possibility exists that these enforcement mechanisms may be used inappropriately in investigating and prosecuting alleged prohibited activities.

Our comments will focus on the following aspects of the CMP proposed rule:

1. The coercive effect of CMPs in fraud and abuse investigations;
2. The imposition of CMPs on excluded individuals who retain ownership or control in a participating Medicare/Medicaid entity;
3. New CMP for upcoding or ordering unnecessary medical services;
4. New Civil Money Penalty for the Offering of Inducements to Beneficiaries; and
5. New CMP for falsely certifying eligibility for Medicare-covered home health services.

I. The Coercive Effect of CMPs in Fraud and Abuse Investigations

In order to detect fraud and abuse, the OIG depends upon a concerted effort that includes:

• the investigative efforts of the HCFA and its carriers;

• complaints from Medicare beneficiaries, their relatives, other physicians or providers; and

• investigations by the OIG scrutinizing specific practices of various segments of the health care industry, such as home health or medical equipment suppliers.
Should the OIG determine that providers have engaged in fraudulent or abusive behavior, they may be subject to civil monetary penalties, and/or exclusion from participating in Medicare, Medicaid, and other federal programs. In addition, the OIG can refer cases to the Department of Justice (DoJ) should they warrant criminal investigation and/or prosecution.

In determining when possible fraudulent and/or abusive activities have occurred, the OIG applies a standard of proof based on the probability that a person “knows”, or “should know” if the activity falls into a prohibited category. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) applies the term “should know” to patterns and practices where there is evidence of “reckless disregard” or “deliberate ignorance” of the truth. Anyone who “knowingly” presented or caused to be presented a prohibited claim, or who is otherwise involved in a prohibited activity is subject to the imposition of CMPs and/or assessments and exclusion.

The “knowledge” standard implies that CMP liability will not be imposed for honest mistakes (i.e., if the provider exercised reasonable diligence and still made a mistake). Under the newly defined knowledge standard in the proposed regulations, individuals and entities would be liable for CMPs only to the extent that the person "acts in deliberate ignorance of the truth or falsity of the information or acts in reckless disregard of the truth."

ASIM is concerned, however, that the OIG may overstep its authority in penalizing physician practices without proving that physicians have acted in "reckless disregard or deliberate ignorance of the truth." The possibility of the imposition of severe civil penalties and assessments, and/or a possible five year exclusion from the Medicare and Medicaid programs may lead many physicians to settle with the OIG for lesser penalties rather than risk potentially larger penalties and to avoid going to court. ASIM is concerned about the possibility that physicians could be pressured into a costly settlement with the OIG, without the OIG actually proving that the physicians’ activities constituted fraud or abuse.

The OIG should be responsible for proving that a physician’s activities constitute fraud or abuse before pursuing any settlements. CMPs, assessments, and exclusions should be pursued as a result of evidence showing a clear and willful violation of fraud and abuse laws.

II. The Imposition of CMPs on Excluded Individuals Who Retain Ownership or Control in a Participating Medicare/Medicaid Entity

Prior to the HIPAA, if an individual retained direct or indirect ownership of, control interest in, or had a management role with, a health care entity that participates in Medicare or any State health care program after the individual had been excluded, the entity itself was at risk of exclusion for as long as the individual maintained his or her relationship with that entity. However, the individual faced no additional liability unless he or she filed, or caused to be filed, a claim for reimbursement.

The HIPAA specifically set forth new CMP authority designed to deter such affiliations by subjecting the excluded individual to a CMP of up to $10,000 for each day he/she retained a prohibited relationship with a participating entity. This new CMP provision applies only to those with an ownership or control interest in a participating entity who knows, or should know, of the action constituting the basis for the exclusion, or any excluded persons who retain positions as officers or managing employees of a participating entity.

ASIM supports efforts to reduce health care costs associated with fraud and abuse. Intentional violators of fraud and abuse statutes should be excluded either temporarily or permanently from
participation in federally-sponsored health care programs, and should not benefit indirectly from
ownership or controlling interests in a participating entity. However, given the complexity of business
arrangements, it may not be possible to immediately divest an ownership or controlling interest.
Therefore, ASIM recommends that the OIG impose this CMP only after the individual has been given
adequate time to dispose of their interest in the participating entity.

III. New CMP for upcoding or ordering unnecessary medical services

HIPAA expressly rendered upcoding and the claiming of medically unnecessary services as
violations of the CMP statute. HIPAA established specific CMP authority for a pattern or practice of
submitting claims, or causing claims to be submitted, based on a code that the person “knows or
should know” will result in greater payment than the code that should have been claimed. However,
a physician whose documentation fails to support the level of service submitted for a service code is
not guilty of fraud or abuse, unless he or she acted “in deliberate ignorance” or “reckless disregard”
of the truth. Submitting a claim for a service that is later found to be medically unnecessary also
doesn’t constitute fraud or abuse without evidence of a deliberate or reckless disregard of the truth
or a knowing and willful intent to defraud the program.

ASIM believes that improper upcoding, for the purpose of increasing revenues, must not be tolerated
in the medical community. However, as there are many issues involved in proper coding, physicians
should not be prosecuted for honest coding mistakes and legitimate differences of opinion over
medical necessity or the appropriate code to use. ASIM supports the new CMP authority that
suggests that honest coding mistakes will not be cause for CMPs when the “knowledge” standard
has not been met. However, ASIM strongly disagrees with the implication that lack of documentation
is synonymous with improper or erroneous payments. While the documentation available in medical
records may not meet the exacting standards of government auditors, it does not mean that services
were billed or paid incorrectly. It is possible that some of the allegedly inadequately documented
services are actually being billed at a lower level than is justifiable.

ASIM recognizes the need to help physicians improve documentation. However, the amount of
documentation in a medical record should be based primarily on what is necessary to assure quality
patient care, not what is needed to satisfy government auditors. ASIM urges the government to work
with the medical profession to educate physicians regarding proper billing procedures in order to
minimize the potential for fraud and abuse violations.

IV. New Civil Money Penalty for the Offering of Inducements to Beneficiaries

HIPAA established a new CMP against individuals or entities that know, or should know, that offering
remuneration or inducements to a program beneficiary will influence the patient’s decision to order or
receive any item or service from a particular provider, practitioner or supplier reimbursable under
Medicare or the State health care programs (these provisions are separate and distinct from the anti-
kickback law). Remuneration includes both the waiver of all or part of the coinsurance and
deductible amounts, and “transfers of items and services for free or for other than fair market value.”

There are three statutory exceptions to the definition of remuneration in this CMP provision. These
statutory exceptions are:

1. Waiving of coinsurance and deductible amounts to indigent beneficiaries or after responsible
collection efforts have failed.
ASIM supports health insurance plan features that contain appropriate deductibles and/or copayments by the patient based on the patient's ability to pay. Such a policy fosters beneficiary responsibility regarding health care consumption and controls costs. ASIM supports the exception for waiver of coinsurance and deductible amounts in cases where responsible collection efforts have failed or when individuals are indigent.

2. **Differentials in coinsurance and deductible amounts as part of a benefits plan design are acceptable where the differentials have been disclosed in writing to all beneficiaries, third-party payors and providers, and the differentials meet standards defined by the Secretary of HHS.**

ASIM supports this exception because alternative insurance plans, with different schedules of deductibles, coinsurance, and premiums, should be available to beneficiaries. Beneficiaries should also be made aware of the financial tradeoffs associated with different plans.

However, this exception is too limited because the proposed rule asserts that this exception would not authorize any benefit plan design that would waive a beneficiary's obligation to pay deductible or coinsurance amounts under a Federal health care program. Seventy-five percent of Medicare beneficiaries own Medigap insurance, which generally covers those out-of-pocket costs. The rule should clarify that this provision would not affect the ability of physicians to be reimbursed for beneficiary copayments and deductibles through Medigap insurance.

Furthermore, there are many employer-sponsored plans that prohibit physicians from billing the plan or the beneficiary for deductibles and copays that occur as a result of a differential between the plan's negotiated fee schedule and the Medicare allowed amount due to prior contractual arrangements. The rule should recognize that such arrangements are a standard practice in the current health care market. ASIM urges the OIG to clarify the rule by requiring all secondary insurers to pay physicians the full Medicare deductible and coinsurance amounts regardless of whether their fee schedules are lower than Medicare, or to allow physicians to bill Medicare beneficiaries directly for the full Medicare deductible and coinsurance amounts because Medicare is the primary insurance and the patient or their secondary insurer should be responsible for the patient's Medicare copay. Should neither of these approaches be adopted, the final rule should provide a new exception to the definition of “remuneration” for the routine waiver of copayments when Medicare is the primary payor and the physician is contractually prohibited by the secondary payor from billing the plan or the patients for the deductible/copayment.

3. **Incentives given to individuals to promote the delivery of preventive care are acceptable. Cash or cash equivalents are not permissible under the proposed rule. Items and services of nominal value would not be prohibited, as long as the aggregate value of such services provided to any individual remained nominal.**

ASIM agrees that health care providers should encourage health care recipients to engage in healthy lifestyles and should practice and promote preventive health care. ASIM, therefore, supports the exception for preventive care incentives.

V. **New CMP for falsely certifying eligibility for Medicare-covered home health services**

HIPAA established a new CMP for false certification of eligibility to receive home health care. Under this provision, if a physician falsely certifies the medical necessity for Medicare-covered home health services knowing that the care is not necessary, he or she may be subject to a CMP of the greater of $5,000 or 3 times the amount of the Medicare payments made for the home health care services. This provision applies to false certifications made on or after August 21, 1996.
ASIM supports the federal government’s efforts to prevent, investigate, and eliminate fraud and abuse associated with the provision of home health services, provided that such increased enforcement activities do not result in increased hassles for internists and/or result in internists unfairly being targeted for investigation for authorizing medically appropriate home health services.

In conclusion, ASIM supports the use of CMPs, assessments and exclusions to penalize those who intentionally defraud and abuse federally sponsored health care programs. However, great care should be given regarding the use of CMPs so that they are imposed only where there has been a clearly proven intent to defraud or abuse these programs, as indicated by the “knowledge” standard. The burdensome investments of time and money constrain the ability of many physicians to mount an appropriate response to fraud and abuse allegations. These constraints should not be compounded by unwarranted or ambiguous claims of fraud and abuse.

As is mentioned previously in this letter, we are very concerned that the increased dollar amount of CMPs create a potential situation where the threat of large CMPs could be used to pressure physicians to settle for smaller penalties before an investigation is completed. Therefore, we would urge the Secretary of HHS and the OIG to ensure that adequate safeguards (e.g., monitoring the application of the “knowledge” standard) are in place to avoid the misapplication of CMP authorities.

ASIM appreciates the opportunity to comment on this proposed rule. Should 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