Department of Health & Human Services

Office of
Inspector
General

# Semiannual Report to Congress

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# Message From the Inspector General

This *Semiannual Report to Congress*, submitted pursuant to the Inspector General Act of 1978, as amended, summarizes the activities of the Office of Inspector General (OIG), Department of Health & Human Services (HHS), for the 6-month period ending March 31, 2011.

This past six months has been a period of intense activity for our office. We have continued to conduct a wide range of audits, evaluations, investigations, and enforcement and compliance activities to protect the integrity of the Medicare, Medicaid, public health, and human services programs. We have led large-scale health care fraud investigations in collaboration with our Federal, State, and local partners. Finally, our outreach to external stakeholders, including the Congress, has been substantial. This threefold approach to our diverse portfolio—making recommendations for improvement in departmental programs; leveraging critical enforcement resources by working closely with our government partners; and targeting outreach to external stakeholders—continues to be a successful strategy.

Our audit, evaluation, and investigative activity over the past six months addresses important program vulnerabilities such as questionable billing by skilled nursing facilities, improper payments for medical supplies, adverse events in hospitals, rebate concerns in the Medicare Part D program, institutional conflicts of interest by National Institutes of Health (NIH) grantees and alleged fraud by pharmaceutical manufacturers. We continue to diligently monitor the impact of our recommendations. Additionally, public dissemination of our work also heightens our ability to educate a broad range of stakeholders. For instance, our hospital adverse event report was downloaded more than 200,000 times from our Web site.

Our partnership with other law enforcement entities as part of the Health Care Fraud Prevention and Enforcement Action Team (HEAT) continues to produce significant results, particularly in its Strike Force actions. This past February, Strike Force teams engaged in an unprecedented health care fraud takedown. Teams across the country arrested more than 100 defendants in 9 cities for their alleged participation in Medicare fraud schemes involving more than $225 million in false billing. Notably, more than 300 OIG special agents participated in coordination with other Federal and State agencies, including other Offices of Inspector General. During this operation, OIG and the Centers for Medicare & Medicaid Services (CMS) worked to impose payment suspensions that immediately prevented a loss of more than a quarter-million dollars in claims submitted by Strike Force targets.

During this reporting period, OIG witnesses testified at five congressional hearings at which we had the opportunity to talk about our work fighting Medicare fraud, waste, and abuse and our recommendations to strengthen program integrity. We also highlighted our efforts to utilize technology, enhanced data, and other innovative tools to identify and prevent fraud schemes before they become pervasive.

Additionally, our outreach to external stakeholders broadens our mission to educate providers regarding the importance of instituting effective compliance measures within their organizations. We recently issued "A Roadmap for New Physicians: Avoiding Medicare and Medicaid Fraud and Abuse." This publication assists new physicians and existing health care providers by offering important information about how to avoid violating health care fraud and abuse laws. We are also currently leading a series of Provider Compliance Training sessions around the country. These sessions have been very successful in educating audiences of health care professionals, including small providers, interested in developing or strengthening their compliance programs.

As we tackle an expanding mission to protect HHS's vital health and human service programs, I would like to express my appreciation to Congress and to the Department for their sustained commitment to supporting the important work of our Office.

Daniel R. Levinson
Inspector General

# Highlights

This edition of the Department of Health & Human Services (HHS) Office of Inspector General (OIG) *Semiannual Report to Congress* addresses the first 6-month period of fiscal year (FY) 2011. It describes the results of our reviews and legal and investigative outcomes and presents recommendations that, when implemented, will save taxpayer dollars, put funds to better use, and/or improve HHS programs and operations and quality of care.

## Summary of OIG Accomplishments

For the first half of FY 2011, we reported expected recoveries of about $3.4 billion consisting of $222.4 million in audit receivables and $3.2 billion in investigative receivables (which includes $620 million in non-HHS investigative receivables resulting from our work in areas such as the States' share of Medicaid restitution).

We reported exclusions of 883 individuals and entities from participation in Federal health care programs; 349 criminal actions against individuals or entities that engaged in crimes against HHS programs; and 197 civil actions, which included false claims and unjust-enrichment lawsuits filed in Federal district court, civil monetary penalties (CMP) settlements, and administrative recoveries related to provider self-disclosure matters.

Here is an outline of activities and findings that are highlighted in this section of the Semiannual Report.

## HEAT: Health Care Fraud Prevention & Enforcement Action Team

The Health Care Fraud Prevention and Enforcement Action Team (HEAT) was started in 2009 by HHS and the Department of Justice (DOJ) to strengthen programs and invest in new resources and technologies to prevent and combat health care fraud, waste, and abuse. OIG's participation in Medicare Fraud Strike Force activities is a key component of HEAT.

### Medicare Fraud Strike Force

Medicare Fraud Strike Force teams coordinate law enforcement operations among Federal, State, and local law enforcement entities. These teams, now a key component of HEAT, have a record of successfully analyzing data to quickly identify and prosecute fraud almost as it occurs. The Strike Force began in March 2007 and is operating in nine major cities. Chicago, Illinois and Dallas, Texas were added during this reporting period. During this semiannual reporting period, Strike Force efforts

have resulted in the filing of charges against 213 individuals or entities, 107 convictions, and $63.9 million in investigative receivables.

In February 2011, Strike Force teams engaged in an unprecedented Federal health care fraud takedown. Teams across the country arrested more than 100 defendants in 9 cities, including doctors, nurses, health care company owners and executives, and others, for their alleged participation in Medicare fraud schemes involving more than $225 million in false billing. The defendants are accused of various health-care-related crimes ranging from violating the anti-kickback statute to money laundering to aggravated identity theft. More than 300 special agents from OIG participated in partnership with other Federal and State agencies, including fellow OIGs. The effectiveness of the Strike Force model is enhanced by interagency collaboration. For example, we refer credible allegations of fraud to the Centers for Medicare & Medicaid Services (CMS) so it can suspend payments to the perpetrators of these schemes. During the February Strike Force operations, OIG and CMS worked to impose payment suspensions that immediately prevented a loss of more than a quarter-million dollars in claims submitted by Strike Force targets.

## Medicare and Medicaid Prescription Drugs

### GlaxoSmithKline LLC Pays $750 Million To Resolve False Claims Violations

GlaxoSmithKline LLC (GSK) agreed to pay $750 million as part of a global resolution of allegations under the False Claims Act (FCA), including criminal fines for violations of the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA). The Government alleged that between January 1, 2001, and April 1, 2005, GSK, via its now closed subsidiary SB Pharmco, manufactured, distributed, and sold certain batches, lots, or portions of lots of drugs consisting of: Paxil CR that contained some split tablets causing consumers to receive either product with no active ingredient and/or with only the active ingredient layer and no controlled release mechanism; Avandamet that contained some tablets with higher or lower amounts of rosigitazone than specified; Kytril that was labeled as sterile but was, in some vials, nonsterile; and Bactroban ointments and creams that, in some packages, contained microorganisms.

### Allergan Pays $600 Million and Enters Global Settlements

Allergan, Inc., and Allergan USA, Inc. (collectively, Allergan), agreed to pay $600 million and enter a global criminal, civil, and administrative settlement in connection with improper marketing and promotion practices of Botox. Under the civil settlement agreement, Allergan agreed to pay the Federal Government $225 million to resolve its liability under the FCA. The settlement resolved allegations that Allergan promoted the sale and use of Botox for a variety of conditions that were not approved by the Food and Drug Administration (FDA),

such as headache, pain, spasticity, and overactive bladder, and that Allergan misled physicians about drug safety and efficacy, instructed health care professionals to miscode claims to Federal health care programs, and offered and paid illegal remuneration to health care professionals as inducements. As part of the settlement, Allergan entered into a comprehensive 5-year corporate integrity agreement (CIA) with OIG.

## Medicare Part A and Part B Highlights

### Patient Safety and Quality

Of the nearly one million Medicare beneficiaries discharged from hospitals in October 2008, an estimated one in seven (13.5 percent) experienced adverse events during their hospital stays.

To establish an estimated adverse incident rate, we included in our review: the National Quality Forum's list of Serious Reportable Events; Medicare hospital-acquired conditions (HAC); and events resulting in prolonged hospital stays, permanent harm, life-sustaining intervention, or death. The incidence rate projects to about 134,000 Medicare beneficiaries experiencing at least 1 adverse event in hospitals during a single month, with such events contributing to the deaths of a projected 15,000 beneficiaries. Physician reviewers determined that 44 percent of events were preventable, most commonly because of medical errors, substandard care, and inadequate patient monitoring and assessment. Our recommendations to CMS included providing incentives for hospitals to reduce the incidence of adverse events through the agency's payment and oversight functions. We also directed recommendations to the Agency for Healthcare Research and Quality (AHRQ). *Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries*. OEI-06-09-00090. Full Report

### Questionable Billing

From 2006 to 2008, skilled nursing facilities (SNF) increasingly billed for higher-paying resource utilization groups, even though beneficiary characteristics remained largely unchanged.

In that period, Medicare payments to SNFs for ultra-high therapy increased by nearly 90 percent, rising from $5.7 billion to $10.7 billion. For billing purposes, SNFs categorize Medicare beneficiaries into resource utilization groups based on their care and resource needs at various points during their stays. Payment rates are generally higher for beneficiaries who are in groups that require physical, speech, or occupational therapy. SNFs further categorize the level of therapy beneficiaries need primarily by the number of minutes that therapy is provided. The resource utilization groups for ultra-high therapy apply to those beneficiaries needing higher levels of therapy. Medicare generally pays the most for ultra-high-level therapy.

This review raised concerns about the potentially inappropriate use of higher-paying resource utilization groups, particularly those for ultra-high therapy. Our recommendations to CMS included strengthening its monitoring of SNFs that are billing for higher-paying resource utilization groups. *Questionable Billing by Skilled Nursing Facilities*. OEI-02-09-00202. Full Report

### Medicare Claims for Home Blood-Glucose Test Strips and Lancets

We estimated that about $169.7 million could have been saved in calendar year (CY) 2007 had controls been in place at three Medicare administrative contractors (MAC) to ensure that claims for blood-glucose test strips and/or lancets complied with certain Medicare documentation requirements.

Medicare Part B covers test strips and lancets that physicians prescribe for diabetics. Medicare utilization guidelines allow up to 100 test strips and 100 lancets every month for insulin-treated diabetics and every 3 months for non-insulin-treated diabetics. Additional requirements apply for reimbursements of claims for quantities of test strips and lancets that exceed the utilization guidelines (referred to high-utilization claims). Our recommendations to CMS's administrative contractors included developing cost-effective ways of determining which claims should be further reviewed for compliance.

Following are three reports completed in this semiannual period: (1) *Review of Medicare Claims for Home Blood-Glucose Test Strips and Lancets-Durable Medical Equipment Medicare Administrative Contractor for Jurisdiction B*, A-09-08-00044, Report; (2) *Review of Medicare Claims for Home Blood-Glucose Test Strips and Lancets—Durable Medical Equipment Medicare Administrative Contractor for Jurisdiction C*, A-09-08-00045, Report; and (3) *Review of Medicare Claims for Home Blood-Glucose Test Strips and Lancets—Durable Medical Equipment Medicare Administrative Contractor for Jurisdiction D*, A-09-08-00046, Report.

## Medicare Part C

### Impact on the Medicare Program of Investment Income That Medicare Advantage Organizations Earned and Retained From Medicare Funds

The Medicare program loses potential savings associated with the investment income that Medicare Advantage (MA) organizations earn between the time they receive Medicare prepayments and the time the MA organizations pay for medical services.

The Medicare Part A and Part B trust funds (which finance the MA program) could have earned approximately $450 million of interest income in CY 2007 had prepayments to MA organizations been delayed until after the beginning of the beneficiary's coverage period by the same number of days that we estimated MA organizations held Medicare the funds before using them to pay for services.

Alternatively, we estimated that Medicare could have saved about $376 million had MA organizations reduced the revenue requirements in bid proposals to account for anticipated investment income. Our recommendations to CMS included pursuing legislation to adjust the timing of Medicare's prepayments to MA organizations. *Rollup Review of Impact on Medicare Program for Investment Income That Medicare Advantage Organizations Earned and Retained From Medicare Funds in 2007*. A-07-10-01080. Full Report

## Medicare Part D

### Concerns With Rebates in the Medicare Part D Program

Part D sponsors underestimated rebates in 69 percent of their bids for plan year 2008, which led to higher beneficiary premiums and caused beneficiaries and the Government to overpay for the benefit.

Sponsors' bids to participate in Part D include estimates of the cost to provide benefits to beneficiaries. Sponsors also negotiate drug manufacturer rebates and other price concessions to reduce the cost of the program to beneficiaries and the Government and must include an estimate in their bids of the rebates they expect to receive for the plan year. CMS uses bids to calculate beneficiary premiums for each plan. Underestimating rebates increases beneficiary premiums. Recommendations to CMS included taking steps to ensure that sponsors more accurately include their expected rebates in their bids. *Concerns With Rebates in the Medicare Part D Program*. OEI-02-08-00050. Full Report

## Medicaid

### New York's Medicaid Rehabilitative Services Claims Submitted by Community Residence Providers

New York State improperly claimed an estimated $207.6 million in Federal Medicaid reimbursement for rehabilitation services submitted by community residence rehabilitation providers during CYs 2004 through 2007.

New York State elected to include coverage of rehabilitation services provided to recipients residing in community residences (group homes and apartments) in its Medicaid program. Of the 100 claims in our random sample, 31 complied with Federal and State requirements, but 69 did not. Our recommendations to the State Medicaid agency included working with the State's Office of Mental Health to implement guidance to physicians regarding State regulations on the authorization of community residence rehabilitation services. *Review of New York's Medicaid Rehabilitative Services Claims Submitted by Community Residence Providers*. A-02-08-01006. Full Report

### Inappropriate Claims for Medicaid Personal Care Services

Our 10-State review revealed that Medicaid paid about $724 million for the 18 percent of personal care services claims that we determined were inappropriate because personal care attendants' qualifications were undocumented.

The qualifications most often undocumented were background checks, age, and education. We estimated that Medicaid paid an additional 2 percent of claims inappropriately because the respondents had no record of providing services to the beneficiaries. Respondents were agencies or individuals that State Medicaid agency officials indicated we should contact to request documentation to support attendants' qualifications. We reviewed claims paid from September 1, 2006, through August 31, 2007. Our recommendations to CMS included working with States to ensure that Medicaid claims for personal care services provided by attendants with undocumented qualifications are not paid. *Inappropriate Claims for Medicaid Personal Care Services.* OEI-07-08-00430. Full Report

## Other Health Care Investigations

### Durable Medical Equipment Supplier Sentenced

Oliver Nkuku, a manager for K.O. Medical, Inc. (K.O.), and Callistus Edozie, a K.O. delivery employee, were sentenced to 120 months and 41 months of incarceration, respectively, and ordered to pay $453,112 and $80,000 in restitution, jointly and severally, for their roles in a durable medical equipment (DME) fraud scheme related to power wheelchairs and other DME that were medically unnecessary and improperly billed as catastrophe-related in connection with Gulf Coast hurricanes.

### Physical Therapy Clinic Submitted Multiple False Claims to Medicare

Bernice Brown, owner of Detroit-area physical therapy clinic Wayne County Therapeutic Inc. (WCT), and Daniel Smorynski, WCT vice president, were convicted on charges of health care fraud for their leading roles in a Medicare fraud scheme. Brown and Smorynski were sentenced to 12 years and 7 months and 9 years in prison, respectively, and were ordered to pay $6.7 million in restitution jointly and severally. From October 2002 to April 2007, WCT caused the submission of multiple claims to the Medicare program for physical therapy, occupational therapy, and psychotherapy services purportedly provided and supervised by WCT staff when, in fact, such services were not professionally provided or supervised.

## Public Health Reviews

### Centers for Disease Control and Prevention's Compliance With Appropriations Laws and Acquisition Regulations

Four research and development and information technology contracts with the Centers for Disease Control and Prevention (CDC) did not fully comply with one or more appropriations laws and acquisition regulations with respect to competition, funding, and pricing.

Pursuant to a congressional request, we are conducting a series of reviews of CDC's contracting practices. During this semiannual period, we are reporting the results of our reviews of four contractors. Our recommendations included adhering to established procedures and developing and implementing policies and procedures to address compliance with appropriations statutes and acquisition regulations.

Following are the reports that were completed in this semiannual period: *Review of the Centers for Disease Control and Prevention's Compliance With Appropriations Laws and Acquisition Regulations—Contractor B*, A-02-09-02005, Report; *Review of the Centers for Disease Control and Prevention's Compliance With Appropriations Laws and Acquisition Regulations—Contractor C*, A-02-09-02006, Report; *Review of the Centers for Disease Control and Prevention's Compliance With Appropriations Laws and Acquisition Regulations—Contractor D*, A-04-09-01066, Report; and *Review of the Centers for Disease Control and Prevention's Compliance With Appropriations Laws and Acquisition Regulations—Contractor E*, A-04-09-06108, Report.

### Institutional Conflicts of Interest at National Institutes of Health Grantees

The National Institutes of Health (NIH) lacks information on the number of institutional conflicts that exist among its grantee institutions and the impact these conflicts may have on NIH-sponsored research.

Institutional conflicts of interest may arise when institutions' financial interests (e.g., royalties, equity, stockholdings, and gifts) or those of senior officials pose risks of undue influence on decisions involving the institutions' research. No Federal regulations require NIH grantee institutions to identify and report institutional conflicts to NIH. We surveyed 250 grantee institutions and requested information on any institutional financial interests related to NIH grants awarded in FY 2008. Despite the lack of Federal requirements, 70 of 156 responding NIH grantee institutions had written policies and procedures addressing these interests. We also found that although not required for institutional conflicts, 69 of 156 responding NIH grantee institutions had written policies and procedures addressing such conflicts. Fifty-nine of the sixty-nine institutions defined, in writing, what constitutes an institutional conflict. We recommended that NIH promulgate regulations that address institutional financial conflicts of interest. *Institutional Conflicts of Interest at NIH Grantees*. OEI-03-09-00480. Full Report

# Education and Outreach Activities

## Roadmap for New Physicians

A recent OIG survey indicated that almost half of medical schools and more than two-thirds of institutions offering residency and fellowship programs reported instructing participants about compliance with Medicare and Medicaid fraud and abuse laws. We developed a guide called *A Roadmap for New Physicians: Avoiding Medicare and Medicaid Fraud and Abuse* (Roadmap). The package includes a slide presentation and speaker notes. You can view the survey and Roadmap on our Web site at http://www.oig.hhs.gov.

The Roadmap summarizes the five main Federal fraud and abuse laws and instructs physicians how to uphold these laws in their relationships with payers such as the Medicare and Medicaid programs, vendors such as drug, biologic, and medical device companies, and fellow providers such as hospitals, nursing homes, and physician colleagues.

## Provider Compliance Training Sessions

In 2011, OIG implemented a Provider Compliance Training initiative. The initiative provides free, high-quality compliance training sessions for medical providers and suppliers, compliance professionals, and attorneys at locations throughout the country. We held three training sessions in the past 6 months. Representatives from OIG, DOJ, CMS, and State Medicaid Fraud Control Units (MFCU) educate communities about fraud risks and share compliance best practices to assist providers in strengthening their compliance efforts.

## Most-Wanted Fugitives List

For the first time, we published a Most-Wanted Fugitives list on our Web site, and captures were soon reported. The 10 individuals on the original list allegedly defrauded taxpayers of more than $126.6 million. As of March 31, 2011, four fugitives from our list had been captured and more were added.

# Congressional Testimony

During this semiannual period, we testified at five hearings conducted by committees of Congress on aspects of waste, fraud, and abuse in Medicare and Medicaid. The full text of the testimony is available on our Web site at http://www.oig.hhs.gov/testimony.asp.

- **March 17, 2011—House of Representatives Committee on Appropriations, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies.**

  Daniel R. Levinson, Inspector General, testified about our efforts to monitor and make recommendations to reduce improper payments in Medicare and Medicaid, to oversee HHS's measurement of improper payments and to prevent, detect, and recoup wasteful payments. Testimony

- **March 9, 2011—United States Senate Committee on Homeland Security & Governmental Affairs, Subcommittee on Federal Financial Management, Government Information, Federal Services, and International Security**

  Daniel R. Levinson, Inspector General, testified about our efforts and those of our partners to combat waste, fraud, and abuse in Medicare and Medicaid. Testimony

- **March 2, 2011— United States Senate Committee on Finance**

  Daniel R. Levinson, Inspector General, testified about preventing health care fraud: new tools and approaches to combat old challenges. Testimony

- **March 2, 2011—House of Representatives Committee on Ways and Means, Subcommittee on Oversight**

  Lewis Morris, Chief Counsel to the Inspector General, testified about improving efforts to combat health care fraud. Testimony

- **March 2, 2011—House of Representatives Committee on Energy & Commerce, Subcommittee on Oversight and Investigations**

  - Gerald Roy, Deputy Inspector General for Investigations, testified about waste, fraud, and abuse: a continuing threat to Medicare and Medicaid. Testimony
  - Omar Perez, Assistant Special Agent in Charge, OIG Miami Regional Office, testified about waste, fraud, and abuse: a continuing threat to Medicare and Medicaid. Testimony