1976

Establishment of the Office of Inspector General, Department of Health and Human Services

1986

False Claims Amendments Act

1996

Health Insurance Portability and Accountability Act

Protecting Public Health and Human Services Programs: A 30-Year Retrospective

Department of Health and Human Services
Office of Inspector General

Department of Health and Human Services
Office of Inspector General

Dear Reader:

On behalf of all of the dedicated men and women of the Department of Health and Human Services (HHS) Office of Inspector General (OIG), I am pleased and privileged to introduce this retrospective on the OIG's first 30 years. Keeping in mind Shakespeare's observation in "The Tempest" that "what is past is prologue," we believe that reviewing where we have been can help us, as well as those affected by or interested in our work, better understand our direction for the future.

This is an especially timely period for this review. In an unusual confluence of milestones, the year 2006 marked the 30th anniversary of the office's creation in 1976, the 20th anniversary of the enactment of the False Claims Amendments Act of 1986, and the 10th anniversary of the Health Insurance Portability and Accountability Act of 1996. These statutes are the legal and policy foundations upon which much of OIG's work is based. This triple anniversary helpfully affords a framework for our narrative. We lay out the initial establishment of the office; examine how its mission was affected by major changes in the structure and size of HHS's programs; and address how the subsequent 1986 and 1996 laws transformed the way in which key initiatives were undertaken to advance the statutory mission of the office to prevent and detect fraud, waste, and abuse and promote the economy and efficiency of HHS programs.

Many of the most significant OIG initiatives have unfolded over a period of years, captured piecemeal in our statutorily mandated semiannual reports to Congress. This review is structured to take account of the different time horizons in which OIG's wide-ranging work occurs. Some OIG activities are episodic in nature; however, much of this office's work requires a considerable investment of time before the impact of the work becomes apparent.

If there are certain imperatives that have driven this office's work across the full spectrum of its activities, they are adaptability, innovation, and collaboration with enforcement and oversight partners. The application of these imperatives will become manifest as this review highlights significant OIG work over the years in audit, investigative, and evaluative oversight of Medicare, Medicaid, and the group of public health agencies that comprise HHS in this era. We will continue to emphasize these important attributes of effective oversight and enforcement not only as we continue our existing work, but also as we confront new issues arising under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the Deficit Reduction Act of 2005, emergency preparedness and response and health information technology initiatives, and other matters of importance in the administration of HHS programs.

We appreciate your interest in our office. We hope you find this review beneficial in understanding how we carry out our mission and the impact of our work.

Sincerely,

Daniel R. Levinson
Inspector General

Table of Contents

A Brief History

Public Law 94-505
94th Congress

An Act

To authorize conveyance of the interests of the United States in certain
in Salt Lake County, Utah, to Shriners' Hospitals for Crippled Child
Colorado corporation.

Be it enacted by the Senate and House of Representatives
United States of America in Congress assembled, That the A
istrator of General Services is authorized, subject to section 2 o
Act, to convey to the Shriners' Hospitals for Crippled Child
Colorado corporation, without consideration, all right, title, and
est remaining in the United States in and to the following des
land, being a portion of the tract conveyed to Shriners' Hospita
Crippled Children by deed of July 12, 1946, pursuant to th
entitled "An Act to authorize the Secretary of War to conve
tain lands situated within the Fort Douglas Military Reservat
the Shriners' Hospitals for Crippled Children", approved Mar
1946 (60 Stat. 55):

Beginning at a point north 0 degrees 01 minutes 57 second
42.07 feet and south 75 degrees 09 minutes 12 seconds east
feet from a Salt Lake City monument at the intersect
Eleventh Avenue and Virginia Street, such point being f
described as north 529.37 feet and east 268.85 feet from the
west corner of the northwest quarter of section 33, town
north, range 1 east, Salt Lake base and meridian; running
south 0 degrees 01 minutes 57 seconds east 30.76 feet;
south 87 degrees 50 minutes 03 seconds east 135.45 feet;
north 75 degrees 09 minutes 12 seconds west 140.04 feet
point of beginning.

SEC. 2. (a) The conveyance to be made under this Act shall be
to the condition that the transferee, the Shriners' Hospitals fo
pled Children, shall reconvey or dedicate the land specifically de
in the first section of this Act to Salt Lake County, Utah, fo
construction purposes.

(b) The costs of any surveys necessary as an incident to t
veyance authorized by this Act shall be borne by the Sh
Hospitals for Crippled Children.

TITLE II—OFFICE OF INSPECTOR GENERAL

SEC. 201. In order to

Public Law 99-562
99th Congress

An Act

To amend title 31, United States Code, with respect to the fraudule
property or money.

Be it enacted by the Senate and House of Represent
United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "False Claims Amendm
1986".

SEC. 2. FALSE CLAIMS.

Section 3729 of title 31, United States Code, is amended
(1) by striking the matter preceding paragraph (1)
ing the following:
"(a) LIABILITY FOR CERTAIN ACTS.—Any person who—";
(2) in paragraph (1) by striking "Government or a
an armed force" and inserting "United States Gover
member of the Armed Forces of the United States";
(3) in paragraph (2) by inserting "by the Governm
"approved";
(4) in paragraph (4)—
(A) by striking "public"; and
(B) by striking "in an armed force" and inserti
Government";
(5) in paragraph (5)—
(A) by striking "in an armed force" and inserti
Government"; and
(B) by striking "or" after the semicolon;
(6) in paragraph (6)—
(A) by striking "a member of an armed force" a
ing "an officer or employee of the Governm
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Public Law 104-191
104th Congress

An Act

Aug. 21, 1996
[H.R. 3103]

To amend the Internal Revenue Code of 1986 to improve portability and continuity of health insurance coverage in the group and individual markets, to combat waste, fraud, and abuse in health insurance and health care delivery, to promote the use of medical savings accounts, to improve access to long-term care services and coverage, to simplify the administration of health insurance, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Health Insurance Portability and Accountability Act of 1996.
42 USC 201 note.

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Health Insurance Portability and Accountability Act of 1996".

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

HEW Office of Inspector General

On October 15, 1976, President Ford signed into law legislation creating an Office of Inspector General (OIG) at the Department of Health, Education and Welfare (HEW). HEW OIG would become HHS OIG in 1980, when the Department was redesignated as the Department of Health and Human Services (HHS).

This law was the culmination of a series of congressional hearings and investigations held between 1974 and 1976, which found serious deficiencies in HEW's ability to address fraud and abuse in its many programs. HEW's program expenditures accounted for almost one third of the Federal budget, but according to the investigations there was no "…central unit with the overall authority, responsibility and resources necessary to insure effective action against fraud and abuse." Resources devoted to fraud and abuse investigations were inadequate and scattered throughout the programs. Additionally, a majority of the investigative staff faced potential conflicts of interest in that they reported to program management whose programs they were investigating. Further there was no central source of information on fraud and abuse in HEW programs available to the Secretary or Congress.

A second set of congressional hearings and investigations found that Medicaid was losing billions of dollars because of fraud at so-called "Medicaid Mills." The Mills were clinics in which ordering unwarranted tests and unnecessary prescriptions and referrals was common practice.

> "This legislation will establish in HEW for the first time a high-level official with no program responsibilities who is charged with giving undivided attention to the prevention of fraud and program abuse and the promotion of economy and efficiency in the administration of HEW's programs, and operations."
>
> – Representative Lawrence H. Fountain
> September 29, 1976

To address the deficiencies identified in these congressional hearings and investigations, Congress introduced legislation to establish an Office of Inspector General for HEW programs. This central office was dedicated solely to fighting fraud, waste, and abuse in HEW. The HEW Audit Agency and Office of Investigative Services were transferred to the HEW Office of Inspector General.

To ensure independence, the Inspector General and Deputy Inspector General were to be appointed by the President, with Senate approval, and could be removed only by the President with a written explanation to Congress. To further ensure the independence of the office, the Inspector General was placed under the general supervision of the Secretary, and in some cases his or her deputy, but no other HEW official. OIG was required to inform the Secretary and Congress about problems and deficiencies relating to the HEW programs and operations through quarterly and annual reports.

HEW OIG was authorized access to all documents and information necessary to achieve its oversight functions. In addition, OIG was given the authority to subpoena information relevant to specific investigations or audits.

Many aspects of the HEW OIG legislation, such as the mission of an OIG, selection of the Inspector General, and relationship with Department officials and Congress, would serve as a template for the creation of other Offices of Inspector General through the Inspector General Act of 1978.

False Claims Amendments Act of 1986

On October 27, 1986, President Reagan signed a set of amendments, championed by Senator Charles Grassley, into a law that rejuvenated the False Claims Act and paved the way for an effective public-private partnership to combat fraud against the Federal Government.

The original False Claims Act was signed by President Lincoln in 1863 to combat war profiteering. This Act made it a crime to defraud the Federal Government through false claims or statements. It also provided for the assessment of double damages against offenders, plus a $2,000 penalty for every false claim submitted. A *qui tam* provision that allowed citizens (relators) aware of fraudulent activity to file suit in civil court and collect up to 50 percent of any damages obtained through the suit was also established. The *qui tam* provision underwent drastic amendment by Congress in 1943. The guaranteed 50-percent share was eliminated and courts were given the discretion to award relators as little as nothing and at most 25 percent of the funds recovered. Further, *qui tam* cases based upon evidence or information already in the possession of the Federal Government were prohibited. As a result, even when the Federal Government possessed the requisite information but was not acting on it, a *qui tam* case was not permitted to go forward. Thus, *qui tam* litigation became virtually nonexistent after the 1943 amendments.

Although use of *qui tam* litigation declined, fraud against the Government did not. For instance, HHS OIG doubled the number of health care fraud convictions in the mid-1980s. Recognizing that Government alone, with its limited resources, was overmatched in the fight against fraud, Congress passed the False Claims Amendments Act of 1986.

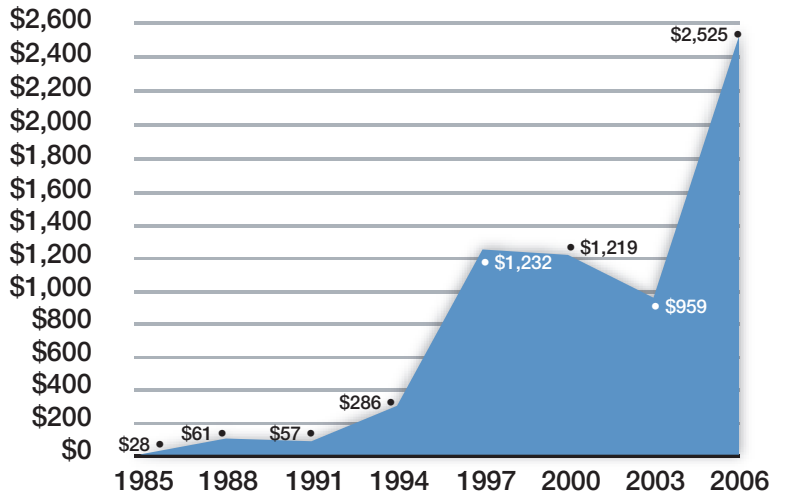
> "White collar fraud is becoming so pervasive and so increasingly sophisticated that only a coordinated effort between public law enforcers and private citizens will help us regain control of the millions or billions of dollars lost each year."
>
> – Senator Charles Grassley, February 6, 1986

The Amendments increased the damages and fines that the Federal Government could seek and lowered the bar of proof for Government cases. Most importantly, the *qui tam* provision was reinstated, providing a mechanism with built-in incentives for private citizens with evidence of fraud to commit their time and resources to supplement the Federal Government's efforts. Relators filing suit were

entitled to 15 to 30 percent of the funds recovered from the defendants. *Qui tam* suits were further encouraged through the elimination of the restrictive "Government possession of information" bar and the requirement that defendants pay for the successful relator's reasonable expenses and attorneys' fees. Along with providing the monetary incentives, the Amendments encouraged relators to step forward through protection from employer retaliation.

The public-private partnership created through the rejuvenated False Claims Act has become an essential tool in uncovering and prosecuting health care fraud cases, accounting for some of the largest returns and recoveries.

Monetary Impositions Resulting From OIG Health Care Investigations
(FY in Millions)



Monetary impositions are rounded to the nearest million and include fines, restitutions, and impositions (including False Claims suits) resulting from OIG investigations related to fraud and abuse against Federal health care programs. These figures represent HHS investigative receivables only; receivables on behalf of other Federal agencies and States are not included.

Source: Department of Health and Human Services, Office of Inspector General.

Health Insurance Portability and Accountability Act of 1996

On August 21, 1996, President Clinton signed the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which enhanced the resources and enforcement capabilities of Federal agencies involved in combating health care fraud.

The budget cutbacks and downsizing of the Federal Government in the early 1990s hampered its ability to effectively detect and prosecute health care fraud. While resources were shrinking, health care fraud had grown beyond individual cases of false billing to sophisticated schemes on a national scale.

Recognizing the need for greater coordination and increased Government resources devoted to health care fraud activities, Congress passed HIPAA.

One of HIPAA's cornerstones was the coordination of Federal law enforcement efforts though the establishment of the Health Care Fraud and Abuse Control (HCFAC) Program funded through an account within Medicare. Under the joint direction of the United States Attorney General and the Secretary of the Department of Health and Human Services, HCFAC provided a management structure to coordinate the efforts of numerous Federal, State, and local government agencies involved in fighting health care fraud. HCFAC was intended to make it easier for the Federal Government to conduct investigations, audits, and evaluations related to the delivery of payment for health care. HIPAA also established a stable source of funding for Federal Government agencies to use in antifraud and abuse activities. Drawn from the Medicare Part A Trust Fund, the account provided extraordinary new resources for Federal agencies involved in the detection and prosecution of health care fraud.

> "…it [HIPAA] prevents fraud and abuse. It toughens penalties and helps us to go after bad apple health care providers who bilk the system of billions of dollars from Medicare, from Medicaid, and from private insurance companies."
>
> – President William J. Clinton
> August 21, 1996

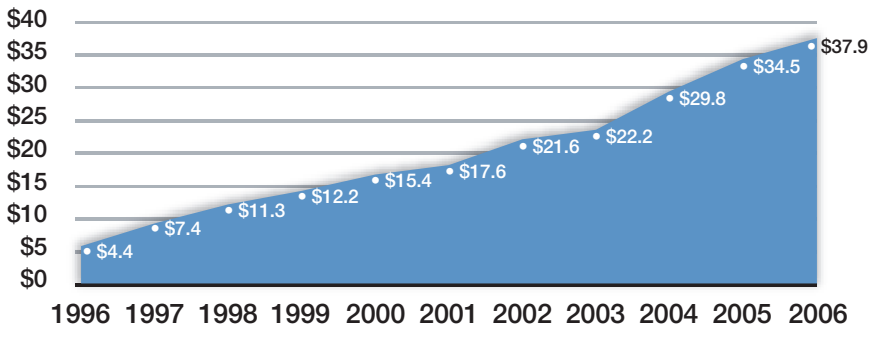
HIPAA also created new responsibilities for OIG to provide greater guidance to the health care industry regarding the requirements of fraud and abuse programs. OIG was directed to establish an advisory opinion process through which an individual or entity could obtain a legal opinion on whether a business arrangement violated fraud and abuse laws. OIG was also to provide the health care community with special fraud alerts on practices that were potentially in violation of laws and regulations. Lastly, OIG was to solicit and respond to proposals for modifications to the Safe Harbor regulations that exempt certain practices from prosecution under the Federal Anti-Kickback Law.

A 30-Year Retrospective

A landmark law, HIPAA has provided increased resources; stronger enforcement tools; and a management structure to coordinate the efforts of numerous Federal, State, and local partners involved in combating health care fraud. Because of HIPAA, OIG was able to expand its presence to every State in the country, launch nationwide initiatives directed at health care fraud, and increase the savings and recoveries returned to the Medicare Trust Fund.

OIG Health Care Savings

(FY in Billions)



OIG health care savings incudes savings related to the Federal health care programs including: funds identified for recovery by management as a result of OIG audits or evaluations; fines, restitutions, and settlements resulting from OIG investigations; and funds put to better use because of legislation, regulations, and policies and procedures implemented in response to OIG recommendations or activities.

Source: Department of Health and Human Services, Office of Inspector General.

30 Years of Results

$840m penalty is expected for drug compan

By Alice Dembner
GLOBE STAFF

The manufacturer of a top-selling prost
cer drug is preparing to pay a record fine -
ably more than $840 million — to settle fede
gations that it inflated the price of the dr
used taxpayers' money to bribe doc
it, according to a source knowled
case.

As the US attorney's office in
negotiations with TAP Pharmaceutical Pr
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U.S. targets phantom companies milking Medicare

By TOM DUBOCQ
Herald Staff Writer

rampant fraud, Medicare has halt
suppliers for 30 da

Hospital Care Quality Examined

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announced in Miami Thursday.
In Dade County alone, 500 phantom compan
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U.S. Seeks to Recover Billions Due Medicare

Private Insurers Liable, HHS Contends

Health care giant targeted in

BLOOMBERG NEWS

Columbia/HCA Healthcare Corp. facilities in six states were served with search warrants yesterday as the federal government widened its probe of Medicare and Medicaid billings by the country's largest hospital chain.

The warrants requested records and documents on hospital laboratory billings and home care operations, the Nashville, Tenn.-based company said in a statement. Those areas are targets in a broader government crackdown on overbilling of the Medicare and Medicaid health insurance programs for the elderly and poor.

"It's my understanding that there has been a lot of focus on blood tests through emergency

The company and the FBI said warrants were served in six states: Tennessee, Florida, North Carolina, Texas, Oklahoma and Utah.

The searches are a sign that investigation will be prolong and could slow Columbia's pace hospital acquisitions, which has ready attracted the attention state regulators, said Jeff Vi wock, an analyst at Robinso Humphrey.

Columbia/HCA was rebuffed its attempt to buy Blue Cross Blue Shield of Ohio in March, an earlier this year dropped plans t buy a California hospital after the state attorney general opposed the transaction.

Columbia/HCA has struggled to

ton, adding it to a networ includes Arlington Hos Reston Hospital Center.

District prodded on foster pay issue

ras

The federal government is urging the District to prosecute anyone who may have illegally received foster care payments for children not in their care, according to officials.

The push from the Department of Health and Human Services came earlier this week in a meeting with officials at the D.C. Department of Human Services.

Judy Holtz, a spokeswoman for HHS' Inspector General's Office, said the meeting was held because federal officials were interested in "protecting the integrity of federal dollars."

"If we find federal dollars were misspent or spent in a way that is considered inappropriate, we would want to recoup those dollars," she said, adding that HHS ha

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✓Voluntary Disclosure

IG EXPANDS VOLUNTARY DISCLOSURE PLAN TO HOSPICES, ISSUES PROCEDURES, MODEL

The Department of Health and Human Services Office of Inspector General June 14 expanded its pilot voluntary disclosure program to cover hospice care facilities as well as nursing homes, home health agencies, and durable medical equipment suppliers.

The HHS IG also June 12 released procedures for administering the two-year fraud demonstration project under "Operation Restore Trust." The program, announced May 3, targets fraud in New York, Florida, Illinois, Texas, and California (6 *MCR* 453, 5/5/95).

"These are clear and concise, step-by-step instructions" on what facilities can expect when they decide to enter the disclosure program, said Judy A. Holtz, HHS spokesperson.

The pilot voluntary disclosure program encourages corporate providers to come forward with evidence of potential problems that they have discovered. Eligible entities may be able to negotiate monetary settlements with regard to their participation in the Medicare and Medicaid programs based on the information disclosed. They also may be able to reduce or avoid criminal prosecution, and program exclusion, according to an HHS press release. By self-disclosing, firms can minimize the cost and disruption of a full scale audit and investigation, HHS said.

In related news, Holtz told BNA that the program's fraud hotline number would be announced June 15; a fraud alert on home health agencies will be issued June 22; and another fraud alert on nursing homes and durable medical equipment suppliers will be issued July 15. In addition, the IG has 15 audits underway as part of the program, she said.

Unneeded medical tests are focus of HHS probe

BY DON MCLEOD

The next time your doctor sends you to a laboratory for an expensive test, one question you might ask is, "Who owns the lab?"

If the doctor himself does, then he may be part of a growing problem that's ripping off both patients and the Medicare system.

According to the Department of Health and Human Services, doctors who have financial interests in health-related facilities, such as laboratories, order about half again as many tests as do doctors with no such ties.

Patients are most likely to suffer from being subjected to medical tests they don't need, but as taxpayers they're also picking up the tab for a practice that's pumping up the costs of the $100 billion-a-year Medicare program.

According to the latest figures from HHS, those added costs were $28 million in 1987.

Recognizing the potential for abuse,

says Stark. "If this problem continu to go unchecked, that figure wou soon reach the billions."

Judy Holtz, spokeswoman for HHS spector General Richard P. Kussero emphasizes that arrangements allowi physicians to refer patients to bus nesses in which they have a financial i terest are not necessarily illegal.

But, Holtz adds, "schemes have b come more elaborate, and, really are crossing over into the kickbac area."

Dan Myer, a spokesman for th AMA headquarters in Chicago, agrees

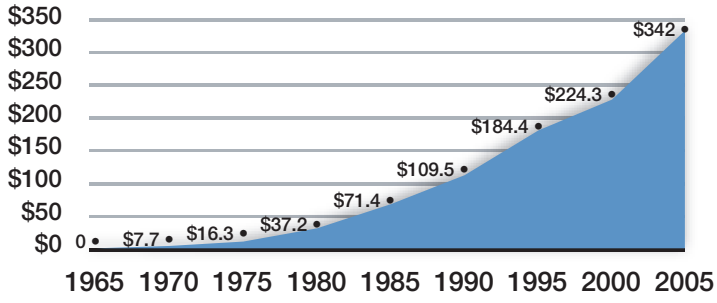
"What there is concern about, an rightly so, is a situation where there might be some kind of kickback," Mye says, "or some situation where a pro moter tells a physician, 'I'm starting up this X-ray lab. If you give me a 10 percent investment, I'll guarantee you this amount back on your investment if you send me all your patients.' That's an unethical situation.

"Or there may be a situation," Myer

Heath Care Integrity

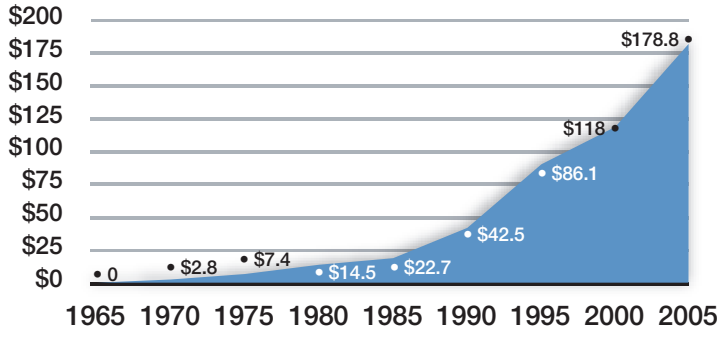
The Medicare and Medicaid programs have grown dramatically since their inception in 1965. As of 2006, Medicare provided health insurance for approximately 43 million beneficiaries, and Medicaid had an enrollment of over 50 million. Federal Government expenditures for Medicare grew from $1.8 billion in 1966 to $342 billion in 2005, and Medicaid expenditures (including payments through Medicaid expansion programs for the State Children's Health Insurance Program, or SCHIP) increased from $632 million in 1966 to $178.8 billion in 2005. Centers for Medicare & Medicaid Services (CMS) actuaries project that in 2015, Medicare expenditures will reach $792 billion and Federal Medicaid expenditures will reach $384 billion.

Federal Medicare Expenditures
(CY in Billions)



Source: Centers for Medicare & Medicaid Services, National Health Expenditure Data.

Federal Medicaid Expenditures
(CY in Billions)



Federal Medicaid expenditures include payments for Medicaid expansion programs for the State Children's Health Insurance Program.

Source: Centers for Medicare & Medicaid Services, National Health Expenditure Data.

The dramatic increase in expenditures reflects an expansion of benefits and programs, increased utilization of services, expanded eligibility, and growth in enrollment. For instance, Medicare added coverage for end stage renal disease, a home health benefit, and most recently, an outpatient prescription drug benefit. Medicaid added payments to hospitals treating a disproportionate share of low-income beneficiaries, and some States implemented the SCHIP through expansions to their Medicaid programs.

With the expansive network of Medicare and Medicaid benefits comes a tremendous responsibility to protect the integrity of these programs and the beneficiaries they serve. OIG has worked extensively with CMS (formerly the Health Care Financing Administration) to identify vulnerabilities in Medicare and Medicaid and recommend improvements, to quantify and reduce improper payments, and to pursue instances of fraud and abuse. To execute these activities, OIG relies on designated funding under the Health Care Fraud and Abuse Control Program, established by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and funding under the Medicaid Integrity Program, established by the Deficit Reduction Act of 2005 (DRA). In 2006, OIG devoted approximately 80 percent of its resources to activities to protect the integrity of these critical health care programs.

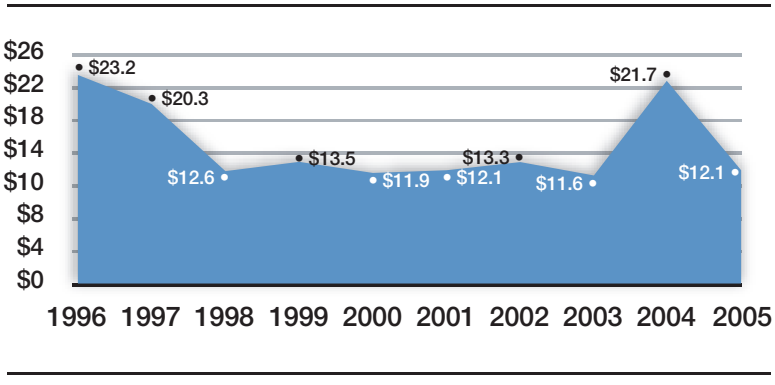
Measuring Improper Payments

Controlling the costs of Medicare and Medicaid and maximizing public health care dollars involves identifying and resolving improper payments. While some providers engage in fraudulent billing, the majority of providers are honest in their Medicare and Medicaid billings. For instance, improper payments may result from clerical errors, misinterpretations of rules, or poor record keeping.

In 1997, OIG created the first comprehensive, statistically valid quantification of improper Medicare fee-for-service claims. To accomplish this objective, OIG determined for a sample of beneficiary claims whether the claims complied with Medicare laws and regulations. The results for the sample were then projected to the Medicare program to determine the quantity, types, and levels of improper payments. OIG determined the annual error rate for Medicare until FY 2003, when CMS incorporated the error rate process as part of its internal Comprehensive Error Rate Testing and the Payment Error Prevention Program.

By quantifying the extent of improper payments, the Medicare Error Rate demonstrated the pervasiveness of improper payments across Medicare services and provided a performance measure for use in identifying and reducing improper payments. This measure enables both OIG and CMS to target efforts toward areas of particular vulnerability as well as to track progress over time in strengthening these vulnerable areas. The effectiveness of the Medicare Error Rate in identifying improper payments lent support

to the passage of the Improper Payments Information Act of 2002, which required Federal agencies to annually review all programs and activities to identify those susceptible to significant improper payments.



Source: Department of Health and Human Services, Office of Inspector General.

State Medicaid Financing Mechanisms

The Federal Government and the States share in the costs of the Medicaid program. States administer the Medicaid program based on State plans that comply with broad Federal requirements. The Federal Government pays its share of medical assistance expenditures to the States according to a defined formula, which yields the Federal medical assistance percentage (FMAP). The FMAP can range from 50 to 83 percent, depending on each State's relative per capita income. Ensuring the appropriate expenditure of Medicaid funds by States has grown in importance as Medicaid expenditures continue to increase. Over the years, OIG has identified financing mechanisms that maximize the Federal share of Medicaid payments and shift costs from the States to the Federal Government.

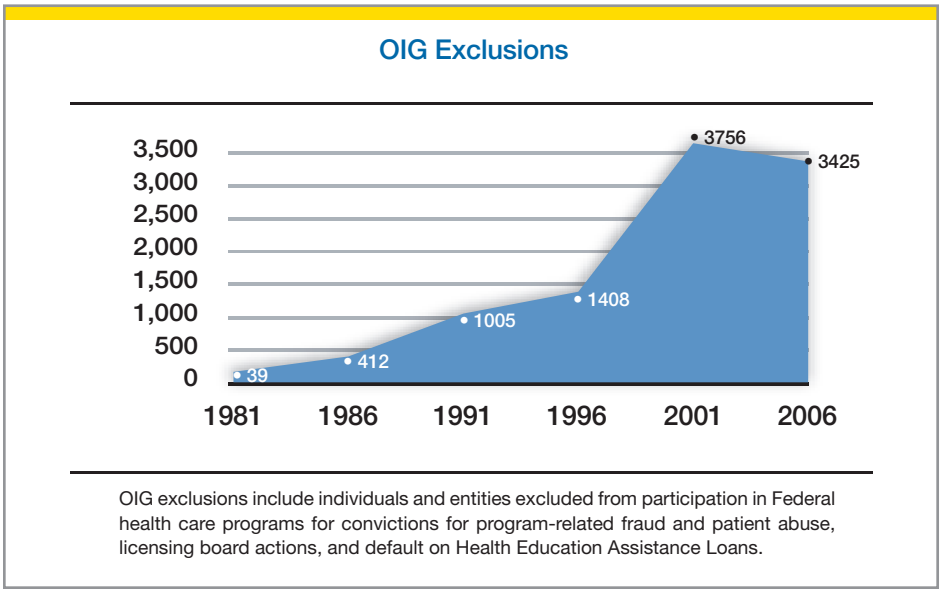
- **Tax and Donation Programs –** A series of OIG reviews found that States were using donations and taxes to maximize the Federal share and that the potential increase to the Federal share resulting from these practices was inestimable. At that time, States were allowed to use donations from public and private organizations and health care-related taxes as part of the State share of Medicaid costs. In response to OIG's findings and other concerns, in 1991 Congress enacted legislation that limited States' use of most voluntary contributions from providers and health care-related taxes to claim FMAP.

- **Intergovernmental Transfers (IGT) –** OIG found that States put Medicaid funds at risk by using IGTs to disproportionately shift the cost of Medicaid to the Federal Government. IGTs are transfers of non-Federal public funds between units of State and/or local governments, which may also be Medicaid providers, and the State Medicaid agency. Financial consequences include an inappropriate increase in the Federal taxpayers' share of Medicaid payments. In some cases, the increased Federal Medicaid funding derived from these transfers becomes commingled in general revenue accounts and can be used for purposes unrelated to Medicaid. Although this practice could occur with any type of Medicaid payment to public facilities, OIG identified problems with the use of IGTs in combination with Medicaid supplemental payments available under upper payment limits. In response to OIG reviews and other concerns, CMS modified Medicaid upper payment limit regulations to curb these abuses.

Program Improvements and Enforcement by Sector

In addition to estimating error rates and identifying inappropriate cost-shifting mechanisms that affect these programs overall, much of OIG's work focuses on the integrity of specific health care benefits and services in a variety of health care sectors. This includes identifying vulnerabilities associated with particular services, payment systems, or health care settings, and recommending improvements, as well as pursuing specific instances of fraud or abuse. As Medicare and Medicaid have grown in size and expenditures, so too have the challenges of ensuring their efficient and effective operation. Many of OIG's audits and evaluations determine whether particular aspects of Medicare or Medicaid are managed properly and whether these programs reimburse appropriately based on other prices available in the health care marketplace. These efforts, as detailed below, have resulted in substantial program savings and increased efficiency and effectiveness.

Likewise, health care fraud schemes that OIG has investigated have also grown in scope and complexity. OIG investigations once focused largely on individual practitioners filing false claims and now often involve sophisticated, large-scale schemes. These cases involve such practices as inappropriate maximization of payments under the prospective payment system (PPS), intricate kickback schemes, and manipulation of pricing systems. OIG works with Federal and State agencies to investigate and prosecute health care fraud under the Civil False Claims Act and related statutes. OIG also utilizes its administrative exclusion authority to remove individuals or entities engaged in prohibited conduct from participation in Medicare and Medicaid.



OIG exclusions include individuals and entities excluded from participation in Federal health care programs for convictions for program-related fraud and patient abuse, licensing board actions, and default on Health Education Assistance Loans.

Individual Practitioners

Many of the early false billing cases investigated by OIG involved individual practitioners, ranging from physicians to pharmacists. Billing for services not performed was, and continues to be, a common scheme employed by individual practitioners to defraud Medicare and Medicaid. Examples of investigations of possible fraud or abuse by individual practitioners include the following:

- In 1977, OIG launched Project Integrity, a joint project with other Federal and State agencies that used computers to perform a nationwide analysis of Medicaid payments to pharmacists and physicians to detect fraud. The 2-year project identified almost 47,000 cases of potential fraud and abuse and helped set the standard for using computers to detect fraudulent behavior. The project's success led to subsequent initiatives that analyzed Medicaid payments to other health care providers and institutions.

- In 1996, a psychiatrist was sentenced to 46 months' imprisonment and fined $1 million for Medicare and private insurer fraud, obstruction of justice, and intimidation of a witness. The psychiatrist filed hundreds of claims, some for more sessions than patients attended and others for patients he never saw. When he became aware of the investigation, he called former patients and attempted to get them to lie on his behalf. He also called a potential witness and threatened to make public the medical records of a family member if she cooperated with the Government.

- In 2006, a podiatrist was sentenced to death for the murder of a grand jury witness in connection with a Medicare fraud case. A jury convicted the podiatrist for murdering a woman days before she was expected to testify before the grand jury about the more than 70 foot surgeries that

were not performed, but which the podiatrist billed to Medicare. The death penalty sentence was an addition to the podiatrist's previous sentence of 78 months in prison and an order to pay $1.8 million in restitution for health care fraud, mail fraud, tampering with a witness, and obstruction of proceeding of agencies or departments.

- In 2006, a former dermatologist was sentenced to 22 years in prison, ordered to pay $3.7 million in restitution, forfeit an additional $3.7 million, and pay a $25,000 fine for performing more than 3,000 medically unnecessary surgeries on more than 800 Medicare beneficiaries. The dermatologist was found guilty of health care fraud and making false statements following a 4-week trial in which the prosecution demonstrated that the doctor routinely falsely diagnosed patients with skin cancer to bill Medicare for expensive and unnecessary invasive surgeries. From 1998 through 2004, a detailed analysis showed that nearly all the biopsies that he performed were diagnosed as cancer and resulted in invasive surgeries. In fact, some of the specimens that he diagnosed as skin cancer were actually slides which contained chewing gum, Styrofoam, or skin tissue of his employees.

Hospitals

OIG has focused considerable attention on the appropriateness of Medicare payments to hospitals. One of the most significant changes in Medicare payment systems was the shift from cost-reimbursement to a PPS, which was implemented in 1984 for most inpatient hospital services. Under the PPS, most hospital inpatient care is reimbursed based on predetermined and fixed amounts depending on the diagnosis of the beneficiary, rather than "reasonable" and "necessary" costs as under the previous system. The rationale behind the development of the PPS was to reduce Medicare expenditures by setting payment rates that fostered cost consciousness. OIG has assessed payments, identified potential vulnerabilities, and recommended modifications to ensure the integrity of payments.

Examples that illustrate the impact of OIG's work to protect the integrity of hospital payment systems include the following:

- **Hospital Profitability –** A series of OIG reviews found that hospitals earned profits in excess of 14 percent under the (then) new PPS, based on 1984 cost reports. In response to OIG's findings and other concerns, Congress limited the increase in PPS payments resulting in a savings of $400 million in FY 1986.

- **Diagnosis Related Group 72-Hour Window Project –** In 1995, OIG and the Department of Justice (DOJ) launched a national project to recover overpayments made to hospitals as a result of claims submitted for nonphysician outpatient services that were already included in the hospitals' inpatient payment under the PPS. Hospitals that submit claims for the outpatient service in addition to the inpatient admission

are, in effect, double billing for the outpatient service. In addition, the project sought to recover for those services rendered to beneficiaries during the inpatient admission that should be included in the diagnosis related group (DRG) but are separately charged. This national project identified 4,660 hospitals that submitted improper billings for outpatient services. Settlements were executed with 2,799 hospitals and over $73 million was recovered.

- **Physicians at Teaching Hospitals –** In 1996, OIG initiated a nationwide review of compliance with the rules governing reimbursement to physicians at teaching hospitals (also known as the PATH initiative). The PATH initiative sought to verify compliance with the Medicare rules governing payment for physician services provided by residents and teaching physicians and to ensure that all claims for physician services accurately reflect the level of service provided to the patient. To receive a separate payment from Medicare Part B for a service rendered to a patient, the teaching physician must have personally provided that service or have been present when the resident furnished the care. The PATH initiative resulted in nine institutions entering into settlements with the Federal Government to resolve potential False Claims Act liability, resulting in the Government's recovery of nearly $100 million. As a condition of settlement, most of these institutions have also implemented compliance programs to prevent and detect future improper claims.

- **Pneumonia Upcoding Project –** In 1999, OIG and DOJ launched an initiative to examine hospital coding practices with respect to pneumonia diagnoses. Medicare inpatient hospital stays are reimbursed based on the DRG that is assigned to the patient's stay. The determination of the appropriate DRG for a particular case depends upon the hospital's assignment of diagnosis code(s) and procedure codes to the inpatient stay. Most pneumonia cases are grouped into one of four DRGs. OIG found that a small percentage of hospitals across the country assigned a disproportionate number of pneumonia cases diagnosis codes that resulted in a discharge being assigned the highest paying DRG. Review of the medical records demonstrated that most of the cases should have been assigned a diagnosis code that would result in assignment of a lower-paying DRG. OIG investigated the pneumonia coding at over 100 hospitals. Thirty-four hospitals settled their respective False Claims Act liability for such coding by paying over $35.2 million and agreeing to corporate integrity requirements.

In addition to these initiatives, OIG and its law enforcement partners have resolved a number of significant cases of alleged fraud by hospitals. Examples that illustrate various types of hospital fraud and the results of OIG investigations include the following:

- In 1994, the Government signed a $375 million civil and criminal settlement with National Medical Enterprises, Inc. (NME) over allegations

of extensive Medicare fraud and illegal kickbacks conducted by its subsidiary NME Psychiatric Institutes of America (PIA). An investigation involving OIG, DOJ, and other Federal and State law enforcement agencies, found that PIA conducted a nationwide scheme to secure the unnecessary hospitalization of patients at its facilities, bill for services not rendered or at a grossly inflated cost, and pay millions of dollars in kickbacks to doctors, medical, and emergency professionals for patient referrals. The settlement included a 5-year corporate integrity agreement (CIA). As a part of the settlement, NME agreed to sell off all of its psychiatric facilities except for four campuses.

"In what could be the largest fraud settlement ever, Columbia/HCA Healthcare Corp. agreed to pay the federal government $745 million to resolve several Medicare-fraud allegations, including its handling of home health care and its billing of laboratory claims."

– The Wall Street Journal
May 19, 2000

- In 2000, HCA Inc., formerly Columbia/HCA, signed a $840 million settlement with the Government and States related to Medicare and Medicaid fraud in its hospitals. The settlement includes a $95 million fine resulting from guilty pleas by two HCA subsidiaries. The settlement was the result of a nationwide investigation that uncovered inappropriate upcoding, lab test unbundling, billing for medically unnecessary lab tests, and fraudulent billing related to home health services at HCA facilities. HCA also entered into a comprehensive 8-year CIA with OIG. In 2003, HCA paid an additional $631 million to resolve civil and administrative claims related to false cost reports, kickbacks and Stark Law violations, and false claims for wound care services provided in its hospitals.

- In 2006, Tenet Healthcare Corporation, formerly NME, agreed to pay over $900 million to the Government to resolve its liability under the False Claims Act and related authorities. Specifically, the Federal Government had alleged that Tenet submitted claims for payment to Medicare using DRG codes that Tenet could not support or were improperly assigned to patient records to increase reimbursement to Tenet hospitals. Tenet also allegedly inflated its charges substantially in excess of any increase in the costs associated with patient care, which resulted in improper outlier payments. Tenet also signed a 5-year CIA with OIG. The CIA requires that Tenet implement a comprehensive compliance program along with specifically tailored provisions that require Tenet's Board of Directors to undertake a review of the effectiveness of Tenet's compliance program and adopt resolutions with respect to this review.

Nursing Facilities

In addition to OIG's focus on quality of care (detailed in the Quality of Care section of this publication), OIG has directed attention toward ensuring the integrity and appropriateness of payments to nursing facilities. OIG's work was influential in Congress's enactment of a PPS for nursing facilities. OIG found that some services for nursing facility patients could be reimbursed under more than one part of the Medicare program, which weakened oversight, created fraud vulnerabilities, reduced incentives to economize, and diluted the responsibility for overall care of these beneficiaries. OIG recommended that the way these programs pay for services be restructured and that a PPS capture as many services as possible into one prospective payment rate. Further, OIG recommended that services not included in the PPS be consolidated into a single bill to be submitted by the facility. Congress enacted a PPS for skilled nursing facility services through the Balanced Budget Act of 1997 (BBA). In addition, the BBA required nursing facilities to submit bills to Medicare for Part B-covered services for residents who are in a Part A-covered Medicare stay, which is known as consolidated billing. According to the Congressional Budget Office, these combined changes by BBA saved an estimated $9.5 billion over 5 years.

OIG's investigation and enforcement activities to fight fraud in nursing facilities have also resulted in substantial recoveries. Examples that illustrate the results of OIG's investigative efforts include the following:

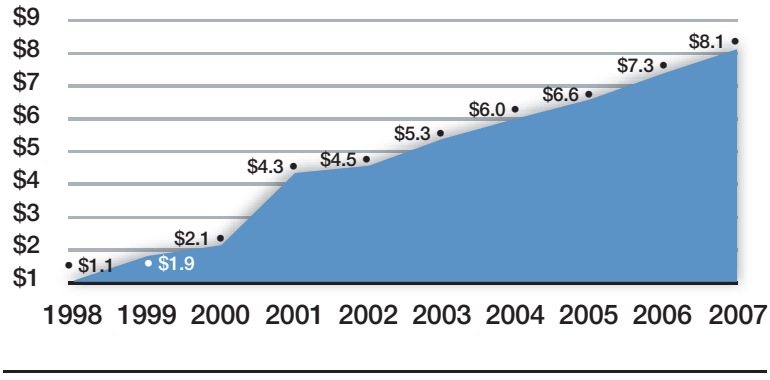
- In 1996, a former nursing home owner was ordered to pay more than $10.5 million for submitting over 7,000 false claims relating to a multi-million dollar Medicare fraud scheme. He billed Medicare for nonexistent medical supplies for his nursing homes and filed cost reports with false expenses. He attempted to conceal the scheme by supporting the cost reports with falsified medical records and fabricated invoices. He was sentenced to 11 years and 3 months' imprisonment and ordered to pay $3.5 million in criminal restitution and more than $7 million to resolve the civil charges. This case was part of an OIG initiative known as Operation Restore Trust (see box on page 25).

- In 2000, Beverly Enterprises, Inc., the Nation's largest nursing home chain, agreed to pay the Government $175 million, based on ability to pay, to resolve criminal and civil liability and entered into a CIA with OIG. This settlement resolved allegations that the nursing home chain engaged in a nationwide scheme to defraud Medicare by inflating nursing costs charged to the program. A company subsidiary, which also pled guilty to criminal charges, paid $5 million in criminal fines and divested itself of 10 nursing homes. This settlement is the largest OIG settlement to date with a nursing home.

Home Health Agencies

Similar to nursing homes, OIG found that problems with and improper payments for home health care were so pervasive that restructuring Medicare's payment system was necessary. Medicare spent $3.5 billion for home health services in 1990 for approximately two million beneficiaries. By 1996, expenditures had grown five-fold to $16.9 billion, and the number of beneficiaries had increased to 3.7 million. OIG reported on its concerns with rapid growth, fraud and abuse, and unexplained variations in payment. In one review, OIG estimated that 40 percent of services in four States from January 1995 to March 1996 did not meet Medicare reimbursement requirements. In 1997, in response to these numerous concerns, Congress created a PPS for Medicare home health care, which was implemented in 2001 following an interim transition. As illustrated in the following chart, the Congressional Budget Office projected substantial savings as a result of this payment reform.

Estimated Savings Resulting From the Creation of the Home Health Prospective Payment System
(FY in Billions)



Source: Congressional Budget Office scoring of the Balanced Budget Act of 1997.

OIG has also pursued cases of alleged fraud by home health agencies, including complex fraud schemes, as detailed in the following examples:

- In 1995, the owner and chief executive officer of Georgia's largest home health agency (HHA) pled guilty to charging Medicare and Medicaid for campaign contributions, ghost employees, and personal vacation trips. She was sentenced to 33 months' incarceration, 3 years of supervised work release, and ordered to pay $11.5 million in restitution and a $2.5 million fine. The company's former vice president was sentenced to 151 months' incarceration, 3 years' probation, and ordered to

pay $790,000 in restitution and fines. He was convicted of making false statements about salaries for ghost employees and a related organization, converting workers compensation premiums to his own use, using Medicare funds to support a consulting business, embezzling employee health insurance and benefit plan funds, committing bank fraud, and laundering money.

- In 2000, five individuals connected with what was once South Florida's highest paid Medicare HHA were sentenced for their roles in a complex Medicare fraud scheme. The HHA submitted over $45 million in false claims. Four of the individuals sentenced were among 26 people indicted in 1998 on Medicare fraud-related charges. These individuals were either directly involved with the HHA or its unlicensed or unapproved HHA subcontractors. The indictment charged racketeering, racketeering conspiracy, money laundering conspiracy, and conspiracy to submit false claims. A fifth individual was sentenced based on his guilty plea to conspiracy charges. This individual worked as the day-to-day manager of operations at a transcription company that provided nursing and home health aide progress notes to the Florida HHA and its subcontractors.

Operation Restore Trust

The increasing scope and sophistication of health care fraud have required OIG and its Federal and State partners to establish new and innovative means to identify, investigate, and prosecute fraud, waste, and abuse. In addition to its reviews and investigations within particular sectors, OIG has undertaken certain broad initiatives that span health care sectors. One landmark OIG initiative was Operation Restore Trust (ORT). Launched in 1995 as a 2-year demonstration project, ORT was an innovative, interagency project in which OIG, CMS, the Administration on Aging, DOJ, and other Federal and State agencies leveraged their resources and skills in an intensive campaign in the growing health care sectors of home health, nursing homes, durable medical equipment and supplies, and hospice. ORT employed multidisciplinary teams in five States to comprehensively fight fraud, waste, and abuse in these health care sectors through audits, evaluations, and investigations. ORT resulted in $187 million in recoveries, 74 criminal convictions, 58 civil settlements, and 218 exclusions from Federal health care programs.

Durable Medical Equipment and Supplies

OIG has produced a body of work examining Medicare oversight of suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) and the appropriateness of Medicare payments for DMEPOS. OIG has identified numerous weaknesses in Medicare's enrollment standards for and

oversight of suppliers and has recommended improvements to address these weaknesses. In addition, OIG has found that Medicare pays too much for certain types of DMEPOS, as compared to other payers or to market prices, and has recommended payment changes to achieve significant savings for Medicare and its beneficiaries. Examples that highlight these payment and oversight concerns include the following:

- **Oxygen Reimbursement –** In 1991, OIG found that Medicare allowed, on average, 174 percent more than the Veterans Administration reimbursement amount for oxygen concentrators. In 1997, in response to OIG findings and other concerns, Congress reduced Medicare reimbursement for oxygen by 25 percent until 1999 and by 30 percent for subsequent years. The Congressional Budget Office estimated that this change would save $2.1 billion over a 5-year period. In 2006, OIG reported that over the 36-month rental period, Medicare's total allowed rental payments for oxygen concentrators were 12 times higher than the average price to purchase new concentrators. If Medicare limited rental payments for concentrators to 13 months, like other capped rental items, the program and its beneficiaries could save an estimated $3 billion over 5 years. OIG recommended that CMS work with Congress to limit the rental period for concentrators.

- **Compliance of DMEPOS Suppliers –** Over the past decade, OIG has performed numerous reviews of DMEPOS suppliers' compliance with Medicare standards. Most recently, in collaboration with CMS, OIG conducted unannounced site visits of more than 1,500 DMEPOS suppliers in three South Florida counties in 2006. OIG found that almost one-third of these suppliers did not comply with two basic Medicare requirements – maintaining a facility at the business addresses that they provided to Medicare and being open for business during posted hours. OIG recommended a number of specific steps for CMS to strengthen the supplier enrollment process and ensure compliance with Medicare standards. In response, CMS described several actions it is taking to implement these recommendations, including revisiting contract requirements to increase the number of unannounced supplier site visits; considering targeted background checks of supplier applicants; drafting a proposed regulation requiring suppliers to post surety bonds; requiring suppliers to become accredited as meeting DMEPOS quality standards; and developing a proposal to revise deactivation requirements for inactive Medicare billing numbers.

In addition to recommending improvements to systemic vulnerabilities, OIG has worked extensively with its law enforcement partners to investigate and prosecute specific cases of fraud. DMEPOS fraud schemes have evolved over time and range from billing for more expensive items than provided to unscrupulous marketing practices. Examples that demonstrate

results of OIG fraud investigations and highlight the scope and ongoing pervasiveness of DMEPOS fraud include the following:

- In 1996, the owner of a medical supply company pled guilty in Florida to conspiracy to defraud Medicare of more than $70 million. As part of his plea, he agreed to forfeit $32 million in seized bank accounts. The owner distributed adult diapers to nursing homes but billed Medicare for more expensive female urinary collections devices. He also billed for components of incontinence kits that were not medically necessary. The owner had previously pled guilty to mail fraud in a similar case in Kansas. The two cases were consolidated and, as a result, the owner was sentenced in 1997 to 10 years in prison and ordered to pay $5 million in damages.

- In 2003, the owner and operator of a group of DMEPOS companies was sentenced to 7 years in prison and ordered to pay $14.8 million in restitution, jointly and severally with other codefendants, for his role in two schemes to defraud Medicare and Medicaid. In addition, the court ordered a $14.8 million forfeiture against him to make restitution. He had previously pled guilty on behalf of six DMEPOS corporations that were set up to launder money. Despite a temporary restraining order, he and his co-conspirators continued to fraudulently bill Medicare and Medicaid and launder the proceeds of the fraud through offshore bank accounts. The conspirators involved in the scheme netted in excess of $25 million. Of the 28 defendants prosecuted, 27 have been sentenced and 1 entered into a pre-trial diversion agreement.

- In 2005, the owner of a DMEPOS company in Texas was sentenced to 41 months' imprisonment and ordered to pay $2.2 million in restitution for health care fraud and money laundering. As part of the scheme, the man paid recruiters for locating Medicare patients and paid physicians for fraudulent certificates of medical necessity and prescriptions for wheelchairs. Though Medicare was billed for motorized wheelchairs, beneficiaries either never received wheelchairs or were provided with much less expensive scooters. This is one example of the numerous cases of wheelchair-related fraud that OIG has investigated.

- In 2006, Lincare Holdings, Inc., and its subsidiary, Lincare, Inc. (collectively, Lincare), agreed to pay the Government $10 million and to enter into a 5-year company-wide CIA. The settlement resolved allegations that Lincare violated the antikickback provision of the Civil Monetary Penalties Law and the Physician Self-Referral (Stark) Law. OIG alleged that Lincare engaged in a nationwide scheme to pay remuneration to physicians to induce referrals of patients to Lincare for DMEPOS. OIG alleged that Lincare gave referring physicians items such as sporting and entertainment tickets, gift certificates, rounds of golf, golf equipment, fishing trips, meals, advertising expenses, office equipment, and medical equipment,

as well as payments pursuant to purported consulting agreements. OIG also alleged that Lincare violated the Physician Self-Referral Law by accepting referrals from parties to the purported consulting agreements.

Laboratories

OIG has conducted work to ensure the integrity and appropriateness of payments for laboratory services since the 1980s. This work has influenced numerous changes to Medicare payments for laboratory services. For example, in 1989, OIG issued a report to Congress that examined financial relationships between physicians and health care businesses to which they refer patients. OIG found that Medicare patients of physicians who owned or invested in independent clinical laboratories received 45 percent more laboratory services than other Medicare patients. In 1989, Congress enacted legislation that prohibited Medicare from paying for laboratory services ordered by physicians who have financial relationships with the entities performing the tests. In another report issued in 1990, OIG found that Medicare paid nearly twice as much as physicians for the same laboratory tests and recommended that Medicare fee schedules be reduced. Subsequent legislation reduced the national cap on Medicare fee schedules. In addition, as detailed below, OIG undertook a national project to investigate laboratory payments and marketing.

"One of the nation's largest clinical laboratories paid a $325 million settlement yesterday to resolve allegations that it overbilled Medicare, Medicaid and other federal health programs by adding unneeded tests to health exams, charging for work that is never performed and inventing diagnoses to justify tests."

– The Washington Post
February 25, 1997

- **Project LabScam –** In 1993, OIG launched Project LabScam to investigate improper billing and abusive marketing practices at major independent clinical laboratories. Project LabScam was the first joint Federal, State, and local law enforcement effort to combat Medicare fraud on a national level. The investigation found extensive unbundling of laboratory tests, billing for tests not performed, false diagnosis codes, and paying doctors for referrals in clinical laboratories across the country. The project resulted in $823 million in recoveries through settlements with major independent clinical laboratories. Among the largest settlements were those involving Laboratory Corporation of America Holdings, which agreed to pay $187 million, and Smith Kline Beecham Clinical Laboratories, which agreed to pay $325 million. As a result of Project LabScam, in 1997 OIG issued a compliance program guidance for clinical laboratories to assist these laboratories in developing compliance programs that detect and potentially prevent fraudulent and abusive practices.

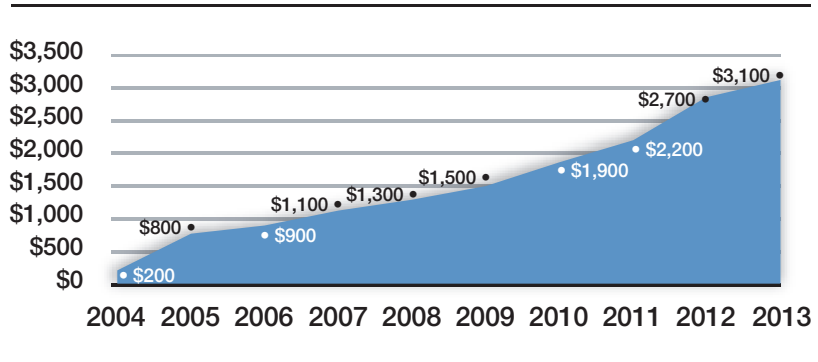
Prescription Drugs

Prescription drugs play an increasingly critical role in health care. Consequently, expenditures for drugs by the Medicare and Medicaid Programs have grown rapidly over the past several decades with combined

expenditures increasing from $813 million in 1980 to $25.5 billion in 2005, according to CMS. Over the course of more than a decade, OIG has produced a body of work examining issues related to drug pricing and payments, including the costs and payment methodologies for prescription drugs under Medicare Part B and Medicaid. More recently, OIG has initiated reviews of Medicare's new outpatient prescription drug benefit under Part D.

- **Medicare Part B Drug Reimbursement –** Through a series of OIG reports and testimonies to Congress, OIG reported that Medicare Part B and its beneficiaries overpaid for many prescription drugs. These overpayments were the result of Medicare's reimbursement methodology, which was based on the average wholesale price (AWP) and resulted in payment amounts that often exceeded the actual costs of these drugs. In response, Congress made substantial changes to the Medicare Part B drug reimbursement system. The new system, which became effective in January 2005, based drug reimbursement on the average sales price (ASP). Unlike the AWP, the ASP is statutorily defined and is calculated from actual sales transactions; therefore, it more closely reflects the prices at which a drug is sold in the marketplace. The Congressional Budget Office estimated that these changes to Part B drug reimbursement would save Medicare $16 billion over 10 years.

Estimated Savings From Payment Reform to Medicare Part B Drugs and Biologicals
(FY in Millions)



Source: Congressional Budget Office scoring of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

- **Medicaid Drug Reimbursement –** Similarly, OIG found that Medicaid paid too much for prescription drugs, especially for generic drugs. In response, Congress changed Medicaid reimbursement for multiple-source drugs (generic drugs) under the Federal upper limit program. The

DRA changed Medicaid's Federal upper limit formula from one based on the AWP to one based on the average manufacturer price (AMP). The AMP is statutorily defined and is calculated from the prices at which manufacturers sell drugs to wholesalers for distribution to the retail pharmacy class of trade. The DRA also required that certain drug pricing information be made available to States and made additional technical changes designed to further contain Medicaid drug costs. The Congressional Budget Office estimated these changes would save Medicaid $11.8 billion over 10 years.

OIG has also devoted substantial resources to investigating and working with DOJ to prosecute prescription drug fraud, and these efforts have produced significant results. Working with its law enforcement partners, OIG has participated in the investigation of pharmaceutical fraud cases that have resulted in more than $4 billion in recoveries since 1999. Fraud schemes in these cases have included fraud and abuse related to prescription drug pricing, prescription drug marketing, noncompliance with the Medicaid drug rebate program, and the delivery and dispensing of drugs. Reimbursement based on the AWP was vulnerable to schemes in which manufacturers reported inflated AWPs and used the increased difference, or "spread," between reimbursement to providers and the providers' acquisition costs to gain market share for their products. OIG has also uncovered price reporting schemes used to inappropriately reduce the amount of rebates that drug manufacturers pay under the Medicaid drug rebate program. In addition, manufacturers have used illegal kickbacks and other abusive marketing schemes, such as the promotion of drugs for non-FDA approved uses. OIG has worked effectively with DOJ to investigate, pursue, and resolve pharmaceutical cases under both the False Claims Act and criminal statutes. Examples include the following:

- In 2001, TAP Pharmaceutical Products Inc. paid more than $875 million to resolve criminal and civil liability resulting from sales and marketing of its prostate cancer drug, Lupron. TAP pled guilty to conspiring to violate the Prescription Drug Marketing Act by causing the sale of free samples and paid $290 million in criminal fines. To resolve the civil claims, TAP paid $585 million, plus interest, to the Government and the States for damages suffered by the Medicare, Medicaid, and TRICARE programs. As part of the civil settlement, TAP also entered into a comprehensive 7-year CIA that requires TAP to report certified pricing information to the Federal and State Governments and requires an outside audit of TAP's sales and marketing practices.

- In 2004, Schering-Plough Corporation agreed to pay $345.5 million as part of a global settlement with the Government and entered into a 5-year CIA with OIG. As part of the settlement, Schering-Plough agreed to pay $293 million to resolve its civil and administrative liabilities in connection with alleged underpayment of rebates owed for its allergy

drug Claritin under the Medicaid drug rebate program. The civil portion of the case focused on Schering-Plough's alleged failure to include the value of certain incentives offered to two HMOs in the company's determination of the best price reported for purposes of the Medicaid drug rebate program. In doing so, Schering-Plough allegedly underpaid rebates due to the States and overcharged entities (such as community health centers) that purchased drugs at ceiling prices that are based on Medicaid drug rebate prices. With regard to the criminal portion of the case, a subsidiary of Schering-Plough, the Schering Sales Corporation, pled guilty to a kickback charge and was sentenced to pay a $52.5 million criminal fine.

- In 2005, Serono Laboratories, Inc., along with its Swiss parent Serono, S.A., entered into a global criminal, civil, and administrative settlement with the Government and States totaling $716 million. The settlement related to Serono's promotion of Serostim, a drug used to treat AIDS-wasting syndrome. Serono Laboratories, Inc., a subsidiary of Serono Holdings, Inc., pled guilty to two criminal conspiracy charges. One related to the illegal promotion of Serostim for non-FDA approved indications. The second charge related to the payment of kickbacks to physicians to induce them to prescribe Serostim. The kickbacks to physicians included all-expense-paid trips to an HIV conference held in Cannes, France, in 1999. Serono Laboratories, Inc., was ordered to pay a $136.9 million criminal fine. Serono Holdings, Inc., the U.S. parent of Serono Laboratories, Inc., agreed to enter into a comprehensive 5-year CIA that will cover the U.S. subsidiaries of Serono Holdings, Inc. The CIA contains several unique provisions, including provisions focusing on Serono's sponsorship of continuing medical education and provisions relating to off-label promotion issues.

Quality of Care

Over the years, OIG has produced a large body of work related to quality of care issues in Federal health care programs. OIG has reviewed quality of care issues in a number of health care settings, such as hospitals, nursing homes, and clinical trials, with a focus on long term care settings. Quality of care issues in nursing homes have been of particular concern for OIG over the past decade because of the increasing number of beneficiaries in these settings and the vulnerabilities associated with this population.

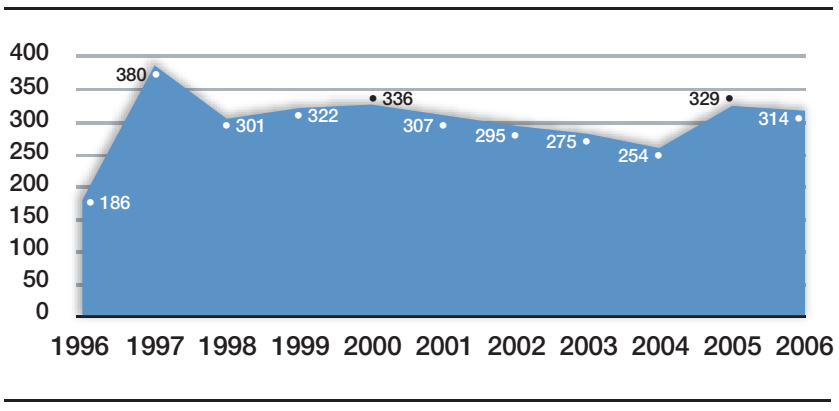
OIG's efforts are twofold: to evaluate the programs and systems involved in oversight of quality of care and to work with State and Federal agencies to investigate and prosecute cases of egregiously substandard care. A key element of this enforcement effort has been the use of False Claims Act suits to recover money and enforce systemic improvements in the quality of care in long term care settings. This, combined with the additional resources provided by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), has proven essential in OIG's efforts to enforce quality of care compliance at long term care facilities. Since FY 1996, the Federal Government has recovered over $221 million from settlements related to quality of care cases.

Failure of Care

Regulating nursing homes that participate in the Medicare and Medicaid programs is primarily the responsibility of CMS and State agencies through their survey and certification efforts. Through periodic facility inspections and individual complaint investigation, CMS and the State agencies assess nursing home performance and determine whether to certify facilities for participation in Medicare and Medicaid. The survey and certification process provides several mechanisms for enforcement of nursing home standards. These include CMS corrective action plans, CMS civil monetary penalties, suspension of intake of new Medicare and Medicaid patients, required changes in management, and decertification.

However, in some cases the quality of care is so deplorable that remedies under the survey and certification process are not sufficient. These extreme cases have involved situations such as egregiously substandard care, systemic and widespread problems, and harm to residents. In essence, certain cases amount to a "failure of care" in that the Federal Government is being billed for services not rendered, constituting a potential violation of the False Claims Act and other statutes applicable to health care fraud. In cooperation with U.S. Attorneys and other Federal and State agencies, OIG developed a means of prosecuting extreme cases of substandard care using False Claims Act suits and criminal health care fraud statutes. In these cases, OIG's first priority is to ensure that nursing home residents receive the care they need. Achieving this has required that OIG work closely with its law enforcement partners as well as Federal and State regulators to strike a balance between recovering money and ensuring

compliance through systemic improvements in quality of care. In a majority of settlements, OIG and its partners use a variety of enforcement tools, including corporate integrity agreements (CIA) and exclusion, to bring about systemic improvements and changes in the quality of care at nursing home facilities.



OIG quality of care exclusions include individuals and entities excluded pursuant to section 1128(a)(2) of the Social Security Act.

Source: Department of Health and Human Services, Office of Inspector General.

OIG and its law enforcement partners have successfully used False Claims Act suits and other administrative authorities in a number of quality of care cases at nursing homes and other long term care facilities. Examples include the following:

- In 2004, ABS Long Term Care Management settled with the Government for $1.6 million and agreed to a 5-year quality of care CIA to settle allegations of egregiously substandard care at one of its Illinois nursing homes. The case stemmed from a *qui tam* suit filed by two former employees alleging that the nursing home billed the Federal and State governments for care that had never been rendered and permitted sexual assaults, theft, and improper medical care that, in some cases, resulted in death. The 5-year CIA covers all 12 facilities owned or managed by ABS and its five individual owners in various combinations.

- In 2005, Hillcrest Healthcare, Inc., a Connecticut nursing home, settled with the Government for $750,000 for allegedly providing skilled nursing services that were not rendered in accordance with applicable laws, regulations, or rules and were so inadequate that they were not reimbursable under Medicare or Medicaid. The Government alleged that poor oversight

and management of the facility's operations led to serious deficiencies in the beneficiaries' care, including bedsores, malnutrition, and the death of at least one beneficiary. The nursing home agreed to a permanent exclusion from participation in the Federal health care programs. Prior to the civil settlement, the facility pled no contest to one count of second-degree manslaughter involving the death of a beneficiary. A year later, Athena Healthcare, which managed the Hillcrest facility, entered into a 5-year CIA with OIG to resolve its liability for failure to provide care to Medicare and Medicaid beneficiaries at the Hillcrest facility.

"AHM's chief executive officer was sentenced to 18 months in Federal prison. He, AHM and three associated nursing homes were also fined a total of $750,000. Civil fines already levied bring the total to $2 million, and civil lawsuits by patients and their relatives cost the company millions more."

– St. Louis Post-Dispatch
March 1, 2007

- In 2005, Lifecare of Lawrenceville, a Georgia nursing home, settled with the Government for $2.5 million and a 5-year quality of care CIA to resolve its False Claims Act liability for billing Medicare and Medicaid for egregiously substandard care. The conduct involved inadequate services in a number of areas, including diabetes management, resident nutrition and hydration, fall prevention and management, and pressure ulcer care. Many of the problems were related to chronic understaffing at the facility. The quality of care CIA requires that the facility pay for an independent monitor selected by OIG.

- In 2005, American Healthcare Management (AHM), a Georgia nursing home company, along with its individual owners and three affiliated nursing homes, agreed to pay the Government $1.25 million to settle allegations of submitting false and fraudulent nursing home billings to Medicare and Medicaid for poor quality of care. The case centered on numerous incidents of residents suffering from dehydration and malnutrition, going extended periods of time without cleaning or bathing, and contracting preventable pressure sores. One resident was found sitting in her own waste and covered by ants. The Government alleged that the lack of quality care was caused by chronic understaffing at the nursing homes. As part of the settlement, the company and the three nursing homes agreed to permanent exclusions, and the principal owner agreed to a 20-year exclusion. AHM, its Chief Executive Officer, and three nursing homes were also convicted on criminal charges of conspiracy to defraud the Medicare and Medicaid Programs. The defendants were sentenced to a combined total of 18 months in prison and 2 years' probation and ordered to pay $750,000 in fines.

Quality of Care Oversight

The resources provided by HIPAA have allowed OIG to devote additional attention to evaluating quality of care in a number of settings from hospitals to clinical trials. OIG has focused on the systems and agencies that provide quality of care oversight in areas such as hospitals and nursing homes.

Through this expanded body of work, a number of programmatic and legislative changes have occurred to improve quality of care.

- **Psychotropic Drug Use in Nursing Homes –** Based on an OIG report, CMS issued a program memorandum to fiscal intermediaries to assist in reminding the provider community about Medicare guidelines for psychotropic drug use in nursing facilities, including guidance on chronic use, lack of documented benefit to the resident, and unnecessary duplicate drug therapy. This memorandum explained Medicare's guidelines for psychotropic drug use in skilled nursing facilities, including the definition of an unnecessary drug, justification for drug use outside guidelines, and antipsychotic drugs.

- **Resident Abuse in Nursing Homes –** In response to several OIG reports, CMS drafted regulations establishing training requirements for nursing home aides and requiring nursing homes to establish processes for handling abuse complaints.

- **Restraints in Nursing Homes –** States, localities, and nursing homes employed recommendations from an OIG report to formulate plans and identify activities that will reduce the use of chemical and physical restraints. The recommendations were part of an OIG report on new Federal rules restricting the use of chemical and physical restraints in nursing homes.

- **Oversight of Clinical Investigators –** In response to an OIG report, the Food and Drug Administration altered its Privacy Act obligations to allow the agency to send Institutional Review Boards (IRB) and sponsors information about potential or actual clinical investigator misconduct that it finds as a result of an inspection. The National Institutes of Health also issued a policy requiring its data and safety monitoring boards to forward summary information to IRBs.

- **Hospital Accreditation Surveys –** In response to an OIG report, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) cancelled its practice of providing advanced notice to hospitals about its upcoming accreditation surveys. Instead, JCAHO switched to random unannounced surveys and expanded the time period during the year in which they could occur.

Compliance/Outreach

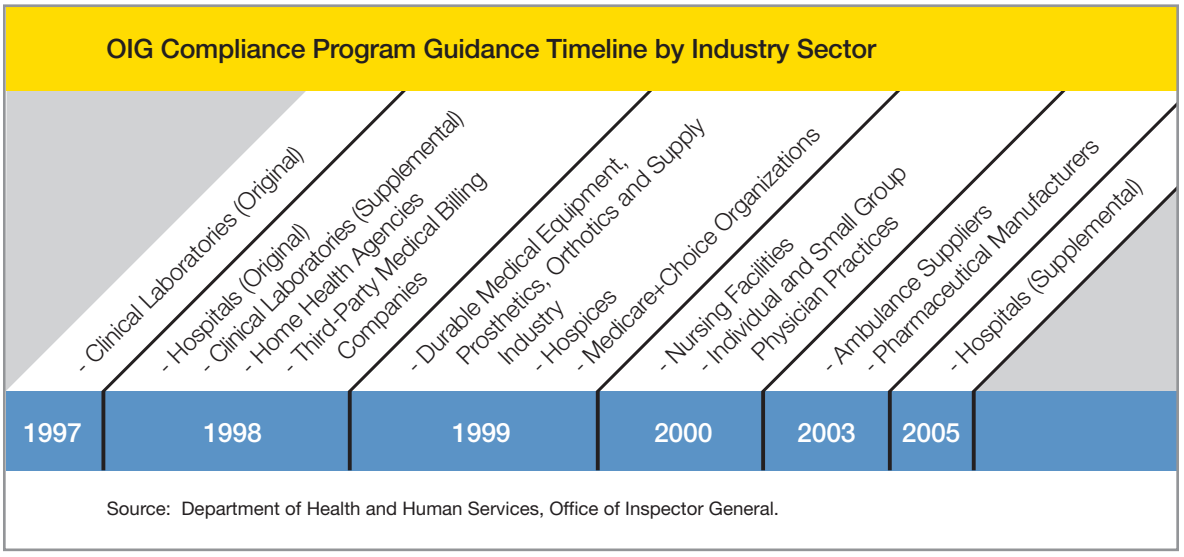
For more than a decade, OIG has engaged in industry outreach efforts to foster a culture of compliance within the health care industry. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) provided a financial and statutory framework to further these efforts. In 1997, following enactment of HIPAA, OIG established the Industry Guidance Branch in the Office of Counsel to the Inspector General specifically to develop and issue advisory opinions, safe harbor regulations, and other industry guidance products. OIG has developed various tools and methods that encourage providers to reduce and prevent fraud and abuse through compliance efforts.

OIG's approach to promoting industry compliance is twofold. First, OIG issues a variety of guidance, including compliance program guidance advisory opinions, fraud alerts, and special advisory bulletins, designed to assist health care providers, suppliers, and organizations in structuring appropriate business arrangements, developing systems and structures to guard against fraud and abuse, and being responsible corporate citizens. These industry guidance efforts have generally been well received by the regulated community.

Second, OIG redresses health care fraud—whether voluntarily disclosed by providers or alleged by the Government. For those individuals or entities uncovering potentially fraudulent behavior, OIG developed a detailed Provider Self-Disclosure Protocol setting forth the processes and potential benefits in disclosing such behavior. In cases in which the Government alleges that an individual or entity has committed fraud, OIG often agrees to not pursue exclusion if the individual or entity enters into an integrity agreement with OIG. Such integrity agreements require the individual or entity to establish or continue compliance programs that safeguard Federal health care programs from fraud, waste, and abuse. OIG integrity agreements result in comprehensive internal control systems and have been a catalyst for change in corporate culture.

Compliance Program Guidance

One of OIG's most significant means of outreach is through developing and publishing voluntary compliance program guidance (CPG). CPGs give providers, suppliers, and organizations from various health care sectors comprehensive frameworks, standards, and principles by which to establish and maintain effective internal compliance programs that detect and prevent fraud and abuse against Federal health care programs and ensure adherence to Federal laws and regulations. OIG develops CPGs based on information from OIG oversight, enforcement, and outreach activities; consultations with Federal and State agencies; and communications with the health care provider community. OIG has issued 13 final compliance program guidances covering all major health industry sectors.



In 1997, OIG issued its first CPG for clinical laboratories to strengthen compliance in an industry that had been the subject of a nationwide fraud-fighting operation. This guidance was updated and expanded in 1998. Over time, OIG's work pertaining to organizations in specific industry sectors contributed to the development of additional guidance tailored to address specific vulnerabilities. For example, the nursing facilities CPG of 2000 included a section on quality of care, which continues to be a prevalent problem in the industry. In 2003, OIG, working with industry input, developed a seminal CPG for pharmaceutical manufacturers, which included an expansive risk areas section focused on accuracy of data reporting and relationships with physicians. In 2005, OIG issued a supplement to its 1998 hospital CPG. The supplement offered a significantly expanded risk areas section, compiled diverse OIG guidance documents into a single document, and included a new section on assessing the effectiveness of existing compliance programs. Although styled as guidance for hospitals, the supplemental hospital CPG is a valuable resource for physicians and others in the regulated community.

> "The guidance is a supplement to the IG's original compliance program guidance to hospitals issued in 1998 and provides expanded discussions about fraud and abuse risk areas and evaluating the effectiveness of compliance programs."
>
> – **BNA Health Care Daily**
> January 28, 2005

The importance of compliance in health care organizations is evident in the Health Care Compliance Association's 2006 Annual Survey of its members, which found that 91 percent of health care organizations have active compliance programs in place, while another 8 percent have formal compliance programs under development. OIG has sought to facilitate these industry compliance efforts through CPGs in combination with other guidance and enforcement efforts. The goal is a more level playing field for the majority of health care organizations, which are honest and law-abiding.

Advisory Opinions

OIG established its advisory opinion program in 1997 pursuant to a HIPAA mandate. OIG advisory opinions provide individuals and entities with legal opinions about the application of OIG's fraud and abuse authorities to existing or proposed health care business arrangements. To apply for an advisory opinion, a requester submits a detailed written submission describing the business arrangement about which an opinion is sought, pursuant to regulations issued by OIG. Advisory opinions apply only to the individual health care business arrangement they address and are published on OIG's Web site. To date, OIG has issued more than 150 advisory opinions on a wide variety of business arrangements from across the heath care industry.

Special Fraud Alerts/Special Advisory Bulletins

OIG regularly issues special fraud alerts and special advisory bulletins that notify the health care community about potentially abusive practices and vulnerabilities under specific fraud and abuse statutes. Fraud alerts and advisory bulletins serve as powerful tools in encouraging compliance by giving providers the opportunity to examine their practices, avoid high-risk conduct, and adjust current practices as necessary. To date, OIG has issued 20 fraud alerts and advisory bulletins that have covered issues ranging from gainsharing arrangements between hospitals and physicians to fraud and abuse in the provision of services at nursing facilities.

In November 2005, OIG issued a special advisory bulletin to the pharmaceutical industry on the application of OIG fraud and abuse laws to patient assistance programs (PAP), which offer assistance in obtaining outpatient prescription drugs to financially needy Medicare beneficiaries who enroll in the Medicare Part D drug benefit. The bulletin provided options for structuring PAPs in ways that would allow drug manufacturers to assist financially needy Part D enrollees with reduced risk under the fraud and abuse statutes. Subsequently, several drug manufacturers applied for and received favorable advisory opinions about their PAP arrangements for Part D beneficiaries. In addition, other notable alerts and bulletins addressed issues such as engaging in joint ventures, marketing pharmaceuticals, renting physician office space, and offering gifts to beneficiaries.

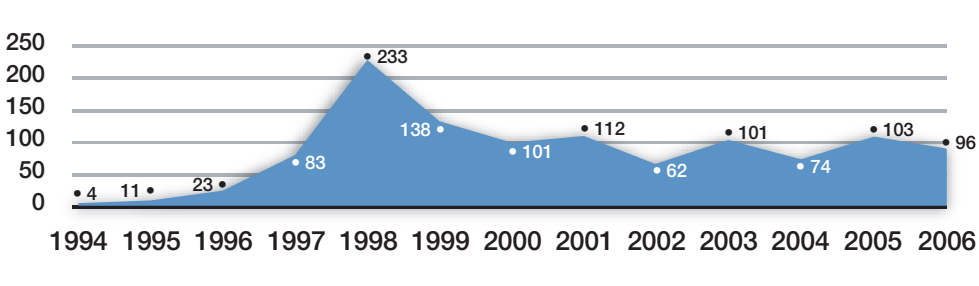
Corporate Integrity Agreements

When the Government alleges that an individual or entity has defrauded Medicare, Medicaid, or any other Federal health care program, OIG has the authority to seek to exclude the individual or entity from future participation in these programs. In the mid-1990s, OIG began to require providers settling civil health care fraud cases to enter into corporate integrity agreements (CIA) as a condition for OIG not pursuing exclusion. Since that time, OIG has entered into more than 1,000 CIAs and similar agreements as part of the resolution of civil and administrative health care fraud cases.

Similar to CPGs, CIAs were originally constructed around the core elements of the Federal Sentencing Guidelines of 1995. CIAs generally require providers to implement compliance measures, such as appointing compliance officers; developing policies and procedures, training programs, and reporting mechanisms; and hiring outside auditors to review Medicare billings and other operations related to Federal health care programs. CIAs also require detailed reporting to OIG. Over time, CIAs have evolved into more sophisticated and detailed documents. One example of how current CIAs focus compliance efforts and make providers accountable is the 2006 CIA with Tenet Healthcare Corporation. Under this 5-year CIA, Tenet must hire outside reviewers to review Medicare billings, cost report submissions, and quality of care. Most significantly, the CIA requires Tenet's Board of Directors to undertake a review of the effectiveness of Tenet's compliance program and adopt resolutions with respect to this review.

In its CIA monitoring role, OIG seeks to promote compliance through providing information and feedback to an entity operating under a CIA. Although most entities operating under CIAs devote resources and institutional effort toward compliance, OIG must sometimes hold entities accountable for failing to comply with their CIAs. For almost 10 years, OIG has included provisions in CIAs that allow OIG to impose stipulated penalties for particular types of CIA breaches and exclusion for material breaches of CIAs. Although OIG tries to work with a provider to address compliance issues and the imposition of stipulated penalties is relatively rare, OIG has imposed stipulated penalties in cases in which an entity breached a CIA and did not take appropriate steps to improve its compliance. In 2006, OIG for the first time used the material breach provisions of a CIA to exclude a provider, South Beach Community Hospital in Miami, Florida, based on material breach of its CIA. This was the result of repeated and flagrant violations by South Beach. Potential exclusion combined with stipulated penalties has strengthened OIG's ability to hold providers accountable for complying with their CIAs.

Number of Corporate Integrity Agreements Executed by OIG
(Fiscal Year)



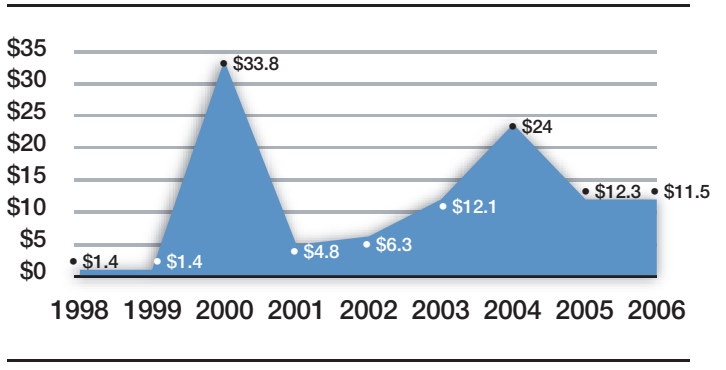
Source: Department of Health and Human Services, Office of Inspector General.

Provider Self-Disclosure Protocol

OIG's Provider Self-Disclosure Protocol was based on a 2-year pilot program introduced in 1995 as part of Operation Restore Trust, an antifraud initiative aimed at durable medical equipment, home health, nursing home, and hospice providers in California, Florida, Illinois, New York, and Texas (see box on page 25). The success of the pilot program convinced OIG to expand the program in 1998 to the larger health care provider community.

OIG developed and published the Provider Self-Disclosure Protocol to provide detailed guidance to health care providers who choose to disclose potential violations of law. The Protocol offers a detailed explanation of how a provider should proceed in investigating and assessing the potential violation and how OIG will proceed in verifying the disclosure information. Although not protected from civil action under the False Claims Act or from criminal action, providers are advised that the self-reporting of wrongdoing could be a mitigating factor in OIG's resolution of the matter disclosed. Since FY 1998, over $107 million has been recovered through OIG's Provider Self-Disclosure Protocol.

Recoveries Resulting From OIG's Self-Disclosure Protocol
(FY in Millions)



Source: Department of Health and Human Services, Office of Inspector General.

Grants Management

The Department of Health and Human Services (HHS) is the largest grant-awarding agency in the Federal Government. In fiscal year (FY) 2005 alone, HHS awarded over 73,000 grants totaling more than $241 billion. HHS grants are designed to fund a variety of projects and services, including health and medical research, disease prevention and treatment, and health and social services programs.

The size and scope of HHS grant expenditures have made grants management a significant challenge, particularly because of the very nature of grants. Unlike the management of other Government expenditures, performance responsibility and management of a grant rest primarily with the grantee, with little or no Government involvement in the funded activity.

Because of the significant dollars involved and the importance of proper disbursement of grant funds, OIG has focused on a variety of issues involving grants management. Employing its audit, evaluation, and investigative tools, OIG has sought to ensure that grant monies are used for their intended purposes and are overseen in the most efficient and effective manner. Through its efforts, OIG has identified weaknesses and risk areas, proposed recommendations for systemic improvement, and investigated cases of grant fraud.

Discretionary Grants

In FY 2005, HHS awarded approximately $37 billion in discretionary (nonmandated) grants. Discretionary grants are awarded on a competitive basis for specific projects ranging from medical research to health care and support for those affected by HIV/AIDS.

Health and Medical Research

Awards for health and medical research projects have always accounted for a significant amount of discretionary grants. In FY 2005 alone, almost half of the discretionary grants were awarded by the National Institutes of Health (NIH) for medical and health care research programs that ranged from traditional research projects by individuals to multidisciplinary research programs. Over 80 percent of NIH's annual budget is devoted to funding such health and medical research grants.

OIG has engaged in extensive oversight of HHS research grants, including those made to colleges and universities. Initially, OIG audited research institutions receiving research grants from HHS. In 1984, Congress passed the Single Audit Act, which required entities, including colleges and universities, receiving Federal grants to have organizationwide audits conducted by independent auditors. These audits are then submitted to the cognizant Government agency for review and followup if necessary. The enactment of the Single Audit Act shifted OIG's auditing responsibility

from conducting individual audits of grants to reviewing organizationwide audits of grant recipients performed by independent auditors.

During the late 1990s, there was an increase in Federal funding for medical and scientific research corresponding with the doubling of NIH's budget between FY 1999 and FY 2003. This increase in NIH appropriations was accompanied by increased grants awarded for health and medical research. Coinciding with this increase in research grant expenditures was an increase in *qui tam* suits related to research grant fraud in universities. These suits uncovered practices such as overstating the time commitment on grants, transferring funds improperly across projects, and double-billing other Federal programs. OIG audit and investigative staff worked closely with other Federal agencies to investigate and prosecute these cases under the False Claims Act.

Significant OIG False Claims Cases Involving Research Institutions

Institution	Alleged Misconduct	Settlement Date	Settlement Amount
University of Minnesota	An unclassified drug was sold and NIH grant funds were mishandled.	1998	$32 million
Mayo Foundation	The Government was charged for research unrelated to the NIH grants.	2005	$6.5 million
Northwestern University	Researchers' time and effort on NIH sponsored projects were overstated.	2003	$5.5 million
University of Alabama-Birmingham	Medicare, NIH, and other Government grant sponsors were illegally billed for clinical trials.	2005	$3.4 million
Johns Hopkins University	Faculty time and effort devoted to NIH grants were overstated.	2004	$2.6 million

Ryan White CARE Act

The Ryan White CARE Act was enacted in 1990 and reauthorized in 1996 to provide funding to States and other public and private entities to develop, organize, coordinate, and operate effective and cost-efficient health care and support services for medically underserved individuals and families affected by HIV/AIDS. Within HHS, the Health Resources and Services Administration (HRSA) administers the Ryan White Program by providing grants to urban areas disproportionately affected by the incidence of HIV/AIDS. OIG has conducted 29 reviews of approximately $533 million in HHS grants for Ryan White services. Since 2001, OIG has examined whether grantees claimed costs appropriately, purchased prescription drugs at the lowest prices, and provided services that were promised. Using the results of these audits, HRSA agreed to recoup misspent funds through

repayment or adjustments. Two of the reviews with the largest savings were a 1998-2001 review of the Indiana Department of Health that resulted in $5.8 million in savings and a 2001-2002 review of the Puerto Rico Department of Health that resulted in $1.6 million in savings.

In addition, OIG has identified systemic vulnerabilities and provided insight to program managers on a variety of Ryan White grant issues. Through this body of work, OIG has made recommendations to HRSA that have assisted the agency and its State partners in improving the efficiency and effectiveness of program operations. Examples of changes resulting from OIG work include the following:

New AIDS Drug Assistance Program Cost Containment Strategies – Based on OIG findings and recommendations, HRSA launched the "Alternative Method Demonstration Project" initiative, which allowed entities in the 340B Drug Discount Program, including Ryan White grantees, to contract with multiple pharmacies to achieve greater savings on prescription drug purchases.

Improvements in Ryan White Evaluation Systems – As a result of OIG recommendations, HRSA instituted a policy that allowed Ryan White grantees to use a portion of the grant for services that enhance the ability of participants to gain access to, adhere to, and monitor their progress in taking HIV-related medications.

Mandatory Grants

In FY 2005, HHS awarded $204 billion in mandatory (required by statute) grants. Medicaid received the largest portion of HHS mandatory grants ($160 billion in FY 2005) and is discussed in the Health Care Integrity section of this publication. Mandatory grants are those that a Federal agency is required by statute to award if the applicant, usually a State, submits an acceptable State Plan or application and meets the eligibility and compliance requirements of the grant program. HHS awards mandatory grants for a number of public health and social services, including adoption assistance and foster care.

Adoption Assistance/Foster Care

HHS, through the Administration for Children and Families (ACF), shares in the costs of administering and providing staff training for State foster care and adoption assistance programs under Title IV-E of the Social Security Act. In general, the Federal Government reimburses State administrative costs at a rate of 50 percent, with an enhanced reimbursement rate of 75 percent for foster care and adoption assistance training costs. Over the past decade, OIG has conducted 42 reviews of approximately $878 million in HHS grants for adoption assistance and foster care. Enhanced reimbursement for training costs has been the subject of many OIG reviews. OIG's work found enhanced reimbursement to be vulnerable to unallowable cost claims maximization by States. Focusing on individual States, the

reviews found a number of cases in which costs were divided improperly between the Federal and State governments and not claimed in accordance with Federal rules and regulations. Using the results of these audits, ACF agreed to take action to recover misspent funds through repayment or cost plan adjustments.

Select OIG Adoption Assistance/Foster Care Reviews With Significant Savings

Review Subject	Review Period	Savings
Missouri	1999-2002	$15.2 million
Nebraska	1994-1999	$11.7 million
Maryland	1999-2001	$6.8 million
Delaware	1999-2003	$5.9 million
Kansas	1992-1996	$4.6 million
Maine	2001-2003	$3 million

In addition, OIG has identified systemic vulnerabilities and provided insight to program managers on a variety of adoption assistance and foster care issues. Through this body of work, OIG has made recommendations to ACF that have assisted the agency and its State partners, as well as lawmakers, in improving the efficiency and effectiveness of program operations. Examples of changes resulting from OIG work include the following:

Caseworker Visits With Children in Foster Care – On September 28, 2006, the President signed the Child and Family Services Improvement Act of 2006, which established funding incentives for States to increase the frequency and quality of caseworker visits with children in foster care. This law specifically cited the findings from an OIG report on State standards and capacity to track frequency of caseworker visits with children in foster care. Moreover, the OIG report findings were instrumental in the amendment of State policies on foster care caseworker visitation.

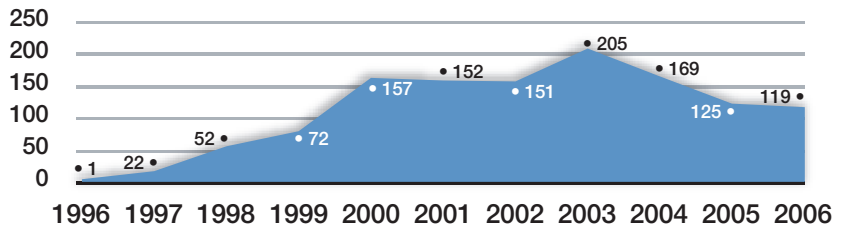
Foster Care Grant Oversight Procedures – In response to several OIG reports, ACF began attaching standard terms and conditions to the mandatory grants it provided in the first quarter of FY 2006. In addition, Thompson Publishing included criteria from one of the reports as "A Sample Process" in its Single Audit Information Service guidance on subrecipient monitoring. The Single Audit Information Service is a subscription service for Federal grantees and auditors and includes a resource binder.

State Policy on Health Care Services for Children in Foster Care – As a result of a series of OIG reports, Georgia instituted the Comprehensive Child and Family Assessment program to provide comprehensive health assessments of children upon entering foster care.

Child Support Enforcement

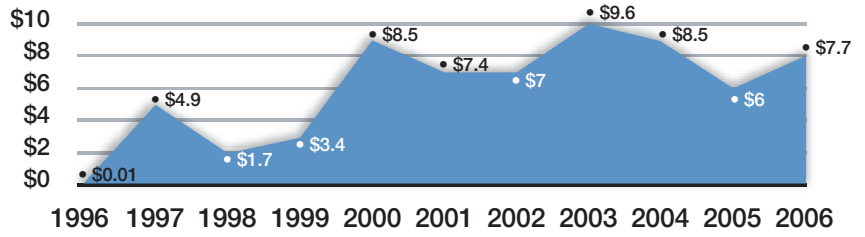
Over the years, the detection, investigation, and prosecution of noncustodial parents who fail to pay court-ordered child support have been priorities for OIG. Working with the Federal Office of Child Support Enforcement (OCSE), the Department of Justice, U.S. Attorneys' Offices, the U.S. Marshals Services, and other Federal, State, and local partners, OIG continues to develop ways to expedite the collection of child support.

Convictions Resulting From OIG Child Support Cases
(Fiscal Year)



Source: Department of Health and Human Services, Office of Inspector General.

Amount of Restitution Resulting From OIG Child Support Cases
(FY in Millions)



Source: Department of Health and Human Services, Office of Inspector General.

Project Save Our Children

Much of OIG's results in the area of child support enforcement are directly attributable to effective collaboration between numerous Federal and State agencies. By using an innovative enforcement program, OIG and its partners have worked together to improve program performance.

Federal authorities have had jurisdiction over interstate child support cases since Congress passed the Child Support Recovery Act in 1992. Initially, the FBI and U.S. Attorneys' Offices, joined in 1995 by OIG, investigated child support cases forwarded by the States. This process proved to be cumbersome because States often referred cases to multiple Federal agencies that did not meet the threshold for Federal prosecution or did not contain the information necessary to adequately investigate. Recognizing these challenges in 1998, OIG and OCSE launched Project Save Our Children (PSOC) to identify and prosecute the most egregious interstate child support cases by leveraging the expertise and resources of Federal and State agencies involved in child support.

"…HHS Inspector General June Gibbs Brown has teamed up with the Office of Child Support Enforcement and the Justice Department, as well as state and local authorities, to strengthen enforcement. Their strategy is to leverage resources by targeting the most egregious offenders and publicizing cases in an effort to discourage others from skipping their own payments."

– Government Executive
December 1998

Based on a task force initiated in Ohio by OIG, PSOC brought together Federal and State law enforcement and child support staff into 10 task forces serving all 50 States. The task forces streamline the process by which the cases best suited for criminal prosecution are identified and investigated. Central to the task forces are the screening units located in each task force region, which are staffed by analysts and auditors from both OIG and OCSE. Working with child support agencies, these units identify the most egregious cases, conduct preinvestigative analyses of these cases through the use of information databases, and forward the cases to Federal investigators for investigation. The completed case packages are then brought to the prosecutor with the evidence needed for prosecution already obtained.

Examples of OIG cases brought to restitution through coordination with PSOC include the following:

- **California –** A man was sentenced to 1 year of home detention, 5 years' probation and 100 hours of community service, and ordered to pay $186,000 in restitution for failure to pay child support. Of approximately $186,000 owed in child support over 16 years, the man had made only a single $660 payment. Even after the custodial parent's suicide, he failed to provide any financial support for his children.

- **Minnesota –** A former attorney once responsible for overseeing a State's child support enforcement division was sentenced to 10 months' time served and 1 year supervised release and ordered to pay $109,000 in restitution for failure to pay child support. He owed approximately $109,000 for 12 years of child support for two children. The investigation found that he was living and working under an alias in Nevada and had received in excess of $30,000 from his father's estate.

- **Pennsylvania –** A former professional football player was sentenced to 6 months in a Federal work-release facility for failure to pay child support. He was ordered to begin paying support from his prison wages and continue during 1 year of supervised release. He was also ordered to pay $142,000 in support for a child with his former wife and $110,000 in a separate case for a child he had with another woman. His last football contract was a 1-year deal worth $1.1 million.

- **Washington –** A former cancer researcher was sentenced to 5 years' probation and 100 hours of community service, and ordered to pay $166,000 in restitution for failure to pay child support. He was also ordered to enroll in a mental health program. The investigation revealed that despite earnings of up to $3 million a year, he failed to pay approximately $166,000 in child support owed over 10 years. Further, he liquidated $15 million from his children's trust fund to buy fine art.

Total Project Save Our Children Results Through FY 2006	
Number of cases referred by the States to PSOC units	10,800
Number of Federal arrests	625
Number of individuals sentenced because of Federal investigations	601
Amount of ordered restitution resulting from Federal investigations	$27.2 million

Improving the Child Support Enforcement System

In addition to performing its law enforcement work, OIG has had an impact on the operation of the child support enforcement system through numerous audits and evaluations. OIG reports have identified systemic vulnerabilities and provided insight to program managers on a variety of issues. Through this body of work, OIG has made recommendations to OCSE that have assisted the agency and its State partners in improving the efficiency and

effectiveness of enforcement operations. Examples of changes resulting from OIG work include the following:

- **Client Cooperation –** In response to OIG recommendations, OCSE conducted national training, awarded grants, and issued policy recommendations to States regarding promoting low-income client cooperation with child support enforcement agencies and encouraging greater collaboration between child support and public assistance agencies.

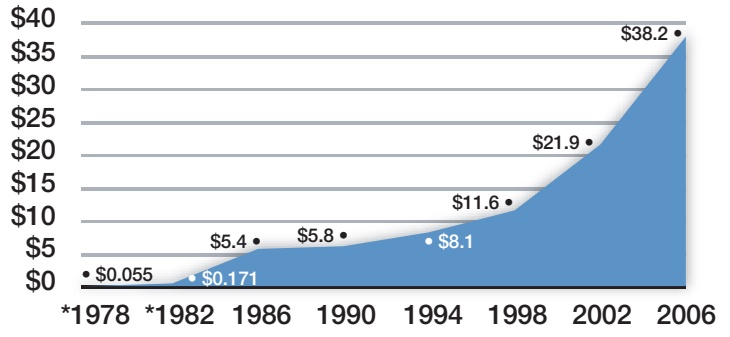
- **Low-income Parents –** Based on OIG recommendations, OCSE issued policy recommendations and grants encouraging States to scrutinize their policies and experiment with new methods of increasing low-income parents' ability to pay child support and promote responsible parenthood.

- **Child Support Case Closure –** In response to OIG recommendations, OCSE issued guidance to the States on using automated processes for properly closing cases, developed a model closure notice, and collaborated with the National Child Support Enforcement Association to host a nationwide teleconference on case closure.

Looking to the Future

As this retrospective reveals, OIG has experienced three decades of conscientious oversight of a growing portfolio of health and human services programs and issues. And if, as observed by American philosopher John William Miller, "history is the story of the consequences of our commitments," we can look back with pride to the billions of dollars saved and the billions of dollars returned to the Federal Government as a result of OIG's long-standing commitment to the economy, efficiency, and integrity of HHS program operations.

OIG Total Cost Savings
(FY in Billions)



*OIG published annual reports based on the calendar year until 1983 at which time it began publishing two semiannual reports based on the fiscal year.

OIG cost savings include: funds identified for recovery by HHS agencies as a result of OIG audits or evaluations; fines, restitutions, and settlements resulting from OIG investigations; and funds put to better use because of legislation, regulations, and policies and procedures implemented in response to OIG recommendations or activities.

Source: Department of Health and Human Services, Office of Inspector General.

As we look toward the future, OIG's mission is on a path toward even greater oversight challenges, in terms of not only absolute dollars but also growing complexity and urgency to the tasks we must assume.

The growth in health care spending, according to CMS actuaries, is expected to double in the next 10 years, and many of these added dollars must be accounted for in the sound and efficacious administration of Medicare and Medicaid programs. This will require not only increased audit, evaluative, and investigative work along traditional lines but also enhancement of existing antifraud instruments and comprehensive strategies toward achieving greater compliance among providers. Innovation will be especially important as OIG addresses the new Medicare Part D prescription drug benefit and a new, more intensive and extensive protection of the Federal funding stream for Medicaid.

In this new century, HHS has been given expanded responsibilities to address global health care preparedness and response. A corresponding obligation

of OIG is to assist in identifying the pathways that reveal, through measurable indicia, how the Department best meets these new demands. Following the devastation of Hurricanes Katrina and Rita in 2005, OIG has built upon its 9/11 work to launch an aggressive and coordinated oversight program with Federal, State, and local partners. OIG's continuing efforts in oversight of select agent issues, pandemic preparedness, and infrastructure response to bioterrorism threats must be pursued rigorously.

Much of the progress toward a healthier and long-lived population depends on the research success of our dedicated and capable cover of medical experts who are federally funded both within HHS and in the wider research community. OIG must continue to exercise vigilance in medical research integrity issues, to help ensure that vital research findings are not compromised, in fact or in appearance.

In addition, ensuring that all HHS officials conduct their official duties in a manner that does not result in personal benefit or financial gain is vital for the American public to have confidence that important decisions affecting individual health and safety are made on merit and are free of improper influence. Increased ethics enforcement and oversight by OIG strengthen the HHS ethics program and help maintain the trust and confidence of Congress and the public. Accordingly, OIG will continue to focus on conflict-of-interest issues.

The capable and vigorous oversight of these and other issues of vital concern to the health and welfare of the Nation, and ultimately to populations around the globe, will occupy our auditors, investigators, evaluators, lawyers, and support staff in the years ahead. OIG will succeed in its critical mission, however, only if it can optimize its human resources and master the technological environment within which it performs its services.

We must leverage our precious human resources to create key synergies among diverse but complementary professional disciplines and work creatively and constructively with departmental partners, the Department of Justice, State partners, the legislative branch, and private sector compliance and antifraud officers and employees.

Technologically, the adoption of electronic health records and the movement toward interoperability promise to define much of what can accurately be described as the health information technology revolution of the 21st century. OIG must build and enhance its core competencies so that it may effectively perform its role to promote a compliance friendly environment that achieves desirable levels of transparency and cost control, enhances quality and reduces the potential for mistakes, protects legitimate privacy concerns, and discourages fraud.

These are exciting and important challenges, and OIG's history, as captured in this brief retrospective, instills confidence that they can be mastered for the benefit of the taxpayers and the Nation.

Department of Health and Human Services
Office of Inspector General

www.oig.hhs.gov