Testimony of
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Good morning Mr. Chairman and members of the Committee.

Health care providers quite reasonably expect the Federal government to provide clear and consistent guidance when administering the Medicare program. At the same time, it is appropriate to expect health care providers reasonably to ensure that the care they provide to Medicare beneficiaries and claims they submit to conform to program requirements. The Office of Inspector General (OIG) is committed to continuing its work with honest health care providers and the Centers for Medicare and Medicaid Services (CMS) to advance these mutual goals.

In my testimony I will describe how the OIG responds to health care providers who submit false claims to the Federal health care programs. I also will discuss the OIG's efforts to promote integrity in the Medicare program through a partnership with the provider community. Finally, I will explain how we are continuing to work with the health care industry to improve many of our integrity initiatives.

The Role of the Office of Inspector General

The OIG plays a critical role within the U.S. Department of Health and Human Services (HHS). Our office's mission is to prevent and detect fraud, waste, and mismanagement, and to promote economy, efficiency, and effectiveness in all HHS programs and operations.

The core mission of the OIG is carried out through a nationwide program of audits, inspections, and investigations related to the operation of HHS programs. Our comprehensive *audits* and *evaluations* are designed to detect problems in the early stages and to define their nature and magnitude. When we find problems, we recommend specific corrective actions to the appropriate policy makers within HHS.

In contrast, our *investigations* are designed to identify and, if appropriate evidence exists, refer for prosecution cases of fraud. In FY 2000 alone, the OIG conducted or participated in 2,597 health care cases, of which 234 resulted in criminal convictions and 352 produced successful civil recoveries. A total of 3,350 individuals and entities were

excluded from participation in the Federal health care programs based on criminal convictions, patient abuse, licensure revocation or other misconduct. The Federal government won or negotiated more than $1.2 billion in health care judgments, settlements and administrative impositions in health care fraud cases.

These enforcement actions were taken against those who knowingly submitted false claims or otherwise intentionally engaged in misconduct. It is important to note that under the laws we help enforce, providers are *not* subject to civil or criminal penalties for innocent errors, or even negligence. The Government's primary civil enforcement tools (the civil False Claims Act and Civil Monetary Penalties Law) cover only offenses that are committed with *actual knowledge* of the falsity of the claim, or *reckless disregard* or *deliberate ignorance* of the falsity of the claim. These statutes do not penalize mistakes, errors, or negligence. For criminal penalties, the standard is even higher – criminal intent to defraud must be proved beyond a reasonable doubt.

Thus, our enforcement actions focus on those companies and individuals who have clearly violated the law. These are not cases of honest mistakes or simple billing disputes. Last year, for example, a major national hospital chain agreed to pay $840 million ($95 million in criminal fines and $745 million in a civil settlement) to resolve allegations of Medicare fraud. The company's subsidiaries entered guilty pleas for: (1) submitting false Medicare cost reports; (2) mischaracterizing the severity of hospital patients' illnesses in order to inflate Medicare reimbursement; (3) paying kickbacks to physicians for patient referrals; and (4) paying kickbacks and filing false cost reports related to a series of acquisitions of home health agencies.

Another OIG case involved three California physicians who purchased Medi-Cal patient identity cards, made up phony patient files, and billed for ghost patients never treated at their clinic. Of about 6,000 patient files, only about 100 were for legitimate patients. Or consider the case of another California physician, who billed for hundreds of services to patients who had died <u>prior</u> to the date of service or who were incarcerated. In another case, six New York practitioners involved in a kickback scheme signed stacks of orders for durable medical equipment without ever seeing the patients, accepted kickbacks for doing so, and filed claims for services not provided.

While the OIG focuses its enforcement efforts on those who engage in reprehensible conduct, we believe that a great majority providers want to bill the program correctly. These providers are our allies in the fight against health care fraud and abuse. Accordingly, I will now describe the OIG's efforts to educate providers about their compliance obligations. I also will describe how the OIG offers a "second chance" to

those providers that have defrauded the Medicare program by requiring them to implement an integrity program to ensure future compliance.

The OIG Commitment to a Government-Industry Partnership

The OIG believes that the vast majority of health care providers are honest, are committed to providing quality care, and share our goal of strengthening the integrity of the health care system. As I have explained, these honest providers are *not* subject to civil or criminal penalties for innocent errors, or even negligence. To the contrary, we recognize that by working in tandem with these providers, we can help preserve the Medicare trust funds for future generations. This Government-industry collaboration also "levels the playing field" for honest providers who compete based on the quality and price of their services rather than by cheating the system through kickback schemes and billing scams. In furtherance of this goal, we have dedicated significant resources to communicate with the health care industry. With the passage of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Congress reinvigorated our mission with the establishment of a national Health Care Fraud and Abuse Control Program under the joint direction of the Attorney General and the Secretary of HHS, acting through the OIG.

One of the five core elements of the HIPAA fraud and abuse control program is the provision of guidance to health care providers regarding potential liability for activities that may be considered fraudulent or abusive. I will focus my comments on four OIG initiatives related to the goal of furnishing guidance to health care providers. Specifically, the OIG: (1) issues legally binding opinions regarding the applicability of the criminal and administrative sanction provisions of the Social Security Act to specific business arrangements and practices; (2) promulgates regulations that protect specified business practices from being prosecuted under the anti-kickback statute; (3) publishes special fraud alerts and bulletins identifying practices that the Inspector General considers suspect or of particular concern; and (4) issues guidance on implementing voluntary compliance programs. Additionally, we participate actively in a variety of public forums where these issues are discussed and debated.

Provision of Binding Advisory Opinions and Safe Harbors

Pursuant to HIPAA, the OIG established an advisory opinion process through which parties can obtain binding legal advice as to whether their existing or proposed health care business transactions or arrangements violate the anti-kickback statute, the civil monetary penalties laws, or any program exclusion provisions. In addition, the OIG

annually solicits proposals for the issuance of new, and modification of existing, "safe harbors" under the anti-kickback statute. Since this provider education function began in 1997, we have issued over 60 advisory opinions, promulgated nine new safe harbors, and clarified or modified many existing safe harbors. In addition to assisting the health care industry comply with the law, the advisory opinion and safe harbor mechanisms enhance the OIG's understanding of new and emerging health care business arrangements and guide the development of new safe harbor regulations, fraud alerts, and advisory bulletins.

Identification of Suspect Industry Practices

The OIG also issues Special Fraud Alerts, Special Advisory Bulletins, and other industry guidance as part of its ongoing efforts to promote ethical and lawful conduct by health care providers. We believe it is sound public policy to notify the public of potentially abusive practices we uncover during our audits, inspections, and investigations so that honest providers can examine their operations and take appropriate corrective actions. As an example, the OIG issued a Special Fraud Alert describing abusive practices associated with the provision of medically unnecessary medical supplies and home health services. These include the payment of a fee to a physician for each plan of care certified by the physician on behalf of the home health agency and disguising referral fees as salaries by paying referring physicians for services not rendered, or in excess of fair market value. The alert also reminds physicians of their responsibilities when certifying the medical necessity of these services for a Medicare beneficiary.

A Special Advisory Bulletin issued earlier this month warned providers of unethical health care business consultants and the types of abusive billing schemes they promote. For example, a billing consultant may promise a prospective client that its advice or services will produce a specific dollar or percentage increase in the client 's Medicare reimbursements. The consultant's fee is often based on a percentage of this increased reimbursement. History has shown that this type of arrangement can encourage exploitation of the reimbursement systems to the ultimate detriment of both the health care programs and the health care provider. The OIG also provided testimony on this subject before the Senate Finance Committee on June 27, 2001.

Development of Voluntary Compliance Program Guidances

In addition to case-specific advisory opinions and industry fraud alerts, the OIG has embarked on a major initiative to promote voluntary compliance programs within

health care organizations. The purpose of a compliance program is to ensure that the organization has adequate systems to prevent and detect violations of law, as well as misconduct by its employees and agents. The OIG has found that providers with an effective compliance program in place not only provide quality care and services, but also have fewer systemic billing errors.

In recent years as the Government has stepped up its anti-fraud efforts, health care providers devoted greater attention and resources to the development of compliance programs. Part of the reason they did so is because compliance programs make good business sense and reduce expenses in the long run. We were concerned, however, that the cost of retaining an outside compliance consultant to develop and implement these programs might put this valuable tool beyond the budget of many providers. Accordingly, our office has worked intensively and cooperatively with CMS, health care providers, and related industry groups, such as the American Hospital Association (AHA) and the American College of Physicians-American Society of Internal Medicine (ACP-ASIM), to produce a series of voluntary compliance program guidances for major sectors of the health care industry. Each guidance provides concrete suggestions for designing and implementing internal controls and procedures to address identified risk areas for the applicable health care sector.

These guidances are not mandatory; they are not regulations. Health care providers are free to accept, reject or adapt the applicable guidance to their particular circumstances and budget. Moreover, our office has considered voluntary compliance efforts a mitigating circumstance when determining the appropriate sanctions to be imposed on providers who have been found (despite their compliance efforts) to have engaged in fraudulent or abusive practices.

A measure of the success of this collaborative approach is reflected in the widespread adoption of compliance programs throughout the health care industry. For example, in 1999, a compliance survey reported by the AHA found that 96 percent of its membership responding to the survey either had a compliance program in place or were planning to initiate one in the coming year. ACP-ASIM modeled its own compliance program for members on the OIG's physicians compliance guidance and noted that "we are particularly pleased to see that the OIG included our recommendation that physicians be encouraged to adopt the active application of compliance principles in their practices, rather than implement rigid, costly, formal procedures." The Health Care Compliance Association (HCCA), whose 3,000 members represent the industry's compliance officers, recently passed a resolution acknowledging the OIG's important contribution and the

compliance guidances as "having been prepared professionally and represent[ing] a highly valuable resource to health care professionals."

To date, we have issued nine compliance guidances pertaining to hospitals, clinical laboratories, home health agencies, durable medical equipment suppliers, third-party medical billing companies, hospices, Medicare+Choice organizations, nursing facilities, and individual and small group physician practices. Currently, we have solicited public comment and are developing guidance for ambulance transportation companies and the pharmaceutical industry.

Access to Essential Compliance Information

Compliance guidances and other fraud prevention tools are of little value unless they are easily, promptly, and widely available to providers nationwide. Accordingly, all of the information I have just described is readily accessible to health care providers, in a single location, by logging on to the OIG's web site at **www.hhs.gov/oig.** Each month the OIG also posts a list of the individuals and entities who are currently excluded from participation in Medicare, Medicaid, and other Federal heath care programs. Publicizing this information to health care providers and prospective employers is critical because excluded individuals present a great risk to the integrity of the business entity, the Federal health care programs and program beneficiaries. In addition, the OIG has created an electronic service that provides an early alert to all interested parties about any new item or document to be posted on the OIG website. There are currently over 9,800 subscribers to this e-mail listserve, which ultimately reaches over 88,000 individuals throughout the health care community.

Promotion of a Government-Industry Dialogue

As a result of our extensive experience in identifying Medicare program vulnerabilities, the OIG must play a leadership role in promoting measures to strengthen the integrity of the program. Equally important, health care providers have insights and perspectives that can only come from operating a business under the complex set of regulations that apply to the Federal health care programs. To devise realistic solutions, the OIG has recognized that we must engage in a continuous dialogue with health care providers. OIG staff have consistently made themselves available to health care provider groups, participating in hundreds of discussion panels and teleconferences on issues as diverse as the OIG work plan and promoting quality care in nursing homes.

For example, the OIG and the HCCA co-sponsored a series of meetings with health care providers to explore new ways to promote compliance. The first of these roundtables in 1999 was an opportunity for the health care compliance industry to inform the OIG of issues encountered in implementing and maintaining compliance programs. This first meeting was also an opportunity for the OIG to present policy objectives underlying its corporate integrity initiatives and compliance program guidance. At the second meeting in 2000, practicing physicians from across the country met with OIG and CMS representatives to discuss the challenges to compliance in physician practices. Based in part on information obtained from this roundtable, the OIG issued its voluntary compliance program guidance for physician practices in September 2000.

The OIG Voluntary Disclosure Program

If a health care provider implements a comprehensive compliance program, there is a reasonable chance at some point it will discover a violation of Federal health care program requirements. After all, one of the precepts of an effective compliance program is the early detection of billing errors and other problems through a system of internal audits and by empowering employees to do the right thing. Furthermore, to receive credit under the criminal sentencing guidelines for having an effective compliance program, the U.S. Sentencing Commission guidelines require a corporation to have a mechanism to report self-discovered errors. For these reasons, many in the heath care industry sought a mechanism through which to report such fraud and abuse.

In response, the OIG created the Self-Disclosure Protocol (Protocol), a copy of which is also posted on the OIG website. The Protocol provides a detailed, step-by-step explanation of how a provider can assess the extent and financial impact of any discovered wrongdoing and report the results of that assessment to the OIG. Providers that made good faith disclosures to the OIG pursuant to the Protocol have received expedited review of their disclosures and, where appropriate, favorable treatment in the resolution of the matter disclosed.

Since 1995, the OIG has received over 120 self-disclosures from health care providers, and the Medicare Trust Fund has recovered over $42 million. Many of these matters were resolved with a simple recovery of the Medicare overpayments. Others were resolved with no findings of provider liability. In more serious cases, the matter has been referred to the Department of Justice (DOJ) for resolution under the civil False Claims Act. In these latter cases, the OIG has made a commitment to take voluntary compliance efforts into consideration when determining the appropriate administrative sanctions to be imposed on providers found to have engaged in fraud.

Corporate Integrity Agreements - "Second Chances" for Providers who have Committed Fraud

As the foregoing demonstrates, the OIG has devoted substantial resources to working with providers to improve the integrity of the Medicare program. We believe that the majority of health care providers are willing and able to use tools such as the compliance guidances and fraud alerts to minimize the risk of billing fraud and other abuses. Unfortunately, despite these efforts, some providers continue knowingly to abuse and defraud the Federal health care programs. This fraud includes, among other things, billing for items that are not provided, upcoding of claims, and providing medically unnecessary care.

When individuals or entities are found to have engaged in fraud, the OIG is responsible for determining whether to exclude them from participation in Federal health care programs. In the Social Security Act, Congress directed that health care providers found to be untrustworthy should not be allowed to do business with the Federal Government for some period of time. In the case of felony convictions related to health care fraud or patient abuse, Congress mandated that the defendant be excluded for a minimum of five years. However, in less serious circumstances, Congress gives the OIG some discretion in deciding whether to impose an exclusion, as well as its length.

In exercising this discretion in civil false claims cases, the OIG has adopted non-binding criteria for deciding whether to exclude providers or, despite evidence that they are untrustworthy, allow them to continue to participate in the Federal health care programs. This issue of programmatic exclusion in false claims cases usually arises in connection with the settlement of allegations of fraud between the provider and DOJ. In the appropriate circumstances, the OIG may offer to waive its exclusion remedy in exchange for the provider entering into a corporate integrity agreement or "CIA." This agreement, which is typically in effect for between three and five years, requires the provider to institute or maintain a series of internal controls that better ensure its future compliance with Federal health care program requirements and ultimately protect the Medicare program and its beneficiaries.

Most of the requirements of the CIA are derived from the seven elements of an effective voluntary compliance program, as outlined by the U.S. Sentencing Commission. By adopting these existing standards, the OIG conforms its own enforcement goals with that of other Federal law enforcement authorities. These compliance program elements include appointment of a compliance officer, development of written standards and policies, implementation of a comprehensive employee training program, auditing of claims submissions to Federal health care programs, establishment of a confidential

disclosure program, disciplinary measures, and restricting employment of ineligible persons. It is our hope that when the obligations of its CIA end, the provider has in place a comprehensive compliance system that has become an integral part of an ethical organization.

In our experience, most health care companies that have implemented voluntary compliance programs have incorporated these variables into their internal control systems. However, two significant requirements of the CIA are not part of a voluntary compliance program: the provider's obligation to submit to the OIG for the term of the CIA an annual report that summarizes its compliance efforts and a billing review, conducted either by an independent review organization (IRO) or, in many cases, by the provider's internal auditing mechanism, with a verification review performed by the IRO. This billing review is intended to assist the provider in avoiding improper billings, as well as identifying and correcting improper billings once they occur. This requirement has proved to be an essential aspect of ensuring appropriate claims are submitted to the Federal health care programs.

While the above components are common to all CIAs, each agreement addresses the specific facts of the conduct at issue in the particular case and is tailored to the existing capabilities and structural organization of the provider. This tailoring allows providers the opportunity to negotiate the terms of the CIA and to help design cost-effective auditing and reporting requirements. As more and more providers have instituted compliance measures, increasingly the OIG is able to customize the integrity agreement in a way that makes good business sense for that particular provider and utilizes the provider's resources and pre-existing compliance measures in the most cost-effective manner.

In response to feedback we have received from providers, we continually evaluate the usefulness of each element of the CIA and have modified many of the requirements to decrease the cost and burden of operating under the CIA. However, we continue to develop ways to improve the process.

For example, to ensure that the IRO function in the CIA serves its intended purpose and does not become an unnecessary burden on the provider, the OIG has undertaken a number of measures. For example, the OIG may allow the annual billing audit to be shifted from the IRO to an internal audit department in the later years of the agreement in cases where the provider can clearly demonstrate that it has developed a robust system of internal controls. This reduced reliance on the IRO not only lowers the cost of the CIA, but also strengthens the provider's internal audit capabilities.

The OIG also has worked extensively in the last two years with the American Institute of Certified Public Accountants (AICPA) to address the role and responsibilities of an IRO in the CIA process. With the OIG's assistance, the AICPA issued a Statement of Procedure (SOP 99-1) that provides detailed guidance and advice on IRO engagements and reviews. The OIG continues to work with a task force of the AICPA on modifying the IRO claims review procedures to make them more cost-effective.

Additionally, we are seeking guidance and suggestions from the provider community by holding another in our series of roundtable discussions. Specifically, on July 30, representatives of health care providers that are currently operating under CIAs will meet with OIG staff and the HCCA to discuss the issues surrounding the implementation and maintenance of compliance programs and CIAs. This roundtable, entitled "A Government-Industry Roundtable on Corporate Integrity Agreements," is part of the OIG's ongoing effort to solicit feedback from providers operating under CIAs, and to adapt its CIAs to the business realities of the health care industry.

Providers that have successfully operated under a CIA, and that have continued to implement compliance measures after the CIA has expired, have found that the CIA is not a punitive mechanism, as it has sometimes been mischaracterized. Rather, it is a tool that assists the provider in focusing its attention on providing quality care, submitting claims that are free from error, and developing a business based on integrity. As the compliance officer for a California medical center explained, "Despite the difficulties of the task, implementing the [CIA] program was a positive opportunity for our healthcare system to not only gain valuable compliance knowledge, but also to enhance operational efficiency and improve patient care." (Mike Powers, Healthcarebusiness, September 2000, at 86.)

The Impact of Integrity Efforts on the Medicare Program

The OIG's enforcement efforts and the joint Government/industry compliance initiatives have helped to improve Medicare's financial outlook. Over the last 5 years, the OIG audit of the fee-for-service part of the Medicare program has shown that the rate of improper payments has been cut in half. For Fiscal Year 1996, improper payments totaled about $23 billion (14 percent of program expenditures), and by Fiscal Year 2000, improper payments had dropped to about $12 billion (7 percent of program expenditures).

Another indicator is the drop in the Medicare "inflation rate." The Congressional Budget Office (CBO) reports that from 1991 to 1996, the inflation rate averaged 10.9 percent per year, but the rate has dropped to an average of 3.2 percent since then.

According to the CBO, "Most of the decline can be explained by a strong effort to ensure compliance with payment rules." (CBO Budget Report, January 2001).

Most significantly, over the last 5 years the Trustees of the Medicare Part A trust fund have extended their estimate of the financial life of the trust fund by 30 years, from 1999 until the year 2029. One of the primary contributing factors cited by the Trustees has been, "the continuing efforts to combat fraud and abuse." (Trustees Annual Report, 1999).

Conclusion

The OIG is committed to protecting the integrity of the Federal health care programs and will continue to work with health care providers to achieve this mission. Our enforcement efforts will continue to focus on those providers who have engaged in fraudulent conduct. We also will continue to collaborate with the vast majority of providers and assist their efforts to comply with program requirements. We appreciate the strong support we have received from the Congress and your continued interest in this critically important subject.

Thank you for the opportunity to testify today. I would be pleased to answer any questions.