

Testimony of:
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Good morning, Chairmen Stark and Lewis, Ranking Members Camp and Ramstad, and distinguished members of the Committee. I am Daniel R. Levinson, Inspector General for the Department of Health and Human Services (HHS). I appreciate the opportunity to appear before you today to discuss the important oversight role of the Office of Inspector General (OIG) and the efforts we undertake to protect the integrity of all 300 programs the Department administers, including Medicare.

I am pleased to come before you at a time when OIG recently commemorated an unusual confluence of milestones: 2006 marked the 30th anniversary of the OIG's creation, the 20th anniversary of the 1986 amendments to the Federal False Claims Act, and the 10th anniversary of the Health Insurance Portability and Accountability Act (HIPAA). All three of these anniversaries are important milestones that have shaped the way our office carries out its work.

Since 1976, the world has dramatically changed and so has OIG. We have seen enormous changes in the health care delivery system, information technology, globalization, and public health emergency preparedness. These changes demand that we keep pace with our oversight efforts. What has remained constant, however, is our core mission to promote integrity, economy, and efficiency in the Department's programs. OIG's work benefits millions of Americans and generates substantial cost savings.

OIG's ability to combat fraud was greatly enhanced by the 1986 amendments to the False Claims Act. These amendments rejuvenated the Act's *qui tam* provisions, resulting in a public-private partnership that has proven invaluable in detecting and prosecuting health care fraud.

Enacted in 1996, HIPAA provided OIG with increased resources; stronger enforcement tools; and a management structure to coordinate the efforts of Federal, State, and local partners involved in combating health care fraud. As a result, our office expanded its presence throughout the country, launched nationwide initiatives directed at health care fraud, and increased the savings and recoveries returned to the taxpayers.

Ensuring the integrity of the Medicare program is challenging, given the program's size and complexity. You have asked me to provide today a broad overview of OIG's organizational structure, funding sources, and methods by which we identify our work priorities. I will also provide an overview of the Medicare program and its vulnerabilities and will touch on a select body of OIG's work that addresses these vulnerabilities. I will conclude with a prospective look at the challenges ahead.

Role and Responsibility of the HHS OIG

Our office was created in 1976 and was the first statutory OIG in the Federal Government. Two years later, the Inspector General Act of 1978 (IG Act), modeled after the law creating the HHS OIG, established OIGs at other Cabinet-level departments of the Federal Government, as well as at some independent Government agencies.

Congress created OIGs to be independent and objective units within Federal departments and agencies for the purpose of: (1) conducting audits and investigations of programs and operations; (2) coordinating and recommending policies to promote economy, efficiency, and effectiveness in the administration of programs; (3) preventing and detecting fraud and abuse; and (4) keeping the Department Secretary or Agency Administrator and Congress informed about the necessity for corrective action.

To achieve these objectives, our office reviews programs to identify systemic vulnerabilities and makes recommendations to improve their efficiency and effectiveness; investigates specific instances of fraud or abuse and takes appropriate enforcement actions; audits specific payments, providers, and programs to identify and recover overpayments; and promotes voluntary compliance by issuing guidance to health care providers and the health care industry.

OIG's effectiveness in protecting the integrity of Medicare relies heavily on leveraging the resources of our law enforcement partners. These partners include the Department of Justice's Civil, Criminal, and Civil Rights Divisions, U.S. Attorneys Offices, and the Federal Bureau of Investigation. Other key partners include the Centers for Medicare & Medicaid Services (CMS) and the Medicaid Fraud Control Units (MFCUs).

OIG Structure and Organization

As one of the largest OIGs in the Federal Government, our more than 1,500 full-time auditors, evaluators, investigators, and attorneys contribute their diverse expertise and skills to carry out our mission to protect the integrity of HHS programs. To ensure national coverage and presence, our staff are located in Washington, DC, Baltimore, Maryland, and 9 regional offices and 80 smaller field offices throughout the country.

Although OIG has five functional units, we take a comprehensive and multifaceted approach to protect the integrity of the Department's programs. These units are the: (1) Office of Audit Services, (2) Office of Evaluation and Inspections, (3) Office of Investigations, (4) Office of Counsel to the Inspector General, and (5) Office of Management and Policy. These units work closely together to accomplish a wide range of oversight and enforcement work involving audits, evaluations, investigations, and fraud enforcement and prevention efforts.

The Office of Audit Services (OAS) is instrumental in identifying improper payments and reimbursements and conducts financial and performance audits of departmental programs, operations, grantees, and contractors. This includes investigative audit work

performed in conjunction with other OIG components. Much of OAS's work in identifying improper payments is complementary to that of the Office of Evaluation and Inspections (OEI), which identifies systemic vulnerabilities in program operations and processes.

OEI conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. Specifically, these evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness in departmental programs. To promote impact, the reports also present practical recommendations for improving program operations.

The Office of Investigations (OI) conducts and coordinates investigations of fraud and misconduct to safeguard the Department's programs and beneficiaries. The size and complexity of Federal health and human service programs require OI to leverage its resources with those of its law enforcement partners. As such, OI collaborates closely with the Department of Justice on investigations of HHS programs and personnel and interacts with CMS, State Licensing Boards, MFCUs, and other entities with regard to program exclusion, compliance, and enforcement activities. These investigative efforts lead to criminal convictions, civil settlements, program exclusions, or civil monetary penalties and assessments.

The Office of Counsel to the Inspector General (OCIG) performs three major functions within OIG. First, it provides general legal services to OIG, including advice and representation on HHS programs and operations, administrative law issues, criminal procedure, and internal OIG management matters. The second major function involves coordinating OIG's role in the judicial and administrative resolution of fraud and abuse cases involving HHS programs, including the litigation and imposition of administrative sanctions, such as program exclusions and civil monetary penalties and assessments; the global settlement of cases arising under the Civil False Claims Act; and the development and monitoring of corporate integrity agreements (CIA) for certain providers that have settled their False Claims Act liability with the Federal Government. Finally, OCIG plays an equally important role in assisting the regulated health care industry in complying with the fraud and abuse laws by issuing voluntary compliance program guidance, advisory opinions, fraud alerts and bulletins, and "safe harbor" regulations under the Federal anti-kickback statute.

The Office of Management and Policy provides mission support services to OIG and its components. Its principal responsibilities include formulating and executing the organization's budget and strategic plan, developing internal policy, and managing information technology resources.

Our staff expertise, national presence, organizational structure, and collaboration with law enforcement partners enable OIG to leverage scarce resources to achieve maximum return for the oversight dollars invested. For the 3-year period from FYs 2004-2006, average return on investment was nearly 13 to 1.

OIG Funding

HHS OIG's funding mechanisms are unique. Since 1997, our funding has come from two primary sources: (1) the Health Care Fraud and Abuse Control Account (HCFAC) allocation, which was established by HIPAA, and (2) a discretionary appropriation. OIG has also benefited from additional temporary funding that Congress has appropriated to augment existing resources.

HIPAA established an annual dollar amount to be funded from the Medicare Trust Fund to combat fraud, waste, and abuse in the Medicare and Medicaid programs. Our HCFAC allocation was determined jointly by the Secretary of HHS and the Attorney General, within the annual ranges specified under HIPAA. HCFAC funds comprise a major portion of OIG's annual operating budget, generally between 75 to 80 percent, which means that most of our activities involve the Medicare and Medicaid programs. In fiscal year (FY) 2003, OIG's HCFAC allocation was capped at \$160 million. However, the Tax Relief and Health Care Act of 2006 established a set annual HCFAC funding amount for OIG beginning in FY 2007. It also establishes annual increases to that funding through FY 2010 by the percentage increase in the Consumer Price Index for all urban consumers.

Discretionary funding represents dollars appropriated by Congress each year to be used for activities related to departmental management issues and the Department's programs other than Medicare and Medicaid. Discretionary funds typically comprise approximately 20 percent of OIG's annual operating budget and in FY 2007 amounted to nearly \$40 million.

Additionally, Congress has provided special funding for Medicare and Medicaid oversight over and above the HCFAC amount. For example, in FY 2005, OIG received \$25 million to fight fraud, waste, and abuse associated with the implementation of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). In addition, the Deficit Reduction Act of 2005 (DRA) increased OIG's funding for Medicaid fraud and abuse control activities. Pursuant to the requirements of the DRA, beginning in FY 2006 and continuing through FY 2010, OIG will receive an additional \$25 million annually for Medicaid integrity activities.

Given the expansion of the Medicare and Medicaid programs, and increases in health care expenditures, OIG acknowledges how critical these additional resources are to meeting increased responsibilities for protecting these programs and their beneficiaries.

OIG Priority Setting, Reporting, and Followup

Each year, OIG develops a work plan, which guides our activities for the upcoming fiscal year. This plan is available to the public on our Web site. Although resource constraints preclude us from reviewing all 300-plus programs of the Department annually, OIG engages in a comprehensive work-planning process to identify the most important and timely issues for the upcoming fiscal year and to direct our resources accordingly.

Among the things that OIG considers in setting its work priorities are findings from previous OIG and external reviews (e.g., Government Accountability Office (GAO) and Medicare Payment Advisory Commission), size of the program (i.e., expenditures, number of beneficiaries served), specific requests from Congress and the Department, and the need to review program areas that warrant revisiting.

As part of the Department's mandated annual Performance and Accountability Report, each year our office identifies the most significant management and performance challenges facing the Department based upon OIG's body of work. This assessment also factors into the determination of work priorities for the upcoming fiscal year. For example, in our most recent assessment, OIG identified the integrity of Medicare payments, quality of care in long-term services, and Medicare Part D as three areas that warrant scrutiny and monitoring. I will elaborate on these areas later in my testimony.

In addition to identifying and planning the priorities for the upcoming fiscal year, OIG must also remain flexible enough to accommodate issues that emerge throughout the year. There is no clearer example of the need for this flexibility than the devastating Gulf Coast hurricanes of 2005. Following the hurricanes, we promptly redirected resources to address critical needs arising in the aftermath of the storms. Unexpected events of the magnitude of the 2005 Gulf Coast hurricanes are fortunately rare. However, each year brings new and emerging issues and our priorities and work-planning efforts evolve to meet new challenges as they arise.

Moreover, along with our work-planning process, and consistent with the requirements of the IG Act, OIG reports to Congress semiannually on our activities. Unlike the work plan, which sets forth OIG's ongoing work and work to be undertaken in the upcoming fiscal year, the semiannual report provides a 6-month summary of OIG's completed body of work during the reporting period. The semiannual report covers the spectrum of OIG audit, evaluation, and enforcement accomplishments.

Each semiannual report identifies significant recommendations described in previous semiannual reports for which corrective action has not been completed. Thus, appendices to each semiannual report list significant unimplemented recommendations. Because of the abbreviated nature of that list in the semiannual reports, OIG has historically issued two complementary publications: (1) the "Red Book," to further highlight the potentially significant impact of cost-savings recommendations resulting from previous audits and evaluations, and (2) the "Orange Book," a compilation of nonmonetary recommendations to improve economy and efficiency in departmental programs and operations.

In an effort to present a comprehensive listing of all recommendations that have not been fully implemented by the operating divisions of the Department, OIG is presently in the process of combining the "Red Book" and "Orange Book" into one publication that will be a "Compendium of Unimplemented Office of Inspector General Recommendations." This document will serve as a useful tool for Congress, the Administration, and the Department in their respective efforts to identify ways to contain costs, maximize the effectiveness of programs and services, and improve the efficiency of departmental

programs. Full implementation of the recommendations in this document could achieve substantial savings and increased effectiveness in the operation of the Medicare program. OIG expects to release this compendium in May 2007. We look forward to providing the Department and Congress with this compendium, as they seek to achieve significant programmatic savings and enhanced program effectiveness.

Medicare Program Size and Complexity

The Medicare program has grown dramatically since its inception in 1965 and now provides comprehensive health care insurance for more than 43 million persons. More than 1 billion fee-for-service claims are processed annually, and Medicare is the largest purchaser of managed care services in the country. Total Medicare expenditures have grown from \$206 billion in FY 1996 to over \$382 billion in FY 2006.

With Medicare's expansive network of health care activities comes a tremendous responsibility to protect the program's integrity. In a program as complex as the Medicare program, incorrect payments to providers will occur. OIG has worked extensively with CMS to develop a process to estimate incorrect fee-for-service payments and institute corrective actions to reduce erroneous payments. In 1996, OIG estimated that over \$23 billion (about 14 percent of expenditures) in improper payments had been made by the Medicare fee-for-service program. CMS has reported that the estimate of incorrect Medicare fee-for-service payments was reduced to \$10.8 billion (4.4 percent of expenditures) in 2006.

Although the Medicare program relies on the provider community to submit accurate and appropriate claims for payment, and the vast majority of providers are honest and trustworthy, provider efforts alone are not sufficient to ensure the integrity of the program. OIG's oversight responsibility plays a key role in protecting scarce program resources and the health and welfare of beneficiaries.

Medicare Vulnerabilities and Related OIG Activities

We are committed to proactively identifying program weaknesses and vulnerabilities to help prevent fraud, waste, and abuse and to improve quality of care. We also bring our investigative tools and enforcement authorities to bear against those who seek to defraud the Medicare program and its beneficiaries.

As noted above, the overall Medicare fee-for-service payment error rate has decreased in recent years. However, the size and complexity of the Medicare program place it at high risk for payment errors. Improper payments and problems in specific parts of the program continue to be identified by OIG audits and evaluations and by CMS's assessment of the Medicare payment error rate. These reviews have revealed payments for unallowable services, improper coding, and other billing errors.

During the course of our most recent annual assessment of the Department's "Top Management Challenges," we highlighted three broad areas of vulnerabilities related to

the Medicare program. These areas are: (1) integrity of Medicare payments, (2) quality of care in nursing facilities, and (3) Medicare Part D. Within the broad category of Medicare payments, we have also identified more specific vulnerabilities within certain services and provider types, some of which are outlined below. The following sections highlight selected areas of vulnerability and OIG's work to identify and mitigate risks and to pursue cases of fraud or abuse.

Integrity of Medicare Payments

Medical Equipment and Supplies

OIG and others have found significant vulnerabilities in Medicare's oversight of suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) and in Medicare payments for certain types of DMEPOS. Over the past 10 years, OIG and GAO have reported on weaknesses in Medicare's enrollment standards for and oversight of DMEPOS suppliers, and we have made recommendations to improve oversight, such as increasing unannounced site visits to DMEPOS suppliers.

In previous work, OIG determined that in 2001, Medicare and its beneficiaries paid an estimated \$96 million for claims that did not meet Medicare's coverage criteria for any type of wheelchair or scooter and also spent an estimated \$82 million in excessive payments for claims that could have been billed using a code for a less expensive mobility device. In addition, OIG has found that over the 36-month rental period, Medicare's total allowed rental payments for oxygen concentrators are 12 times higher than the average price to purchase a new concentrator. If Medicare limited rental payments for concentrators to 13 months, like other capped rental items, we estimated that the program and its beneficiaries could save more than \$3 billion over 5 years. We recommended that CMS work with Congress to limit the rental period for concentrators.

We are continuing our examination of enrollment, compliance, and oversight of DMEPOS suppliers, including collaborations with CMS and the Department of Justice on specific efforts in high risk geographic areas. In addition, we also have ongoing work to determine the appropriateness of Medicare payments for certain medical equipment and supplies, such as wound care equipment.

A recent example of our collaborative enforcement efforts involved a DME company that was ordered to pay \$8.4 million pursuant to its guilty plea to false statements relating to health care matters. This company provided equipment almost exclusively to beneficiaries residing in assisted living facilities. Over a period of several years, the DME supplier billed Medicare and Medicaid for equipment provided to beneficiaries who did not meet coverage criteria, created false documents to support the false claims, and routinely misled assisted living facility personnel and physicians when marketing and servicing the equipment.

Home Health Agencies

Our office has had long-standing concerns with the accuracy of payments made to home health agencies (HHAs). For example, we found that in developing the prospective payment system rates for HHAs, CMS did not adjust for substantial unallowable costs claimed by HHAs, which were identified in our prior audits. As a result, we are concerned that the base rates are inflated and that improper payments may ensue.

We have several reviews planned or underway that examine Medicare payments made to HHAs. We plan to review the extent to which Medicare HHAs accurately coded information on the assessment form that is used to determine payment rates and to identify the extent of inappropriate payments made to HHAs. We will also determine whether rehabilitation services provided by HHAs were provided by appropriate staff and were medically necessary. In addition to addressing our concerns about payments to HHAs, we are assessing the quality of care provided by HHAs. For example, we are examining trends and patterns in HHA survey and certification deficiencies and determining whether CMS is taking appropriate action against noncompliant HHAs.

We have also pursued cases of alleged fraud by HHAs. One recent enforcement case involved a corporation that operated home health care and medical staffing businesses across the country. The agency agreed to pay \$8 million to resolve its liability for allegedly submitting false claims to Medicare, Medicaid, TRICARE, and CHAMPUS over a period of several years. The Government alleged that the company submitted claims for home health services that were not provided by a qualified person; lacked physician orders and plans of care; lacked sufficient documentation of the patient's homebound status; lacked an Outcome Assessment and Information Set evaluation; and/or were improperly coded.

Hospital Payments and Operations

OIG has also identified a number of vulnerabilities in hospital operations and has made recommendations to recover overpayments and improve payment accuracy and payment systems. For example, OIG audits identified more than \$72 million in improper payments to hospitals that incorrectly coded claims as discharges to home rather than transfers to postacute care facilities. We recommended recovery of these overpayments, and CMS implemented claims processing system edits to identify future miscoded claims.

OIG audits of specific hospitals have also found hundreds of millions of dollars in misreported wage data, which are used to calculate wage indices that affect Medicare payments. Hospitals that overstate their wage data will receive higher payments at the expense of hospitals that report accurate or understated wage data. Our reviews found that there were wide-spread inconsistencies among hospitals in reporting certain wage-related costs. As a direct result of our work, CMS clarified in regulation its requirements for reporting these types of costs.

Our review of hospital outlier payments showed that changes were needed in how outlier payments were calculated to eliminate hospitals' ability to construct and manipulate charges, allowing them to receive payments to which they were not entitled. CMS issued a regulation to correct these problems, resulting in an estimated savings to the Medicare trust fund of \$9 billion over 5 years.

To illustrate OIG's enforcement efforts involving hospitals, a hospital chain recently agreed to pay \$265 million and enter into a 6-year CIA to resolve its civil liability. The Government alleged that the chain artificially inflated its cost-to-charge ratio, triggering the outlier payments to which it was not entitled.

We will continue to focus attention on hospital payments and operations to ensure the integrity of Medicare payments and to protect the health and welfare of Medicare beneficiaries.

Part B Prescription Drugs

Over the past decade, OIG has produced a large body of work on payments for prescription drugs under Medicare Part B. OIG has consistently found that Medicare's drug reimbursement methodology led to overpayments and was vulnerable to abuse. For example, one OIG review found that Medicare and its beneficiaries would save \$761 million a year by paying for 24 drugs at the prices available to physicians and suppliers. For four of the drugs, the median catalog prices available to physicians and suppliers were less than half of the Medicare reimbursement amount. And for one drug, the Medicare reimbursement amount was more than 6 times higher than the median catalog price.

Consistent with the recommendations in our body of work, the MMA included provisions that instituted a new drug reimbursement methodology for Part B. Recognizing the critical role OIG played in reforming Part B drug reimbursement, Congress also included provisions in MMA mandating that OIG monitor Part B drug reimbursement and certain market prices for Part B-covered drugs on an ongoing basis. In addition to this required price monitoring, OIG has undertaken audits of the prices reported by pharmaceutical manufacturers to CMS for purposes of Part B reimbursement.

In addition to our substantial audit and evaluation work on Part B drug pricing issues, we have pursued a number of enforcement cases involving pharmaceutical manufacturers. For example, one drug manufacturer paid more than \$875 million to resolve criminal and civil liability resulting from the sales and marketing of a prostate cancer drug. The company pled guilty to conspiring to violate the Prescription Drug Marketing Act by causing the sale of free samples and entered into a civil settlement related to the company's pricing, sales and marketing practices for the drug.

Another drug manufacturer agreed to enter a global criminal, civil, and administrative settlement that included the payment of \$704 million plus interest and a 5-year CIA. The global settlement resolved allegations that included the illegal promotion of an

HIV/AIDS-related drug. The Government alleged that the company offered and paid illegal remuneration to Medicare participating physicians and pharmacies to induce them to prescribe and/or purchase the drug.

Quality of Care in Nursing Facilities

With the expected growth and vulnerability of the long-term care population, ensuring quality of care provided to beneficiaries in long-term care facilities warrants significant attention to ensure that Federal dollars are spent on appropriate care that meets Medicare's conditions of participation.

OIG's body of work over several years has led to a number of programmatic and legislative changes to improve quality of care in nursing facilities. For example, in response to several OIG reports, CMS promulgated regulations that established training requirements for nurse aides in nursing homes and required nursing homes to establish processes for handling abuse complaints. States, localities, and nursing homes also employed OIG recommendations to formulate plans and identify activities that will reduce the use of chemical and physical restraints used for nursing home residents. CMS issued a program memorandum to fiscal intermediaries designed to clarify 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.

Despite these improvements, we have some continuing concerns regarding oversight of nursing facilities. A recent OIG report found that for the majority of cases requiring mandatory termination of nursing facilities, CMS did not apply the remedy due to both late case referrals by States and CMS's staff reluctance to impose this severe remedy. In another recent review, OIG found that CMS did not investigate some of the most serious nursing home complaints within the required timeframe and that CMS's oversight of nursing home complaint investigations is limited.

OIG is currently conducting a series of reviews to further address payment and quality issues in nursing homes. Examples of topics include: use of psychotherapy services in nursing homes, impact of Medicare Part D on dual eligible residents in nursing homes, and appropriateness of payments and care for hospice beneficiaries residing in nursing homes.

Some nursing home care problems are so serious that they constitute "failure of care" and thereby implicate the civil False Claims Act. These cases often involve allegations of widespread or systemic problems such as excessive falls, medication errors, an undue number of residents with facility-acquired pressure ulcers, and chronic staff shortages. OIG continues to work with U.S. Attorneys and the Department of Justice on development and settlement of these egregious cases. OIG is also working on more cases jointly with the MFCUs to help protect the health and safety of this especially vulnerable population. OIG has developed exclusion actions against individuals and entities whose conduct causes the furnishing of poor care, with particular emphasis on higher-level

officials of nursing facilities and chains. Additionally, OIG continues to negotiate quality-of-care CIAs as part of the settlement of such False Claims Act cases.

In one example of such a case, a nursing home settled with the Government for \$750,000 based upon allegations that the facility provided 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 bed sores, 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 and also agreed to an indefinite suspension from the State Medicaid Program. Prior to the civil settlement, the facility pled no contest to one count of second-degree manslaughter involving the death of a beneficiary.

Medicare Part D

The MMA established the new Medicare prescription drug benefit, known as Medicare Part D, which took effect on January 1, 2006. This voluntary benefit is available to all 43 million Medicare beneficiaries. According to a recent Congressional Budget Office estimate, Medicare outlays for Part D in 2006 were \$28 billion. The magnitude of expenditures and impact of this benefit on beneficiaries, from both a health and financial perspective, make it critical that Medicare Part D operate efficiently and effectively and be protected from fraud and abuse.

The structure and operation of the Part D benefit contain features that present significant management challenges. Administration of the Medicare Part D benefit depends upon extensive coordination and information sharing among a number of diverse entities, including Federal and State Government agencies, private drug plan sponsors, contractors, and health care providers. Payments to drug plan sponsors based on bids, risk-adjustments, and reconciliations add to the complexities of the benefit. In addition, for standard plan designs, the relative financial responsibilities of Medicare, drug plan sponsors, and beneficiaries vary through three distinct phases (the initial coverage period, the coverage gap, and catastrophic coverage), depending on the beneficiary's total drug costs at a given time. Alternate plan designs include variations of these relative responsibilities. Finally, the complexities of this benefit also create challenges for educating beneficiaries in selecting a Part D plan, because beneficiaries face a wide variety of drug plans with varying costs, formularies, and pharmacy networks.

To address the challenges of this new and complex benefit, OIG has developed and is implementing a strategic plan to fight fraud, waste, and abuse in Part D and to protect the health and welfare of its beneficiaries. Our work covers five broad areas: (1) enforcement and compliance, (2) payment accuracy and controls, (3) beneficiary access and protections, (4) drug pricing and reimbursement, and (5) information technology and systems. We have ongoing investigations of Medicare Part D cases, along with audits and evaluations underway.

OIG Outreach and Guidance to Health Care Industry

One of the most significant ways in which OIG has effected change is by reaching out to the health care industry to promote a culture of compliance. Through outreach activities, OIG supports industry efforts to prevent fraud and abuse in the Federal health care programs. Over the past decade, OIG has implemented a comprehensive program to promote voluntary compliance by health care providers and suppliers. We have developed tools and incentives that encourage providers to prevent or reduce fraud and abuse.

OIG's approach to promoting industry compliance is twofold. First, OIG issues a variety of guidance, including advisory opinions, fraud alerts and special advisory bulletins, and compliance program guidance designed to assist health care providers and suppliers to develop systems and structures to guard against fraud and abuse, ensure appropriate billing, and be responsible corporate citizens. OIG has issued voluntary compliance program guidance for 11 major health care sectors. These guidances have received substantial support from the provider community. OIG has also issued 20 fraud alerts and special advisory bulletins, which identify practices in the health care industry that are particularly vulnerable to abuse and more than 150 advisory opinions to individuals and entities seeking advice on whether specific arrangements implicate the Federal anti-kickback statute or other fraud and abuse laws.

Second, our approach to compliance addresses health care providers that the Government alleges have defrauded Medicare, Medicaid, or other Federal health care programs. In such cases, the Department of Justice may seek money through the civil False Claims Act and OIG may seek to exclude the provider from future participation in Federal health care programs. In the context of a civil and administrative settlement of a health care fraud case, OIG often agrees not to pursue exclusion in exchange for the provider entering into an integrity agreement with OIG. Such integrity agreements require providers to establish or continue a compliance infrastructure, policies and procedures, training programs, internal controls and reporting mechanisms, review procedures, and reporting to OIG. OIG integrity agreements have been a catalyst for change in corporate culture and result in comprehensive internal control systems. Over the past decade, OIG has executed more than 1,100 integrity agreements.

Conclusion

Innovation continues to improve the efficiency of business, in turn, influencing the delivery of health care. However, as technological advances increase operational efficiency, they also create new vulnerabilities and opportunities for fraud. OIG has adapted, and will continue to adapt to, the ever-changing environment in which we operate. Additionally, we will continue to leverage our own resources and those of our law enforcement partners. We remain committed to staying at the forefront in our efforts to achieve effective oversight and enforcement in both our existing work and in meeting new challenges presented in the 21st century.

Thanks to the dedicated professionals of OIG and the additional funds recently appropriated by Congress, we will continue to carry out our mission to protect the integrity of HHS programs and their beneficiaries.

I thank you for the opportunity to be part of this important discussion today about the integrity of the Medicare program, as well as for the opportunity to highlight in detail the mandate, organization, and activities of the HHS Office of Inspector General.

I welcome your questions.