FY 2010 TOP MANAGEMENT AND PERFORMANCE CHALLENGES IDENTIFIED BY OFFICE OF INSPECTOR GENERAL

Pursuant to the Reports Consolidation Act of 2000 (P.L. No. 106-531), each year the Office of Inspector General (OIG) summarizes what OIG considers to be the most significant management and performance challenges facing the Department of Health & Human Services (the Department or HHS) and the Department's progress in addressing those challenges. In 2010, OIG identified the following top management challenges for fiscal year (FY) 2011. This document is divided into four parts: (1) health care reform; integrity of the Medicare, Medicaid and the Children's Health Insurance Program (CHIP); (3) integrity of the Department's public health and human services programs; and (4) cross-cutting issues that span the Department.

PART I: Health Care Reform

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the Affordable Care Act or the Act) sets forth the most comprehensive changes to Federal health care programs and the national health insurance system since the inception of the Medicare program in 1965.

Management Issue I: Incorporating Integrity into Health Care Reform Implementation

MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

The Act's 10 titles include private insurance market reforms, Medicare and Medicaid amendments, quality and efficiency of care, public health, the health care workforce, and Community Living Assistance Services and Support (CLASS). The Congressional Budget Office (CBO) has estimated the costs of the new programs to be $940 billion over the next 10 years. The magnitude of expenditures and impact on providers, insurers, employers, and beneficiaries from financial and health perspectives make it critical that Affordable Care Act programs operate efficiently and effectively and are protected from fraud and abuse.

Under the Affordable Care Act, the Department has broad new responsibilities. It will manage the significant modification and expansion of many existing programs; develop and implement new programs, promulgate regulations, issue and oversee billions of dollars in grants and loans, develop strategic plans; conduct a variety of studies, prepare reports for Congress, and enforce program rules. Much of this has occurred and will continue to occur with short implementation timelines.

Many components within the Department are responsible for implementing the Affordable Care Act, including the new Office of Consumer Information and Insurance Oversight (OCIIO), Centers for Medicare & Medicaid Services (CMS), Food and Drug Administration (FDA), National Institutes of Health (NIH), Indian Health Service (IHS), Centers for Disease Control and Prevention (CDC), Administration on Aging (AoA), Agency for Healthcare Research and Quality (AHRQ), and OIG. In addition, implementing the Act requires that the Department work closely with other Federal agencies, including the Department of Labor and the Department of the Treasury. Successful implementation depends on extensive intra-agency and inter-agency collaboration and coordination.

Successful implementation of the Affordable Care Act also requires clear and effective communication with program beneficiaries, private citizens, and health care industry stakeholders. For example, the Department has substantial new involvement with the private insurance markets, requiring subject-matter expertise, new oversight strategies, and new technologies and approaches in generating and disseminating consumer information.

Implementation of the law merits thoroughness, scrutiny, and oversight. A significant challenge for the Department will be identifying key vulnerabilities and prioritizing oversight resources. Based on OIG's experience in auditing, evaluating, and investigating fraud, waste, and abuse, areas that warrant vigilant HHS oversight include:

- Programs implemented under expedited timeframes. The Department can draw upon experience gained in two recent programs that were implemented with short timeframes – the Medicare Prescription Drug Benefit and the American Recovery and Reinvestment Act (Recovery Act) of 2009 (P.L. No. 111-5).
- Programs involving data collection to ensure accuracy and completeness of data.
- Grant programs.

- Ensuring accuracy of payments involving risk corridors, reconciliation payments, or similar payment structures.
- Changes to Part D and other Medicare and Medicaid payments.
- Activities, such as insurance scams, that may put beneficiaries at risk. Already, OIG has received reports that criminals, preying on the fears and confusion that surround the new program, are offering fake insurance policies.

The Department has taken many steps to address the challenges posed by implementation of the Act. For example, to address internal coordination challenges, the Department has established a structure of cross-component subject matter working groups to promote effective collaboration. To ensure timely and complete implementation, the Department has engaged dedicated staff to maintain a database with a dashboard feature to track implementation milestones and deliverables. Representatives from HHS components confer regularly to monitor progress in meeting the implementation goals. In addition, the management of individual components meets regularly to discuss and track policy development and implementation of the Act as it pertains to their components.

The Department is also building infrastructure to support implementation of the Act. For example, the Department created and is staffing up OCIIO to focus on private insurance issues (including enforcement), CMS created the new Center for Medicare and Medicaid Innovation to focus on innovative delivery models and established the Center for Program Integrity to strengthen its oversight of the Medicare and Medicaid programs. The Department is also devoting additional resources and effort to enhance the use of information technology to foster effective implementation of the Act, including the use of sophisticated performance tracking tools.

Finally, the Department has provided guidance about new requirements to affected stakeholders by issuing many proposed and final regulations implementing Affordable Care Act provisions and a variety of subregulatory guidance documents. More remains to be done as implementation proceeds.

The Department, including OIG, must work with its partners to respond to vulnerabilities in current Federal health care programs and in the expanded and new programs established through the Affordable Care Act. The Department, including OIG, must identify new risks posed by the changing dynamics of Federal health care programs and the evolving nature of fraud and abuse schemes and respond effectively to those risks.

PART II: INTEGRITY OF MEDICARE, MEDICAID, AND THE CHILDREN'S HEALTH INSURANCE PROGRAM

For Federal health care programs to best serve beneficiaries and remain solvent for future generations, the Government must pursue a comprehensive strategy to prevent, detect, and correct fraud, waste, and abuse. Based on its experience in combating health care fraud, waste, and abuse, OIG has identified five principles that it believes should guide the Department's integrity strategy for Medicare, Medicaid, and CHIP. These principles offer a framework for implementing programs, as well as designing integrity safeguards and putting them into practice.

- **Enrollment** – Scrutinize individuals and entities that seek to participate as providers and suppliers before they enroll in health care programs.
- **Payment** – Establish payment methodologies that are reasonable and responsive to changes in the marketplace.
- **Compliance** – Assist health care providers and suppliers in adopting practices that promote compliance with program requirements, including quality and safety standards.
- **Oversight** – Vigilantly monitor programs for evidence of fraud, waste, and abuse.
- **Response** – Respond swiftly to fraud, impose appropriate punishment to deter others, and promptly eliminate program vulnerabilities.

Consistent with these principles, OIG has applied this framework to identify the top management challenges that the Department faces in protecting the integrity of its health care programs, meeting the needs of beneficiaries, and keeping Federal health care programs solvent.

Ensuring that the beneficiaries receive quality health care has many dimensions, including overseeing providers' compliance with quality-of-care standards, ensuring patient safety, and identifying opportunities for improvements in quality of care.

Management Challenge and Assessment of Progress in Addressing the Challenge:

Large Federal Government expenditures on the Medicare and Medicaid programs attract certain individuals and entities that may seek to exploit the health care system for financial gain. Although the vast majority of health care providers and suppliers are honest and well intentioned, the Department faces challenges in ensuring the integrity of the programs' provider and supplier enrollment processes. A small percentage of providers and suppliers intent on defrauding these programs has exploited weaknesses in the enrollment process, causing significant harm. These providers and suppliers drain resources that should be spent on providing care to beneficiaries. OIG's oversight and enforcement work identified weaknesses in provider and supplier enrollment that enable unqualified, dishonest, and unethical individuals and entities to access a system they can easily exploit. OIG also identified weaknesses in the oversight of provider and supplier eligibility to receive payments under Medicare and Medicaid.

A number of OIG's concerns have been addressed in the Affordable Care Act. Provisions of the Act require the Secretary, in consultation with OIG, to establish more rigorous enrollment and screening processes and to provide for enhanced oversight measures, disclosure requirements, enrollment moratoriums, and requirements for developing compliance programs. The Act also requires that any home health or durable medical equipment (DME) prescription or referral covered by Medicare Parts A or B be written by a Medicare-enrolled physician or nonphysician practitioner and authorizes the Secretary to extend this requirement to other Medicare-covered items and services. The Act also requires any agents, clearinghouses, or other alternate payees that submit claims on behalf of Medicaid health care providers to register with the State and the Secretary in a form and manner specified by the Secretary.

In the area of enforcement, the Affordable Care Act introduces new civil monetary penalties (CMP) for certain types of infractions, including falsifying information on provider enrollment applications. The Act also expands the Inspector General's discretionary authority to exclude individuals and entities from participation in Medicare, Medicaid, and all other Federal health care programs to include situations in which an individual or entity makes a false statement or misrepresentation on an enrollment application.

All these provisions, when implemented, will help the Government to better know and control with whom it is doing business. Protecting programs and beneficiaries from unqualified, fraudulent, or abusive providers and suppliers upfront is more effective than trying to recover payments or redress fraud or abuse after it occurs.

Enrollment Process and Oversight Activities

Ensuring adequate and appropriate provider and supplier enrollment standards and screening is an essential first step to strengthening the integrity of the Medicare and Medicaid programs. OIG identified certain characteristics that may indicate a provider's increased potential for fraud, including interest in or ownership of other health services providers and related businesses with Medicare or Medicaid debt; other evidence of financial instability; no evidence of a physical business facility; previous criminal history, suspension, or exclusion from participation in Federal health care programs; or sanctions by State Medicaid agencies or other health care organizations. The Affordable Care Act requires the Secretary to implement screening procedures for different categories of providers and suppliers based on the risk of fraud, waste, and abuse. The screening must be applied to all new enrollments starting March 23, 2011, and all providers and suppliers must be subject to the same process by March 23, 2013.

The Affordable Care Act has several additional provisions aimed at reducing vulnerabilities in provider and supplier enrollment, including subjecting new providers and suppliers to enhanced oversight, such as prepayment review for 30 days to 1 year after enrollment. Providers or suppliers applying for enrollment on or after March 23, 2011, must disclose any direct or indirect, current, or previous affiliation with a provider or supplier that has uncollected debt or that has been subject to a payment suspension, program exclusion, or revocation or denial of its billing privileges under a Federal health care program. The Secretary may also impose a temporary moratorium on enrollment of providers and suppliers or on enrollment of certain categories of providers and suppliers, if necessary, to prevent or combat fraud, waste, and abuse. The Secretary's authority was expanded to impose surety bond requirements on DME and home health providers by allowing the imposition of a larger requirement based on the suppliers' or providers' volume of billing, as well as by allowing the extension of the surety bond requirements to other types of providers. Finally, the Secretary has the authority to require that providers and suppliers maintain compliance programs as a condition of enrollment. Effective use of these new tools and authorities will be critical to addressing fraud, waste, and abuse in the future.

The Department has responded to vulnerabilities in provider and supplier enrollment with measures to enhance enrollment standards for DME suppliers. The response includes a final rule published August 2010 (CMS-6036-F), which clarifies and expands the existing enrollment requirements for DME suppliers. The Department also initiated a demonstration project requiring reenrollment of DME suppliers in south Florida and southern California as a condition for remaining enrolled in the Medicare program. OIG recognizes the Department's progress and continues to recommend further improvements to oversight and enforcement of provider enrollment standards. OIG will also monitor progress under the competitive bidding program for DME suppliers once it is fully implemented in 2011 to determine whether the application and enrollment process is sufficiently rigorous to prevent suppliers prone to fraud, waste, and abuse from receiving contracts.

In other work, OIG investigations identified a fraud scheme involving foreign nationals who obtained Medicare provider numbers that they used to submit fraudulent claims. Unknown individuals recruit foreign nationals who are in the United States on student visas to obtain Medicare provider numbers. These provider numbers are used to fraudulently bill Medicare while the foreign nationals return to their home countries. OIG alerted CMS to this fraud scheme and recommended that CMS adopt guidelines with regard to foreign nationals' obtaining Medicare provider numbers. CMS responded that it was unclear whether it had the authority to implement the recommended actions and noted that when conducting reviews, surveyors examine the Employment Eligibility Verification document (Form I-9) for facility owners and key employees as part of the accreditation process. While surveyor reviews may identify some schemes, until the vulnerabilities brought to light by this fraud scheme are addressed, Medicare continues to risk exposure to fraudulent claims by ineligible providers.

The Department also faced challenges stemming from the variation in Medicaid provider and supplier enrollment standards, which can differ across States and for providers within a State. For example, an OIG evaluation of State Medicaid enrollment requirements for personal care attendants found that State Medicaid programs established multiple sets of provider requirements that often vary among programs and by delivery models within programs, resulting in 300 sets of provider requirements nationwide for personal care attendants. OIG is examining whether States enforce their requirements for personal care attendants. The Affordable Care Act requirements, when implemented, should create a more consistent approach to the enrollment and screening process.

OIG has identified challenges related to nursing home ownership transparency. (See Management Issue 7 for more information on this topic.) Greater transparency in the enrollment process for nursing homes would help the Government know with whom it is doing business and whom to hold accountable in cases of noncompliance, fraud, or abuse. Congress recognized this in enacting the Affordable Care Act, which requires nursing homes to disclose information about the identity of parties with an ownership or management interest. This information will be made public. OIG will monitor implementation of this provision to ensure that it addresses vulnerabilities in nursing home enrollment.

Provider and Supplier Eligibility for Certain Payments

The Affordable Care Act includes provisions that address program vulnerabilities to prevent ineligible providers from enrolling in the Medicare and Medicaid programs. The Act also includes provisions to enhance OIG's authority to obtain any information necessary from any individual or entity to validate claims for payment under Titles XVIII or XIX for evaluation of the economy, efficiency, or effectiveness of these programs. Together, these provisions should help the Department oversee the programs and prevent providers that are improperly enrolled from participating in the programs or receiving payments for which they are not eligible.

OIG identified instances in which Medicare and Medicaid made payments to providers that were improperly enrolled or were not eligible to receive payments. For example, OIG found that between FYs 2000 and 2006, 397 hospitals received $21.9 million in capital disproportionate share hospital (DSH) payments for which they were not eligible. Further, OIG reviewed States' compliance with Medicaid DSH payment requirements and found that from July 2000 through June 2003, one State paid $142.3 million ($88.2 million Federal share) to three State-owned psychiatric hospitals that were not eligible for such payments.

OIG also determined that from July 1, 1996, through June 30, 2007, one State paid $26.2 million ($16.3 million Federal share) to a hospital that was not eligible to receive Medicaid payments for inpatient psychiatric services because it did not show compliance with certain Medicare Conditions of Participation requirements. OIG audits at numerous Medicare fiscal intermediaries (FI) found that unallowable payments of about $4.9 million were made to providers that were not eligible for payment because the services were provided on or after the dates that the providers were terminated from the Medicare program.

The Department responded to these vulnerabilities by directing the Medicare administrative contractors (MAC) and FIs to assess capital DSH eligibility as part of their review processes. CMS will also include an edit to the hospital cost report software to prevent ineligible hospitals from claiming capital DSH payments on their cost reports.

OIG continues to encourage the Department to implement payment safeguards to ensure that payments are made only to eligible providers and suppliers. As described above, the Affordable Care Act authorizes the Department to establish procedures to strengthen provider and supplier enrollment standards. Fully implementing the new procedures should lessen the risk of improper enrollments or payments for which providers are not eligible.

Management Issue 3: Integrity of Federal Health Care Program Payment Methodologies

Management Challenge and Assessment of Progress in Addressing the Challenge:

The Federal Government must act as a prudent purchaser of health care. Medicare and Medicaid payment methodologies must ensure access to quality care without wasteful spending. Achieving this objective is critical to maintaining an effective and efficient health care delivery system. The challenges associated with meeting this objective are complex and are evolving, especially in the context of implementing health care reform. Initial payment methodologies must be set to reimburse providers and suppliers fairly for appropriate care. Payment methodologies must also be responsive to ensure that they remain reasonable and appropriate as the health care marketplace and medical practice evolve. Finally, CMS must be nimble enough to safeguard against the financial incentives and fraud and abuse risks associated with each payment methodology that is established.

Setting Initial Payment Methodologies

As Federal health care programs are created, expanded, or revised under the Affordable Care Act, which creates new payment methods and updates existing payment methods, it is critical to establish initial payment rates based on the most accurate data available and on reasonable assumptions and projections. OIG has identified instances in which issues with the data used in the development of initial payment methodologies have resulted in increased expenditures by Medicare and its beneficiaries. For example, because of earlier work, OIG is concerned that the Part A prospective payment systems (PPS) for home health services, Skilled Nursing Facility (SNF) services, and Part B PPS for hospital outpatient department services, were based on data known to be problematic, which may have resulted in inaccurate payment rates. CMS will need to address this challenge when it rebases the home health PPS, as required by the Affordable Care Act. With the new and expanded programs enacted under health care reform, it is important to strengthen oversight of these programs.

Setting proper payment rates for Medicare Part B services has also proved challenging. OIG reviews have determined that Medicare payments for certain categories of DME do not accurately reflect the costs of these products because the payment rates are based on historical average prices and do not reflect current market prices. For example, in 2006, OIG found that Medicare allowed more than $7,000 for 36 months of rental payments for oxygen concentrators that cost $587, on average, to purchase. OIG also found that Medicare allowed an average of $4,018 to purchase standard power wheelchairs and $11,507 for complex rehabilitation power wheelchair packages, compared with supplier acquisition costs of $1,048 and $5,880, respectively. OIG has recommended that CMS determine whether these amounts should be adjusted using its inherent reasonableness authority, using information from the Competitive Bidding Acquisition Program, or seeking legislation to ensure that fee schedule amounts are reasonable and responsive to market changes. OIG's 2009 findings that more than half of power wheelchair claims submitted by suppliers do not meet the requirements for payments underscores the need to closely align the amount Medicare pays for power wheelchairs with the costs to suppliers.

The Competitive Bidding Acquisition Program is CMS's main initiative to reduce beneficiary costs and improve the accuracy of Medicare payments for certain categories of DME. Legislation delayed its implementation, and contracts under the program's first round of bidding are to become effective on January 1, 2011, and CMS plans to expand the program.

Payments to Medicare Advantage (MA) organizations under Part C may also be higher than necessary. Based on numerous reviews of the Medicare + Choice program (MA's predecessor), OIG concluded that the data and estimates used to calculate monthly capitation payments were flawed, resulting in higher payments. The inflated base-year data continue to affect MA payments, which have not been adjusted to take into account problems with Medicare + Choice data that OIG had identified. OIG plans to further examine the accuracy of the data used to adjust capitation payments to MA organizations. In addition, the Affordable Care Act will reduce payments to MA organizations in 2012.

Appropriate payment rates for Medicare Part D continue to be a challenge. OIG is examining the extent to which Part D Plans report all rebates and direct and indirect remuneration they receive. In earlier work, OIG found that estimated costs in sponsors'

bids were higher than their actual costs, which resulted in higher Medicare payments and premiums. In response, CMS agreed to ensure that sponsors' bids accurately reflect the cost of providing benefits and noted that it incorporates data submitted to CMS for reconciliation of prior years into its bid review process.

Responding to Changes in the Marketplace and Health Care Practices

The Department faces a substantial challenge in reacting swiftly and appropriately to changes in health care delivery systems and standards of care so that the programs continue to effectively reimburse for quality care. OIG has conducted reviews of Medicare and Medicaid payment methodologies and found that when reimbursement methodologies do not respond to such changes, the programs and their beneficiaries bear the cost.

Medicare Part B payments for new wound therapy pumps provide one example of the costs of failing to update payments in response to market changes. When Medicare first covered wound pumps, it covered only one model and Medicare based the payment on that model's purchase price. As new models became eligible for coverage, Medicare continued to reimburse suppliers based on the original model's purchase price, which OIG found is more than four times the average price currently paid by suppliers for new pumps.

Another example is demonstrated in OIG work, which found that Medicare has paid physicians for evaluation and management (E&M) services that were included in global fees for eye surgery but were not provided during the global surgery periods. The misalignments in global eye surgery payments are attributable, in part, to CMS's not updating payments to reflect changes in medical practice. Over time, the average number of E&M services provided during the global period has decreased, but payments continue to be based on estimates that a higher number of E&M services are provided.

Other examples include Medicare Part B payments for laboratory tests and for certain drugs. OIG found that Medicare Part B payments for laboratory tests, which were established over 20 years ago, vary within and between Medicare contractors. The variances did not appear to reflect geographic differences in costs. OIG recommended that CMS seek legislation to establish a new process for setting accurate and reasonable payment rates. CMS stated that it would consider OIG's recommendation as the agency continues to monitor the effects of its current payment policies. OIG work has also shown that Medicare payments for certain Part B drugs are higher than actual costs in the marketplace when newly available generic versions first enter the market.

Payment methodologies for other benefits also present challenges in responding to marketplace changes. The average manufacturer price (AMP), which is used in calculations of both Medicaid drug rebates and the Federal Upper Limit (FUL), has been redefined in the Affordable Care Act. This change may resolve the disparity between what Medicaid pays for drugs and the prices available in the marketplace.

Payment Incentives and Risks of Fraud and Abuse

Payment methodologies inherently create incentives and risks for fraud. Fee-for-service (FFS) payments create financial incentives to provide excessive, complex, or unnecessary services. Conversely, under capitated or bundled payment systems, financial incentives may encourage providers to stint on needed care. The Affordable Care Act introduces several new payment models, such as accountable care organizations, medical homes, and shared savings programs. A key challenge for the Department will be ensuring that it strikes the right balance between protecting the integrity of the health care programs and fostering innovation that increases quality, efficiency, and cost effectiveness. Because fraud schemes develop and multiply quickly, it is crucial that the Department rapidly identify and address the risks inherent in new payment models.

OIG's work on Medicare and Medicaid outlier payments highlights the importance of addressing the integrity of payment methodologies. Recent investigations have identified abuses of CMS's home health outlier payment methodology, which has resulted in providers' receiving significant outlier payments to which they were not entitled. In response to evidence of abuse in this area, CMS caps outlier payments to individual home health agencies. Continuing OIG work is examining vulnerabilities linked to this payment methodology.

Similarly, OIG found in previous work that Medicare payment methodologies for inpatient outlier payments had loopholes whereby inflated charges submitted by hospitals and delays in FI financial analysis of hospital data resulted in hundreds of millions of dollars of wasteful spending. Policy changes were made, and financial settlements with several hospital groups were

reached. OIG work in several States has shown that if the State Medicaid programs modified their outlier payment policies to mirror changes made in the Medicare program, they could save tens of millions of dollars.

OIG has also found other instances in which payment methodologies have created incentives for providers to alter their practices to maximize reimbursement. For example, ongoing OIG work has found that the current SNF payment methodology gives SNFs an incentive to fraudulently increase the level of services and therapy needed by each beneficiary to qualify for higher per diem rates. This has resulted in severe overutilization of SNF therapy services, including therapy for patients for whom any therapy is inappropriate.

Certain types of services may be vulnerable to abuses such as upcoding, or billing a higher complexity code than the one appropriate for the service performed. OIG has observed that Medicare payments for E&M services increased by over $9 billion between 2000 and 2009, in part because of a trend of increased billing for high-complexity E&M codes. E&M services may be particularly vulnerable to abuse because the differences among complexity levels are less distinct than the differences in other services and because monitoring by CMS and contractors is lacking.

Medicaid's reliance on published prices as the basis for drug reimbursement also creates fraud vulnerabilities. OIG investigations of allegations that pharmaceutical manufacturers have manipulated prices to decrease Medicaid rebate payments and increase Medicaid drug reimbursement have resulted in significant False Claims Act (FCA) settlements. In late 2009, Mylan Pharmaceuticals, Inc., paid $118 million to resolve allegations that it misclassified drugs in informational filings to the Government to reduce the amounts it paid under the Medicaid Rebate Program. AstraZeneca Pharmaceuticals LP and Ortho MacNeil Pharmaceuticals, Inc., each settled similar allegations in 2007. In 2007, Aventis Pharmaceuticals, Inc., paid $182.8 million to resolve allegations that it inflated its prices for products paid for by Federal health care programs. Because of the alleged illegal pricing, programs, including Medicaid, overpaid for Aventis's drug, Anzemet.

The Department's challenge to react to payment methodology vulnerabilities is not limited to abuses by providers and suppliers. OIG has found problems with States' implementation of financing mechanisms involving certain intergovernmental transfer of funds, which resulted in an inappropriate inflation of the Federal share of Medicaid payments. Through these arrangements, States often retained funds that were intended to reimburse Medicaid providers. Another way in which States have inappropriately increased the Federal share of Medicaid payments is requiring hospitals to return larger portions of their disproportionate share payments to the States. This practice is contrary to the program's purpose, which is to compensate hospitals that care for large percentages of Medicaid beneficiaries and uninsured patients.

As the Medicare and Medicaid populations grow, the importance of establishing and maintaining the integrity of payment methodologies becomes more critical so that scarce resources are not lost to fraud, waste, and abuse, and beneficiary care is not diminished.

Management Issue 4: Promoting Compliance With Federal Health Care Program Requirements

MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

Provider compliance with Federal health care program requirements is essential to the integrity of the Medicare and Medicaid programs. Compliance prevents fraud, waste, and abuse and promotes efficiency and economy. To ensure compliance, the Department must partner with health care providers. The Medicare program pays for health care services for about 47 million beneficiaries rendered by 1.2 million participating providers and suppliers, including hospitals, nursing homes, physicians and other practitioners, DME companies, and others. An estimated 1.2 billion Medicare FFS claims are processed by CMS annually, amounting to an average 4.6 million claims processed each working day. In FY 2009, Medicare FFS payments totaled $327.8 billion. Medicare is required to process and pay electronically submitted claims within 30 days of receipt. The Medicaid Federal Medical Assistance Percentage (FMAP) payment totaled $252.9 billion in FY 2009, helping to address the care needs for about 51 million Medicaid recipients.

The Medicare and Medicaid programs rely on the premise that providers and suppliers submit legitimate and accurate claims by providers and suppliers. Although most providers and suppliers are honest and well intentioned, even honest providers and suppliers can make mistakes or fail to comply with the rules. Though small in number, dishonest providers and suppliers attempt to game the system by exploiting or circumventing payment and coverage rules. The challenge facing the programs is illustrated by a December 2009 OIG study, which found that 60 percent of claims for standard and complex rehabilitation power wheelchairs did not meet Medicare documentation requirements and that error rates varied by power wheelchair type and supplier volume during the first half of 2007, with greater documentation error rates accompanying claims for complex

rehabilitation wheelchairs than for standard models. CMS concurred with all of OIG's recommendations for improving documentation processes to reduce improper payments in this area and noted multiple efforts underway to improve compliance. For example, a contract was recently awarded to a Program Safeguard Contractor (PSC) to conduct medical review on power mobility claims submitted by certain providers. In addition, CMS will instruct MACs to examine whether beneficiaries were receiving the correct wheelchairs for their conditions and whether correct documentation was present.

A June 2010 OIG report reveals how noncompliance with even the most basic documentation safeguards challenges Federal health care programs. Medicare Part D sponsors and beneficiaries paid pharmacies $1.2 billion in 2007 for claims in which the listed prescriber identifiers did not correspond to practicing physicians. Without a valid prescriber identifier, CMS and its contractors cannot determine whether a physician actually prescribed the drug or whether the physician was validly licensed and had not been excluded from the Medicare program. Furthermore, invalid prescriber identifiers inhibit OIG investigations by making it more difficult to identify questionable prescribing patterns and the parties responsible for potential fraud.

Effectively combating fraud, waste, and abuse includes ensuring that a provider and supplier community is well informed about program rules and is actively engaged in compliance efforts.

The Costs of Noncompliance

Assisting health care providers and suppliers in adopting practices that promote compliance with program coverage, payment, and quality requirements must be an integral part of the Department's program integrity strategy. The benefits of industry compliance include reduced risk of fraud and abuse, as well as fewer billing and payment errors; better quality of care; and the fostering of an ethical culture that enhances public confidence in the system.

The risks associated with failing to create a culture of compliance and the costs of noncompliance are significant. CMS estimated that in FY 2009, improper FFS payments cost Medicare $24.1 billion (7.8-percent error rate). Changes were implemented during FY 2009 review year, and as a result, the 7.8 percent was a combined error rate using two different methodologies. The revised methodology is more stringent. The national paid claims error rate for those claims reviewed under the strictest criteria, when applied to the entire year, is 12.4% or $35.4 billion. CMS estimated that in FY 2008, improper Medicaid State and Federal payments cost $28.7 billion (8.71-percent error rate). OIG has identified inappropriate Medicare payments for specific services and products. (See also management issues 2, 3, 5, and 6.) OIG recently found that certain DME claims did not meet Medicare program requirements, resulting in potentially more than $200 million in improper payments. OIG found that New York's Medicaid program paid more than $414.5 million ($207.6 million Federal share) to providers in New York City for rehabilitation services claims that did not meet program requirements. Error rates and improper payment estimates include paid claims that do not meet program rules, whether because of error, fraud, or other factors.

OIG has also identified fraud and abuse that have resulted in substantial costs to Federal health care programs: expected OIG recoveries for the 6 months that ended March 2010 include about $667 million in audit receivables and $2.5 billion in investigative receivables. In addition, noncompliance with standards of care can be so egregious as to constitute a failure of care and jeopardize patient health and safety. (See Management Issue 7.) When settling allegations of fraud and abuse, OIG often requires health care providers to enter into Corporate Integrity Agreements (CIA) in exchange for OIG's agreement not to exclude the provider from participation in Federal health programs. OIG tailors CIAs according to the conduct and circumstances of each case. However, CIAs generally require providers to implement compliance programs that include a compliance officer or committee, written standards and policies, employee training programs, confidential disclosure mechanisms, reviews by an independent reviewer, and various reporting requirements.

Education and Guidance Efforts

Provider education and guidance are important tools for fostering compliance. However, several factors create challenges in promoting industry compliance with program rules through education. Federal health care programs are governed by complex statutes, regulations, and subregulatory guidance. There are national rules, such as statutes, regulations, and national coverage determinations, and local rules, including local medical review policies. These rules and regulations are frequently updated or changed by law or by administrative action. In a complex programmatic environment, it is a challenge to ensure that guidance is clear, informed, complete, and audience appropriate.

The audience for compliance education is diverse in terms of sophistication, size, and resources. Medicare providers range from health care corporations that hire top legal and management advisors to small operations with minimal legal or regulatory expertise. Some are integrated delivery systems that need to master the rules and regulations for multiple benefit categories,

while others are purveyors of only one item or a few items and services. Some providers may have limited resources to devote to compliance, which competes with other priorities, such as providing care, managing business operations, and earning a profit. Others are affiliated with well-established, large, multi-facility organizations with a widely dispersed workforce and significant resources to devote to compliance.

To address these challenges, the Department must work to ensure that it is providing guidance that assists providers and suppliers in understanding and complying with program requirements, educating providers and suppliers effectively about program requirements, and promoting industry adoption of effective internal controls and other compliance measures. The Department must also ensure that its claims-processing contractors are knowledgeable about program requirements, that the contractors provide useful guidance on their policies, and that they offer adequate education for the providers and suppliers whose claims they process.

The Department has a variety of tools and approaches available for this effort. These include regulatory and subregulatory issuances (including manuals, frequently asked questions, advisory opinions, and other materials), provider listservs, Web sites (such as the Medicare Learning Network), and live educational opportunities (such as open-door forums and sponsored education programs on requirements of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 (P.L. No. 108-173). CMS is also exploring the use of new media, such as podcasts and RSS feeds, to reach provider and supplier audiences. It recently launched a series of national listening sessions related to OIG reports in an effort to educate provider and suppliers on specific vulnerabilities that exist in DME, Part A, Part B, and home health and hospice settings.

A National Health Care Fraud Summit was held in Washington, DC, in January 2010. The Department is working with the Department of Justice (DOJ) on additional live educational opportunities, such as Regional Fraud Prevention Summits; summits have been held in Miami and Los Angeles. At this point, additional summits have been planned for New York, Detroit, Boston, and Philadelphia. The summits bring together representatives from Federal, State, and local law enforcement agencies and representatives from the private sector, including health care providers, hospitals, and doctors for a day of panels and training sessions that facilitate the sharing of information about trends in health care fraud that will ensure effective referral mechanisms and procedures. The Department also works with the private sector to promote compliance. For example, CMS has a Provider Partnership Program through which it shares Medicare FFS information with national organizations that are Medicare billers or serve as intermediaries for Medicare billers. Through the Medicaid Integrity Program, CMS funds contracts for educating health care providers and suppliers, managed care entities, and beneficiaries to promote payment integrity and quality of care.

OIG also collaborates with health care providers to promote compliance. As discussed more fully in Management Issue 7, OIG has worked with nursing home providers through roundtables that focus on how boards of directors can better monitor and ensure quality of care. OIG will Another collaborative live educational opportunity will be represented by the OIG's Provider Compliance Training initiative, to begin in 2011. The Provider Compliance Training Initiative will bring together representatives from a variety of government agencies to provide compliance training at no cost to local provider, legal, and compliance communities in Medicare Strike Force cities and other locations across the country. Strike Forces are multiagency teams of prosecutors and investigators that use real-time analysis of Medicare billing data to assist in the identification, investigation, and prosecution of individuals and entities that have committed fraud.

The continuing challenge is determining which tools and approaches are most cost effective, which are best suited to a diverse and rapidly evolving health care industry, and which produce the greatest benefit for increasing compliance.

Provider and Supplier Adoption of Compliance Programs

Implementation of effective compliance programs is another method of fostering an industry culture of compliance and a continuing commitment to delivering quality health care. Successful compliance programs should establish internal controls to decrease providers' and suppliers' risk of practices that result in billing errors, fraud, and abuse. Quality assurance and improvement programs should ensure compliance with Federal health care program requirements and result in tangible benefits to the organization and the beneficiaries it serves.

One challenge, historically, is that the implementation of compliance programs has been largely voluntary. Before enactment of the Affordable Care Act, most Medicare and Medicaid providers were not required to adopt compliance programs. Compliance programs have been required only among certain categories of providers and suppliers, including Medicare Part D drug plan sponsors and MA organizations, which are required by statute to implement compliance plans and individuals and entities that have entered into CIAs with OIG. In addition, Medicaid providers in New York have been required by the State to implement effective compliance plans as a condition of Medicaid participation. Several other States besides New York have imposed

compliance plan requirements on certain types of health care providers or entities. In some sectors of the health care industry, such as hospitals, voluntary compliance programs have been widespread and sophisticated; other sectors were slower to adopt internal compliance practices and may have had fewer resources to devote to compliance. As discussed below, the Affordable Care Act promises improvements because it contains provisions that effectively mandate compliance programs across provider categories.

Voluntary compliance program efforts are supported through OIG's compliance program guidance (CPG). CPGs give health care providers, suppliers, and organizations comprehensive frameworks, standards, and principles by which to establish and maintain effective internal compliance programs. CPGs also strongly encourage providers to identify and focus compliance efforts on those areas of potential concern or risk that are most relevant to their organizations.

OIG has recommended that all Medicare and Medicaid providers and suppliers be required to adopt compliance programs as a condition of participating in the Medicare and Medicaid programs. Passage of the Affordable Care Act entails major changes in the role of provider and supplier compliance plans in Federal health care programs. Section 6102 of the Act requires, among other things, that nursing homes develop effective compliance and ethics programs to be in place by March 2013. More broadly, section 6401 of the Act sets out provider screening and enrollment requirements for Medicare, Medicaid, and CHIP, which include compliance program mandates for providers and suppliers. The compliance programs for providers and suppliers within a "particular industry or category" will need to meet certain core elements to be developed by the Department in consultation with OIG. Implementation timelines for the compliance program requirements are to be determined by the Secretary.

Even where compliance programs have been required, however, the Department has faced challenges in implementing a comprehensive safeguard strategy. OIG's reviews of the Part D program indicate that CMS's program integrity efforts have been limited in scope and may not sufficiently protect the program. While some of CMS's safeguards are functional, other critical safeguards have been implemented to a limited extent or have not been put in place. OIG found, for example, that CMS relied largely on complaints to identify potential fraud in Part D and that not all complaints were investigated in a timely manner.

OIG recently completed an indepth audit of one plan sponsor's internal controls for the Part D program during 2007 and 2008 and found that although most of the sponsor's internal controls were adequate, they had several weaknesses that compromised the sponsor's ability to detect, correct, and prevent fraud, waste, and abuse. In another report, issued in 2008, OIG found that plan sponsors vary widely in the identification of potential fraud. Although sponsors are the initial gatekeepers for protecting the Part D program, OIG found that not all of them identified potential fraud and abuse, conducted inquiries, initiated corrective actions, or made referrals for further investigation.

Failure to implement effective compliance programs can be a contributing factor that enables fraud and abuse to go unaddressed. CMS's task is to determine what Part D sponsors can do to improve program safeguards based on the information collected in audits of individual sponsors. After Medicare Drug Integrity Contractors (MEDIC) conducted 16 desk-review compliance plan audits, however, CMS found that these audits were of only limited value in monitoring and oversight efforts. As a result, in 2009, CMS revised its approach to compliance audits, changing from reliance on desk review, to on-site review.

CMS also found that it needed to develop more comprehensive, meaningful, and robust compliance plan audit protocols focused on evaluating and validating the effectiveness of compliance programs, including measures to prevent, detect, and correct fraud, waste, and abuse. The new audit protocols were piloted in 2009 and early 2010, and changes were made based on lessons learned.

The benefits of promoting compliance, and highlighting the costs of noncompliance, will grow as beneficiary populations and health care costs increase. The Department must assist an ever larger and more diverse population of Medicare and Medicaid providers and suppliers in complying with program requirements.

The new mandates in the Affordable Care Act should ensure an expanded and redefined role for compliance programs. The Department is implementing several provider compliance education efforts and exploring many others. OIG will continue to provide compliance tools and resources to the provider and supplier community and work closely with the Department to meet this essential but difficult challenge**.**

MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

The Department's health care programs have been founded largely on a system of trust. Although most providers are honest and well intentioned, a system based on trust is vulnerable to exploitation by a minority of providers intent on gaming or defrauding the system. Thus, oversight and monitoring to detect potential fraud, waste, and abuse are critical. However, tension exists between the dual goals of implementing measures preventing and detecting fraud, waste, and abuse, and making timely payments to legitimate providers.

The Department is further challenged to provide effective oversight and monitoring of Federal health care programs because the programs are large and complex, with increasing expenditures and growing numbers of beneficiaries. The size of the programs means that fraud, waste, and abuse in claim submission and payments can result in substantial financial losses. Schemes have become increasingly sophisticated, and criminals adapt to oversight efforts.

Analysis of claims data is a key method of identifying fraud, waste, and abuse. Each program compiles an enormous amount of data on beneficiaries, providers, and the delivery of services. Processing, managing, and analyzing these vast and varied types of data is challenging. These challenges will grow with the additional data collection and reporting required under the Affordable Care Act. The Department often fails to use these data effectively for oversight and monitoring, resulting in the loss of Federal health care dollars. Claims-processing and payment systems have traditionally relied on claim-by-claim review. However, in many cases, fraud or abuse can be detected only by reviewing aggregated claims and billing patterns because each claim may appear on its face to be legitimate. OIG has identified opportunities for the Department to improve its collection, analysis, and monitoring of data to better fight fraud, waste, and abuse. As will be discussed in more detail later, CMS plans to enhance the data available to monitor payment accuracy and integrity across the Medicare and Medicaid programs.

Measuring Error Rates

Measuring error rates is key to monitoring program integrity and the scope of inappropriate payments. In its reviews of CMS's annual Comprehensive Error Rate Testing (CERT) program, OIG has raised concerns that the Medicare error rates for certain provider types may be understated. To address these problems, CMS in 2009 made substantial changes in the CERT medical record review process, including revising the *Program Integrity Manual* to clarify requirements and promote uniform interpretation of its policies. As a result of the changes and a more complete accounting of improper payments, the FY 2009 national paid claim error rate was 7.8 percent, compared with the FY 2008 error rate of 3.6 percent. The changes were implemented during the FY 2009 review year, and as a result, the 7.8 percent was a combined error rate using two different methodologies. The revised methodology is more stringent. If the results from the revised methodology were annualized, the error rate would have been 12.4 percent. The Department has reported the 12.4 percent error rate and has set out-year targets based on that rate.

Measuring payment errors and their causes in the Medicaid and CHIP programs is particularly challenging because of the diversity of State programs and the variation in their administrative and control systems. CMS's Payment Error Rate Measurement (PERM) program was designed to measure error rates for three components of Medicaid and CHIP: FFS, managed care, and eligibility. OIG is performing audit work to determine whether problems similar to those discovered in the CERT program exist in the PERM program.

Improper payments are also a significant problem across Federal programs. In November 2009, the President signed Executive Order 13520, Reducing Improper Payments, and in July 2010, the Improper Payments Elimination and Recovery Act (IPERA) was enacted. The purpose of the Executive Order and IPERA is to reduce improper payments by intensifying efforts to eliminate payment error, waste, fraud, and abuse in the major programs administered by the Federal Government, including the Department's health care programs, while continuing to ensure that Federal programs serve and provide access to their intended beneficiaries. The requirements of the Executive Order and IPERA will further help to reduce improper payments by boosting transparency, holding agencies accountable for reducing improper payments, and creating incentives for States and other entities to reduce improper payments and increasing penalties for contractors who fail to disclose improper payments in a timely manner. The Department and OIG are working together to implement requirements of both the Executive Order and IPERA.

Oversight through Effective Analysis of Data

The health care system compiles an enormous amount of data on patients, providers, and the delivery of health care items and services. However, OIG has found numerous examples in which Federal health care programs have failed to use claims-

processing edits and other information technology effectively to prevent improper claims. The following are examples of how vigilant claims analysis could assist the Department in monitoring programs for fraud, waste, and abuse.

Claims analysis can reveal instances in which providers bill for medically unnecessary services to defraud programs. In December 2008, a Miami physician was sentenced to 30 years in prison and ordered to pay more than $8.2 million in joint and several restitution in connection with her role in an HIV infusion fraud scheme. In another example, at the Saint Jude Rehabilitation Center, Inc., HIV-positive Medicare patients were paid cash kickbacks in exchange for allowing the physician and her co-conspirators to prescribe medically unnecessary infusion treatments; the case was brought by the Medicare Strike Force (see Management Issue 6).

Claims analysis can also reveal instances in which providers bill for more services than are physically possible. In one of the largest civil fraud recoveries ever against a single U.S. hospital, Staten Island University Hospital agreed to pay $88.9 million in a global settlement resolving allegations that it defrauded Medicare and Medicaid. OIG identified potentially fraudulent billing, among other allegations, for inpatient alcohol and substance abuse detoxification treatment for more beds than the facility was authorized by the State of New York.

Claims analysis can also identify service areas in which providers submit questionable claims. OIG found that providers in a south Florida county accounted for more home health outlier payments in 2008 than the rest of the counties in the Nation combined. Twenty-three more counties nationwide also exhibited aberrant home health payment patterns similar to that of the Florida county but to a lesser extent. CMS has taken steps to address widespread abuse of Medicare outlier payments to home health providers.

Challenges in Using Data Effectively

In some cases, program data are insufficient to support effective oversight and monitoring. OIG found that Medicare data are insufficient to determine consistently whether Medicare Part B chemotherapy administration payments are appropriate. Part B data do not identify drugs that are not billed to the program even when their administration is billed to Part B. In these cases, when there is no matching drug claim, the data alone cannot be used to determine whether the administration fee has been appropriately billed for administering a qualifying drug.

In other cases, CMS does not effectively use the safeguards available to monitor claims. Unique provider identifiers are a primary tool for ensuring that Medicare services and products are ordered by qualified, legitimate providers. However, OIG work has uncovered vulnerabilities related to the misuse of physician identifiers. OIG found that more than 18 million Medicare Part D prescription drug claims accounting for $1.2 billion contained invalid prescriber identifiers in 2007. These identifiers either were not listed as valid identifiers in the National Provider Identification (NPI), Drug Enforcement Administration (DEA) number, or Unique Physician Identification Number (UPIN) registry databases or had been deactivated or retired before January 1, 2006. In another review, OIG found that Medicare Part B allowed almost $28 million for claims with inactive referring physician UPINs, including $5 million for claims with dates of services after the dates of death of the referring physicians. In 2008, CMS completed its transition from UPINs to a new NPI system for Medicare claims processing. However, OIG has concerns that the vulnerabilities associated with the UPIN system may also affect the integrity of the NPI system.

The Medicaid program has unique data challenges because key program operations occur in States, rather than on a national level. The Medicaid Statistical Information System (MSIS) is the only source of nationwide Medicaid claims information, and weaknesses in MSIS data limit its usefulness for oversight and monitoring of the program. OIG determined that during FYs 2004 through 2006, MSIS data were an average of 1.5 years old when CMS released the data to users for data analysis purposes. And MSIS did not capture many of the data elements that can assist in fraud, waste, and abuse detection. CMS did not fully disclose or document information about the accuracy of MSIS data; however, CMS maintains a Data Anomalies/State Issues document, which identifies State-specific data issues by file type and year.

The effective use of data is critical to the Department's oversight and monitoring activities and in turn will support the overall success of the Department's anti-fraud efforts.

Recent and Planned Oversight Enhancements

The Department is making progress in improving the oversight and monitoring of Federal health care programs. CMS is augmenting its oversight capabilities by contracting with outside entities to perform many oversight and monitoring functions

for Medicare and Medicaid. CMS is also acting to enhance data systems available for use by these contractors. The Affordable Care Act creates new implementation challenges in directives requiring the Department to collect, use, and share data. The Act requires the Department to expand CMS's Integrated Data Repository to include claims and payment data from Medicaid, the Department of Veterans Affairs (VA), the Department of Defense (DOD), the Social Security Administration (SSA), and IHS. The Act also contemplates real-time access by law enforcement to Medicare claims data. To facilitate oversight, the Act exempts OIG from prohibitions against matching data across programs. The Act also provides OIG with more streamlined access to data and will improve its ability to oversee the integrity of Federal health care programs.

For Medicare, CMS is transitioning program safeguard functions from PSCs and MEDICs to Zone Program Integrity Contractors (ZPIC). These new contractors will be responsible for ensuring the integrity of all Medicare-related claims under Parts A and B (e.g., hospital, skilled nursing, home health, physician, and DME claims); Part C (MA health plans); and Part D (prescription drug data) and for coordinating Medicare-Medicaid data matches (Medi-Medi). As of November 2010, CMS had awarded four ZPIC contracts, with three more contracts planned. With the transition to ZPICs, determining whether the change in contractors has brought about improvement in the use of proactive methods in analyzing claims data will be important. OIG is examining ZPICs' efforts to identify program vulnerabilities and detect and investigate fraud and abuse.

In 2003, Congress authorized the Department to establish a demonstration program for Recovery Audit Contractors (RAC) to identify underpayments and overpayments and to recoup overpayments under Part A or B of the Medicare program. Under this authority, Congress provided for payments to RACs on a contingent basis for detecting and correcting overpayments and underpayments. In 2006, Congress mandated that the Department implement RACs on a nationwide and permanent basis. As of October 2009, CMS completed implementation of the national RAC program in all 50 States. CMS reported that the RAC demonstration project successfully returned almost a billion dollars to Medicare, which represented a new mechanism for detecting improper payments, and provided CMS with a tool for preventing and reducing future improper payments. CMS will require RACs to help develop plans designed to address vulnerabilities found during their reviews. RACs are also responsible for referring to CMS any cases of potential fraud that are found during their reviews. However, OIG noted that over the 3-year demonstration period, RACs referred only two cases of potential fraud to CMS. OIG and CMS are working together to ensure appropriate referrals of suspected fraud under the national RAC program. CMS has agreed to implement a system to track fraud referrals and to require RACs to receive mandatory training on the identification and referral of fraud. Section 6411 of the Affordable Care Act expands the RAC program, giving it additional responsibilities to address improper payments in Medicaid and Medicare Parts D and C.

As part of the Medicaid Integrity Program, CMS has hired contractors to perform data analysis to detect aberrant billing patterns and to audit claims to identify improper payments. OIG is examining the contractors' work. The Medicaid Integrity Group developed a data engine, a central component of its data strategy and information technology infrastructure. The data engine combines State Medicaid claims data to facilitate detection of fraud, waste, and abuse. The need for an accurate and comprehensive Medicaid claims database that can be used at the national level for data mining and fraud detection is important.

In 2009, OIG formed a cross-disciplinary, interdepartmental Advanced Data Intelligence and Analytics Team (Data Team) to support the work of the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative and the Medicare Fraud Strike Forces. (See Management Issue 6 for further discussion of this issue.) The Data Team consists of investigators, auditors, and evaluators from OIG as well as DOJ personnel; the team combines sophisticated data analysis with criminal intelligence gathered through traditional law enforcement techniques to identify fraud trends. Using Data Team analysis, in December 2009 the HEAT Operations Committee announced several metropolitan "hot spots" for new Strike Force operations. In April 2010, the Data Team provided additional national-level analysis in support of the planned expansion of HEAT operations.

Despite the progress described and plans for enhancements, the Department needs to make continued improvements in oversight and monitoring to meet the challenges that have been outlined. As fraud schemes become more sophisticated and migratory, the use of advanced data analysis to monitor claims and provider characteristics becomes even more important. (See Management Issue 6 for further discussion of this issue.) Needed improvements in using data analysis to support program oversight include sufficient access to data for investigations and analysis; uniform, comprehensive data elements; more timely collection and validation of data; robust reporting of program data by States and others; interoperability of systems; consistent data extraction methods; and the ability to select and analyze claims and provider data across Medicare Parts A, B, C, and D and Medicaid.

Management Issue 6: Response to Fraud and Vulnerabilities in Federal Health Care Programs

MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

Responding to fraud and program vulnerabilities requires a high degree of coordination and collaboration between multiple Federal and State agencies and contractors. Federal health care programs are built on a range of regulations, program requirements, and payment methodologies that are often the result of detailed rulemaking and programmatic balancing of competing stakeholder interests. The size and complexity of Federal health care programs also make implementing a comprehensive and swift response to fraud and vulnerabilities difficult. Adding to this complexity, the Medicare administration and program integrity responsibilities are divided among a variety of contractors, and Medicaid and CHIP have their own systems and contractors. The programs compile an enormous amount of data on patients, providers, and the delivery of health care items and services, which are often housed in many locations with different data infrastructures. Operating within this complex framework, it is often difficult for the programs to respond nimbly in the face of a vulnerability, which can result in a significant monetary loss before a remedy or sanction is applied.

OIG work has identified fraud and vulnerabilities across the Department's health care programs. (See also Management Issues 2-5 and 7.) It is a challenge for the Department to prioritize and respond to the most serious vulnerabilities in the face of limited resources to implement the response. Further, once perfected, many fraudulent schemes are easily replicated and move quickly through communities and across the country. Law enforcement may respond with criminal prosecutions in one jurisdiction only to see the scheme replicated in another part of the country. Fraud schemes are also becoming increasingly sophisticated and often evolve in response to Government's detection and enforcement efforts. An effective response must be swift; too often, program funds are lost and unrecoverable by the time data are analyzed and the fraud scheme is detected.

These and other factors create conditions that are ripe for those who would take advantage of Federal health care programs. In the face of this significant challenge, the Department brings to bear a law enforcement response through OIG and a programmatic response through CMS.

Law Enforcement Response

The law enforcement response to fraud and program vulnerabilities falls into three categories: criminal prosecution, civil litigation, and administrative remedies. Challenges in these three areas are described below.

While most health care providers submit legitimate claims, a minority abuse the system. Adding to this are an increasing number of criminals whose sole purpose is to defraud the program. These are often career criminals running sophisticated and organized criminal enterprises, and the most appropriate response is criminal prosecution. Of particular concern has been the increase in medical identity theft in a broad range of cases. Medical identity thieves often sell and resell beneficiary information. It is not unusual for physicians or beneficiaries to have their identities compromised multiple times.

In response, HHS and DOJ took strong and decisive enforcement action through the creation of Medicare Fraud Strike Forces as part of the HEAT initiative to combat health care waste, fraud, and abuse. HEAT built on the successful Medicare Fraud Strike Force (Strike Force) initiated in south Florida by expanding Strike Forces to other metropolitan areas across the country. These Strike Forces use advanced data analysis techniques (see Management Issue 5) to identify criminals operating as health care providers and detect emerging or migrating fraud schemes. Strike Force teams operate in Miami, Los Angeles, Detroit, Houston, Brooklyn, Baton Rouge, and Tampa, and 13 more teams are to be established in other cities as resources permit. As of September 30, 2010, Strike Force efforts have resulted in charges against approximately 625 individuals or entities, more than 300 convictions, and approximately $315 million in investigative receivables. Strike Forces have been successful, but the teams require sufficient staffing and resources to respond effectively to health care fraud schemes.

The Affordable Care Act increases criminal penalties for health care offenses under the Federal Sentencing Guidelines, and it expands the types of conduct that constitute Federal health care fraud offenses under Title 18 of the United States Code. As a result, those who commit health care fraud will serve longer prison terms and face larger criminal fines, and the Government will have a broader range of tools to address criminal health care fraud schemes.

In addition to criminal prosecution, civil litigation continues to be an important response to fraud and program vulnerabilities. Complex corporate fraud and other matters can be resolved through civil litigation in addition to or as an alternative to criminal enforcement. Despite multimillion-dollar, and even billion-dollar civil settlements, corporations often write checks and continue their abuse of the system. Large corporations that engage in health care fraud often resolve a criminal case through a guilty plea of a nonoperating subsidiary. In those cases, which involve admitted criminal conduct, OIG may have no basis to exclude the parent-company defendant or any other operating company from future participation in the Federal health care

programs based on the criminal conviction. Even when there may be a basis for a permissive exclusion of the parent company or when a company has engaged in multiple schemes and its subsidiary has been convicted in more than one criminal case, OIG must carefully consider how beneficiary access to vital medical products and services could be affected by any such exclusion of the parent company.

A comprehensive law enforcement response to fraud must use all tools available to the Government. In addition to criminal and civil actions, the appropriate response in a particular case may include alternate remedies, such as OIG's use of targeted CMPs and program exclusions. For example, where DOJ might pursue civil litigation against a large corporate defendant that paid health care kickbacks, OIG might bring a parallel case under the CMP Law against the individual recipients of the kickbacks. Where a health care fraud case involves potential harm to program beneficiaries, the most appropriate response will often include OIG's exclusion of the defendant from future participation in the programs. Wherever possible, OIG works with its law enforcement partners to tailor the response to a given scheme in a way that maximizes the use of resources and effectively utilizes administrative tools, in addition to criminal and civil remedies.

Federal Health Care Program Responses

Law enforcement actions alone will not eliminate fraud and abuse; and yet where vulnerabilities are accurately identified, it can be a significant challenge for the Department to respond effectively and ensure that the problems are corrected. During a series of unannounced site visits to DME suppliers in south Florida in 2007, OIG found that 491 of 1,581 suppliers failed to meet Medicare standards; CMS revoked their billing privileges. Nearly half of these suppliers appealed the revocations and received hearings, and 91 percent had their billing privileges reinstated. Two-thirds of those suppliers who were reinstated have since had their privileges revoked again, and some individuals connected with reinstated suppliers have been indicted. In a report on DME supplier appeals, OIG found that because there are no criteria for the types of evidence necessary to reinstate providers' billing privileges, hearing officers made decisions based on a variety of evidence, which resulted in inconsistencies. CMS agreed that it should consider establishing consistent guidelines on the evaluation of evidence that a hearing officer will review during the appeal process. Establishing consistent guidelines will continue to be a challenge for the Department.

OIG is assessing other Medicare contractors' use of enrollment-screening mechanisms and post-enrollment monitoring to identify DME and home health agency applicants that pose a risk of fraud to Medicare and will determine the extent to which applicants omitted ownership information on enrollment applications, potentially circumventing the program's safeguards. (See Management Issue 2.)

Despite CMS's and its contractors attempts to address billing problems in high-risk areas, aberrant billing problems persist. In a 2009 review, OIG's analysis of Medicare billing patterns in south Florida for inhalation drugs used with DME uncovered evidence of abusive billing. Medicare paid almost $143 million for inhalation drugs in Miami-Dade County alone, an amount 20 times greater than was paid in Cook County, Illinois, the jurisdiction (outside south Florida) with the next-highest total payments. However, according to Medicare enrollment data, Cook County is home to almost twice as many Medicare beneficiaries as Miami-Dade County.

In response to this scheme, CMS reported that its contractor had implemented a "medically unlikely" edit for the inhalation drug, budesonide, and after the edit there was an immediate 50-percent decrease in allowed and billed amounts for budesonide in Miami-Dade and Broward Counties in October 2008. Although CMS response was an important first step, experience tells us that this alone will not solve the problem. The same criminals who were exploiting the system with respect to budesonide will attempt to circumvent this response by billing for other items or services.

Therefore, it is important to use analytic tools such as data mining to monitor whether and how criminals are adapting their fraud schemes in response to the Government's program integrity efforts. CMS is developing such tools through its Integrated Data Repository (see also Management Issue 5). OIG's experience tells us that such approaches can be effective in identifying and responding to fraud. For example, in the coming months, OIG will issue a report analyzing how use of certain inhalation drugs may have changed in the wake of Medicare program integrity efforts relating to budesonide. OIG is also using a combination of claims and sales data to determine whether the amount of a different inhalation drug billed by south Florida suppliers and paid for by Medicare exceeded the total amount of the drug distributed for sale in the area. By using innovative data analysis to detect unusual patterns, OIG is able to target high-risk services and geographic regions and make recommendations for a more comprehensive approach to address systemic vulnerabilities.

As described above, the programs rely on contractors to pay claims and to administer the response to fraud and vulnerabilities. This dual reliance on contractors presents a unique challenge for CMS. In February 2010, OIG evaluated the results of CMS's

3-year RAC demonstration project. Three RACs participated in the project. Although they were not responsible for reviewing claims for fraudulent activity, they were responsible for referring to CMS any instances of suspected fraud found during their reviews. However, the RACs have a disincentive for referring instances of suspected fraud because they are paid through contingency fees based on overpayments collected. In case of suspected fraud, overpayments are generally not collected while the fraud is being investigated. Despite their identification of more than $1.03 billion in Medicare improper payments, between 2005 and 2008, the RACs referred only two cases of potential fraud to CMS. As the RAC demonstration shows, it will continue to be a challenge for the Department to ensure that its response to program vulnerabilities captures not only improper payments but also fraud and that the contractors on which it relies have the tools, training, resources, and incentive to appropriately address improper payments and make appropriate fraud referrals.

In addition, CMS contracts with MEDICs to perform integrity functions, such as identifying and investigating potential fraud, waste, and abuse in the Part D program. OIG found that CMS's program integrity efforts have been limited in scope and that major challenges remain to sufficiently protect the Part D program. One of the key aspects of CMS's strategy to combat fraud in Part D was the MEDICs' use of innovative techniques for proactive data analysis. While proactive data analysis is a key element of MEDICs' responsibility, OIG found in a 2009 review that MEDICs identified most incidents of potential fraud through external sources, such as beneficiary complaints, rather than proactive data analysis. MEDICs may not have been aware of some potential fraud and abuse incidents because Part D plan sponsors are not required to refer them. Finally, CMS did not give MEDICs approval to conduct audits of sponsors' compliance plans in FY 2008. In November, 2009, after the issuance of this report, CMS restructured the MEDIC program. However, CMS indicated that it does not have the regulatory authority to require sponsors to report these incidents.

Given the significant expenditures at issue, responding quickly and comprehensively to identified weaknesses in the Part D program is imperative. Ensuring that Part D and its beneficiaries are paying appropriately for the benefit will remain a significant challenge for the Department. OIG is performing reviews on questionable billing patterns, sponsors' anti-fraud training, the status and results of all audits of sponsors, Part D electronic-prescribing initiatives, invalid prescriber identifiers on prescription drug data, payments made to excluded providers, reconciliation calculations, and Part D rebates and pharmacy discounts.

OIG has also found that challenges remain in the programs' efforts to respond to fraud, waste, and abuse vulnerabilities in home health and personal care services similar to those described above for DME. OIG analyzed all Medicare home health claims that were submitted and fully paid in 2008 to identify geographic areas that exhibited aberrant Medicare home health outlier payment patterns. OIG's review found that Miami-Dade County, Florida, accounted for more home health outlier payments in 2008 than the rest of the Nation combined. OIG also found that 23 other counties nationwide exhibited aberrant home health outlier payment patterns similar to that of Miami-Dade County. Despite the programs' focus in this area, these findings demonstrate that home health services in Miami-Dade County, as well as in other counties nationwide, warrant additional attention as part of continuing anti-fraud activities, such as HEAT.

Another challenge for the Department is to respond to detected vulnerabilities by suspending payments to providers upon credible evidence of fraud. This is critical in an environment in which claims are submitted and paid electronically, with potentially large sums of money being paid by the Government in a very short period if the payment suspension is not implemented in a timely manner. The Affordable Care Act expressly authorizes the Secretary to suspend payments to providers if the Secretary determines, in consultation with OIG, that there is a credible allegation of fraud. To mount a comprehensive response to fraud and program vulnerabilities, the Department must use the payment-suspension authority wherever it is warranted to protect the programs while also protecting the rights of providers.

As discussed in other sections, the Affordable Care Act strengthens the Government's ability to detect fraud and abuse and to respond rapidly to health care fraud. The law also requires the Department to expand CMS's integrated data repository to include claims and payment data from Medicaid, VA, DOD, SSA and IHS and fosters data-matching agreements among Federal agencies. These agreements will make it easier for the Federal Government to identify fraud, waste, and abuse. It will then be a challenge for the Department to integrate all of this data into its systems for analysis and response. The challenge remains to obtain real-time information across all areas of the programs, which will enable the Government to respond to fraud more quickly, bring criminals to justice, and recoup stolen funds. Timely data are also essential to responding with agility as criminals shift their schemes and locations to avoid detection.

By using the new tools described above to meet these challenges, the Department, including OIG, must continue to work with its many partners to respond to vulnerabilities in Federal health care programs. The Department must work to reduce improper

Medicare and Medicaid payments resulting from fraud, waste, and abuse across all service areas by addressing vulnerabilities and weaknesses with all available tools.

OIG's *Compendium of Unimplemented Recommendations* identifies many significant vulnerabilities and provides recommended responses requiring action by the Department or Congress. The Department, including OIG, must also identify new risks posed by the changing dynamics of Federal health care programs and the resulting evolving nature of fraud and abuse schemes and act promptly and effectively.

Management Issue 7: Quality of Care

MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

Ensuring quality of care for beneficiaries of Federal health care programs continues to be a significant challenge for the Department. This challenge has many facets, such as ensuring that the Department adequately oversees health care providers' compliance with quality-of-care standards and ensuring that beneficiaries do not receive substandard care and are not abused or neglected. The Department also faces challenges in adopting tenets of the patient-safety movement, which focuses on improving care through quality improvement initiatives, measurement, and reporting.

Oversight of Compliance with Existing Quality Standards

Overseeing compliance with quality standards represents a challenge for the Department. The growing number of beneficiaries receiving care in hospitals, in nursing facilities, and from home health agencies underscores the need to ensure beneficiaries receive quality care and to enforce quality standards.

Ensuring quality care for nursing home residents remains a significant challenge. OIG is examining whether atypical antipsychotic drugs provided to residents are in compliance with CMS standards for unnecessary drugs. OIG is also examining SNFs' compliance with Federal requirements for quality of care by reviewing their plans of care and discharge planning. In addition, OIG is updating its 2006 review of SNF compliance with emergency preparedness planning standards. In future work, OIG will review poorly performing nursing homes. (See Management Issue 9 for further discussion of emergency preparedness in nursing homes.)

OIG will also examine quality of care in Medicaid home- and community-based settings, such as assisted-living facilities and adult day health centers. This work will determine whether the care provided follows the plans of care and will assess the extent of CMS's oversight of quality of care in these settings.

The Department has made progress on its oversight of quality standards. For example, CMS expanded its oversight of accreditation organizations and effective mid-2010, it approved the Joint Commission's deeming authority for hospitals. The Joint Commission previously held a unique statutory status that allowed it permanent deeming authority, but now this authority must be periodically reapproved by CMS. CMS also proposed rules that would require unannounced and extended surveys of home health agencies and the imposition of sanctions when they are found to be out of compliance with Federal standards.

Protecting Beneficiaries From Substandard Care and From Abuse and Neglect

Protecting beneficiaries is an ever-present challenge for the Department. Identifying and addressing instances of substandard care are central to this challenge.

OIG investigations and enforcement cases demonstrate that some beneficiaries receive substandard care or are abused or neglected by providers. In January 2010, five Cathedral Rock Corporation nursing homes pleaded guilty to felony health care fraud, and Cathedral Rock Corporation's chief executive officer (CEO) entered into a 2-year deferred prosecution agreement for submitting claims for worthless care resulting in serious harm and patient death. The five homes and the CEO were jointly assessed a $1 million criminal penalty. Cathedral Rock Corporation paid $628,000 to resolve its civil FCA liability and entered into a 5-year CIA requiring Cathedral Rock to retain an independent quality monitor selected by OIG.

As cases resolved in 2010 indicate, these problems exist across provider types. In January 2010, FORBA holdings paid $24 million to resolve allegations that it provided substandard and medically unnecessary dental services to Medicaid patients at its pediatric dental clinics. In April 2010, Harbor Senior Concepts, an assisted-living facility chain, paid $258,000 to resolve allegations that it provided substandard care to Medicaid beneficiaries resulting in patient harm.

Other OIG work has also identified instances of patient abuse and neglect. For example, OIG found serious quality-of-care issues in the delivery of Medicaid personal care services, which are delivered in beneficiaries' homes. Beneficiaries alleged that they were abused, neglected, and mistreated, and that personal care attendants stole their property. OIG recommended that States improve monitoring. In future work, OIG will examine hospital reports of restraint-related deaths and subsequent investigations by State agencies.

Complex ownership arrangements that include multiple entities present a particular challenge for holding nursing home owners accountable for substandard care. Pursuant to the Affordable Care Act, the Department must promulgate regulations within 2 years requiring nursing homes to report their ownership in a standard format and, within 3 years, to make it public. Promulgating these regulations promptly and making effective use of the new authority provided by the Affordable Care Act poses a continuing challenge for the Department. Collection and publication of this information should facilitate more effective oversight and response to quality-of-care problems.

Medicare's primary program for addressing substandard care is the Quality Improvement Organization (QIO) program, which was established to promote the effective, efficient, and economical delivery of Medicare health care services and ensure the quality of those services. However, in 2007, OIG found that only 11 percent of cases reviewed by QIOs were for quality-of-care concerns and that sanction referrals were rare. Moreover, QIOs routinely failed to respond to OIG referrals on beneficiary care. CMS has improved the QIO program, adding the use of management information tools, such as milestone and project tracking. The use of these tools is intended to ensure that QIOs' services improve beneficiary care.

The Department also relies, in part, on the State Medicaid Fraud Control Units to investigate and address abuse and neglect in State-regulated Medicaid facilities. In addition, as part of the Affordable Care Act, the Elder Justice Act will improve reporting and investigation of allegations of abuse, neglect, and misappropriation of funds of residents in nursing homes. It requires nursing facility owners, operators, employees, managers, and contractors to report a reasonable suspicion of a crime against residents in nursing facilities to the Department and to law enforcement officers. Failure to report may result in significant penalties and, in cases where further harm occurred after the failure to report, exclusion from participation in the Federal health care programs. In addition, the Federal Elder Justice Interagency Working Group provides a forum for the exchange of current agency activities, emerging trends in policy and research, promising practices, and legislative developments related to elder justice.

The Patient Safety Movement and Incentives for Quality Improvement

The Department, which represents a major purchaser of health care, faces challenges in adopting tenets of the expanding patient-safety movement, which focuses on quality improvement, measurement, root-cause analysis, transparency, and public reporting.

The OIG's recent work on adverse events underscores the significance of this challenge. OIG reported that 13.5 percent of hospitalized Medicare beneficiaries experienced serious adverse medical events that prolonged a hospitalization, required life-sustaining intervention, or contributed to permanent harm or death and that another 13.5 percent of beneficiaries experienced temporary-harm events requiring medical intervention. These events, nearly half of which (44 percent) were preventable, cost the Medicare program $324 million in additional costs in a single month. OIG is reviewing the extent to which internal hospital incident-reporting systems capture adverse events, report the information to external patient-safety entities, and use the information to improve practices. OIG also is assessing CMS's response to adverse events in hospitals.

The Department faces a challenge in working with health care providers to ensure that they are knowledgeable about and consistently implement quality-improvement processes. OIG has sponsored roundtables with hospital and nursing home representatives to explore involving boards of directors and trustees in quality-improvement matters. In 2010, OIG began incorporating requirements for board and trustee members' increased involvement in quality-of-care CIAs.

The Department has implemented a number of programs as part of the challenge to ensure patient safety and become a more prudent purchaser of health care. It established the Office of Healthcare Quality, which is leading and coordinating an initiative on preventing health-care-associated infections. Also, CMS continues to fund demonstrations on value-based purchasing and gain-sharing to provide payments to improve quality and efficiency. And it continues to have its QIOs work with providers to improve their performance on clinical measures related to patient safety and disease prevention.

The Department continues to make hospital, nursing home, and dialysis facility ratings available to consumers. AHRQ has also made considerable progress in implementing Patient Safety Organizations (PSO), which encourage clinicians and health care

organizations to voluntarily report and share quality and patient safety information without fear of legal discovery. PSOs play an important role in collecting and studying data regarding adverse events.

OIG will examine hospitals' controls regarding the accuracy of quality-related data reported to CMS. OIG will also determine whether States have sufficient controls in place to ensure appropriate incentive payments in Medicaid programs aimed at rewarding high-quality care.

Related Challenge of Health Care Reform

The Affordable Care Act further underscores the importance of the challenges associated with ensuring quality of care. It creates an interagency workgroup on quality and calls for developing a national strategy to improve health care delivery. It calls for new models for patient care while focusing on greater transparency and accountability. In addition, it links payment to health care outcomes. It also requires background checks for those who will be working directly with patients in long-term care facilities. The successful implementation of these and other quality mandates in the Act will ensure enhanced quality of care in the health care delivery system, but the magnitude, complexity, and timely implementation of these changes present a challenge for the Department.

PART III: INTEGRITY OF THE DEPARTMENT'S PUBLIC HEALTH AND HUMAN SERVICES PROGRAMS

The Department faces challenges in ensuring the integrity of its public health and human services programs. These include oversight systems to ensure the safety of food, drugs, biologics, and medical devices; efforts to effectively prepare for and respond to a public health emergency; and oversight of the awarding, appropriate use, and effectiveness of departmental grants.

Management Issue 8: Oversight of Food, Drugs, and Medical Devices

MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

Recent outbreaks of foodborne illness and increased drug and medical device recalls underscore the importance of ensuring the safety and security of the Nation's food supply, human and veterinary drugs, biologics, and medical devices. However, the Department's oversight responsibilities for these products are vast, creating a number of management challenges. For instance, responding to food safety emergencies often involves multiple State and Federal public health agencies, which makes coordination difficult. Likewise, ensuring that medical products, once proven to be safe and effective, are labeled and advertised appropriately is more demanding than ever given technological advances in the media used to promote such products. In the increasingly globalized market for food, drugs, biologics, and medical devices, these challenges -- combined with new statutory authorities that expand the Department's oversight role to include new products, such as tobacco -- elevate the significance of the Department's oversight function.

Despite these difficulties, the Department has made progress in addressing challenges in the oversight of food, drugs, biologics, and medical devices. FDA opened field offices in China, India, and Costa Rica to conduct more inspections and work with local officials to improve the safety of foods exported to the United States. In September 2009, FDA also required food facilities to report in a new registry all instances in which an article of food might cause serious health consequences and to investigate the causes of any adulteration reported. The Department has also made efforts to improve the safety of drugs and biologics through initiatives such as a new Risk Evaluation and Mitigation Strategy, which is designed to ensure that the benefits of a drug or biologic outweigh its risk. Although these efforts highlight the strides the Department has made, OIG work in the areas of food, drugs, biologics, and medical devices illustrates that more effort needs to be made to ensure quality and safety.

Oversight of Food Safety

More than 300,000 Americans are hospitalized and 5,000 die annually after consuming contaminated food and beverages. FDA is responsible for finding the contamination source during a food emergency and overseeing the voluntary removal by manufacturers of these products from the market. Yet recent OIG reports found that recordkeeping issues, inspection coverage, and recall problems impair FDA's ability to effectively resolve food emergencies.

Food facilities' failure to comply with FDA's recordkeeping requirements is a vulnerability that impedes the Department's ability to ensure the safety of the Nation's food supply. FDA requires some food facilities to maintain information about their product sources, recipients, and transporters. However, in a food traceability study, OIG found that only 5 of the 40 products

purchased could be traced through each stage of the food supply chain back to a farm or a border. Fifty-nine percent of selected food facilities did not comply with FDA's recordkeeping requirements. Twenty-five percent of the facilities were not aware of such requirements. In another report, OIG found that 5 percent of selected facilities failed to register with FDA as required. Of those that did register, almost half failed to provide accurate and complete information.

The absence of guidelines establishing a minimum frequency with which FDA should conduct food facility inspections is problematic. OIG found that FDA inspects less than a quarter of food facilities each year and that more than half of food facilities have gone 5 or more years without an FDA inspection. Furthermore, because FDA lacks adequate internal inspection procedures, the agency took actions against less than half of the food facilities where inspectors found objectionable conditions that warranted FDA's most severe inspection classification.

OIG also identified vulnerabilities in FDA's oversight of pet food recalls. OIG found that FDA lacks the statutory authority to require manufacturers to initiate pet food recalls and did not always follow its own procedures in overseeing the recall of pet food tainted with melamine. Nor were FDA's procedures always adequate for monitoring recalls as large as those required in the pet food incident of 2007.

OIG will continue to oversee the Department's management of food safety issues. As part of that oversight, OIG is reviewing FDA's monitoring of State agencies that contract with FDA to conduct food facility inspections; food facilities' compliance with requirements of FDA's Reportable Food Registry; FDA oversight and operations related to imported pet food and feed products; and the extent to which it tested human food for contamination from melamine and other contaminants.

Oversight of Drugs, Biologics, and Medical Devices

The Department is responsible for ensuring that all drugs, biologics, and medical devices are safe and effective. The Department must also ensure that once a drug, biologic, or device has been approved for use, it is marketed appropriately. However, OIG work in this area has exposed weaknesses in FDA's ability to adequately oversee the safety of drugs, biologics, and medical devices. In particular, OIG work found vulnerabilities in FDA's ability to ensure the timeliness of drug application reviews, the adequate monitoring of adverse-event reporting, and the prevention of off-label marketing of drugs, biologics, and medical devices.

FDA faces challenges in approving generic drug applications in a timely manner. In its June 2008 report, OIG found that FDA exceeded the 180-day review for nearly half of the original generic drug applications. FDA has implemented some changes that are consistent with OIG's recommendations to improve the generic drug approval process. In July 2008, FDA published a final rule that required it to review generic drug applications and describe all deficiencies to the applicant within 180 days. FDA also issued additional guidance on what information to include in generic drug applications. The Affordable Care Act expanded FDA's authority to include approval of biosimilars (generic biologics). Because of the unique nature of biologics research and production, FDA faces additional challenges in implementing this new responsibility.

Providing adequate oversight of adverse events associated with the use of medical devices is a challenge for FDA. The agency receives about 200,000 adverse-event reports each year about medical devices. However, OIG found that FDA did not use the reports in a systematic manner to detect and address safety concerns. In a 2009 report, OIG found that FDA did not document follow-up on adverse events nor did it consistently read adverse-event reports in a timely manner. FDA has since developed a new database that will enable it to more effectively review adverse-event reports and conduct follow-up.

Although this is a step in the right direction, the Department still faces a number of obstacles in its oversight of medical device safety. For example, preventing the use of unapproved medical devices and the illegal marketing of potentially harmful devices continues to be a challenge. In December 2009, Spectranetics Corporation agreed to pay $4.9 million in civil damages plus a $100,000 forfeiture to resolve allegations that the company illegally imported unapproved medical devices and provided them to physicians for use in patients, conducted a clinical study in a manner that failed to comply with Federal regulations, and promoted certain products for procedures for which the company had not received FDA approval or clearance.

Among the Department's challenges is ensuring that drugs, once they have been determined to be safe and effective, are marketed appropriately. OIG has investigated a number of cases involving the illegal promotion of drugs by pharmaceutical manufacturers. In September 2009, Pfizer, Inc., and its subsidiary Pharmacia & Upjohn, Inc., agreed to pay $2.3 billion to resolve criminal and civil liability arising from alleged illegal promotion of Bextra, an anti-inflammatory drug pulled from the market in 2005, and three other drugs. In April 2010, AstraZeneca LP and AstraZeneca Pharmaceuticals LP entered into a $520 million civil and administrative settlement to resolve allegations that it illegally marketed the antipsychotic drug Seroquel. In

January 2009, Eli Lilly and Company entered a $1.4 billion global criminal, civil, and administrative settlement to resolve allegations that it illegally marketed its antipsychotic drug Zyprexa.

OIG is investigating many more allegations of fraudulent marketing and promotional practices in the pharmaceutical and medical device industries and is reviewing over 100 sealed *qui tam* complaints involving pharmaceutical and medical device fraud and abuse. Also, OIG is increasingly using its administrative authorities to sanction individuals and entities engaged in fraudulent and abusive practices in the pharmaceutical and medical device industries. Even as cases are investigated and enforcement remedies are pursued, the Department faces the task of identifying systemic responses that can reduce illegal off-label marketing.

Oversight of Human Subject Protections in Clinical Trials

The Department's ability to protect human subjects enrolled in clinical trials and to ensure the identity and security of data collected in those trials remains a challenge that OIG continues to monitor. In 2007, OIG found that the lack of a clinical trial registry and inconsistencies in inspection classifications inhibited FDA's ability to manage its oversight of clinical trials. OIG also found that FDA inspected only about 1 percent of clinical trial sites during fiscal years 2000-2005. A recent OIG report found that sponsors relied heavily on foreign clinical trial data to support their marketing applications for drugs and biologics. OIG found that FDA inspected clinical investigator facilities at less than 1 percent of foreign sites. Logistical and jurisdictional challenges in conducting foreign inspections and data limitations also inhibited FDA's ability to monitor foreign clinical trials. FDA has taken steps to improve its oversight of foreign clinical trials. To leverage its inspection resources, FDA reached an agreement with the European Medicines Agency to share inspection-related data and other information. FDA is also piloting a data analysis tool to identify foreign and clinical investigator sites for inspection.

As the agency tasked with ensuring the safety and efficacy of food, cosmetics, drugs, biological products, medical devices, and products that emit radiation, the Department faces important challenges with respect to increasingly globalized markets. These challenges will only be exacerbated with new legislative mandates increasing the Department's oversight responsibilities, such as new authority to regulate the content, marketing, and sale of tobacco products. Despite making progress and plans for improvement, the Department must make strides in its oversight efforts to meet those challenges.

Management Issue 9: Public Health Emergency Preparedness and Response

MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

Recent natural disasters, such as hurricanes, wildfires, floods, and the outbreak of the H1N1 virus, highlight the importance of a comprehensive national public health infrastructure that is prepared to respond rapidly and capably to emergencies. The ability to effectively prepare for and respond to a public health emergency requires planning, coordination, and communication across a range of entities, including Federal agencies; States, localities, and tribal organizations; the private sector; individuals and families; and international partners. This combination of organizations with significantly different roles and structures poses unique and unprecedented demands on the Department.

In its FY 2010 budget, the Department requested over $5.1 billion to fund programs to enhance the Nation's emergency preparedness activities to better respond to large-scale public health emergencies, such as natural disasters, infectious disease outbreaks, or acts of bioterrorism. (See Management Issue 8 for discussions of preparedness for and response to foodborne illness and related emergencies.)

The Department has continued to work with States and selected localities to improve their public health emergency preparedness and response capacity. However, OIG work assessing preparedness as recently as June 2010 shows both progress and the need for significant improvements in the public and private sectors' preparedness and response capabilities during public health emergencies.

State and Local Public Health Emergency Preparedness Planning

Documented emergency preparedness plans that are current and cohesive and contain sufficient detail are critical for ensuring that States and localities are prepared for a public health emergency. The Department provides guidance to States and localities on the development of emergency preparedness plans. However, variations in State and local health department structures and the size of the populations they serve make it challenging to provide Federal guidance that is tailored to an individual jurisdiction's needs.

In its evaluation of the Nation's pandemic influenza preparedness, OIG found that most selected States and localities had begun emergency preparedness planning but had not addressed in planning documents most of the items in departmental guidance. States and localities also varied in the extent to which they exercised their emergency response plans and addressed lessons learned. OIG recommended that the Department (1) work with States to help localities improve preparedness and (2) ensure that States and localities consistently document their exercises and lessons learned. In response to these recommendations, the Office of the Assistant Secretary for Preparedness and Response (ASPR) and CDC have developed guidance for States and localities that addresses the gaps found by OIG. ASPR implemented a new standardized reporting template to improve documentation of emergency preparedness exercises in health care systems and data collection. CDC now requires that grantees develop and submit mass vaccination after-action reports and improvement plans as a part of the Public Health Emergency Response grant application and the Public Health Emergency Preparedness cooperative agreement.

In its audit of State agencies' pandemic influenza funding expenditures in three States, OIG found that the States spent 51 percent (about $13.6 million) of their total funding as of June 2008. States cited delays in CDC guidance, funding, and timing problems with the State's fiscal year as reasons that they spent only about half of their total funds. States that OIG reviewed generally complied with most, but not all, Federal cost requirements. The three States spent about $1.2 million in unallowable or unsupported costs.

OIG is reviewing State and local preparedness for radiological and nuclear incidents. In its review, OIG will determine the extent to which selected States and localities are prepared to respond to the public health challenges of a radiological and nuclear incident and how they have used Department guidance in their preparedness efforts.

Federal and State Drug Storage and Laboratory Capability and Security

Early and accurate detection and reporting of biological and chemical agents are critical components of a national public health response. These threats include anthrax, influenza, nerve agents, and foodborne pathogens that cause outbreaks such as E. coli and salmonella. It is also important that the drugs used to treat these agents be available and effective during a public health emergency. However, OIG's findings reveal vulnerabilities in the Nation's preparedness to respond to potential biological and chemical threats.

For example, weaknesses exist in the Nation's laboratory system capability and security. CDC provides funds to States, in part, to improve public health laboratory preparedness. State public health laboratories rely on private clinical laboratories, which are not under the authority of the State, to perform diagnostic tests ordered by physicians. Yet in its review of laboratory capacity, OIG found that not all clinical laboratories have the ability to conduct initial screenings and refer suspicious specimens to a State laboratory, which could confirm the presence of public health threats. OIG recommended that CDC continue to assist States in meeting the requirement to decrease the time needed to detect and report biological public health threats, and CDC concurred with that overall recommendation.

OIG reviewed Department and external laboratories to determine their compliance with the regulations governing select agents (i.e., pathogens or biological toxins that pose a severe threat to public health and safety) and found that some laboratories did not adequately safeguard the agents against theft or loss. In its recent audits at six departmental laboratories, OIG found problems with access controls, training, and/or recordkeeping, among other findings. These problems mirrored those found during earlier work at universities and public and private laboratories. Through its authority to impose CMPs against persons or entities who violate select agent regulations, including universities and nonpublic laboratories, OIG has collected over $2 million for such violations as conducting unauthorized research with select agents, conducting unauthorized select agent transfers, failing to secure select agents against unauthorized access, and allowing unauthorized individuals access to select agents.

OIG also reviewed CDC's CHEMPACK project, which places nerve agent antidotes in monitored storage containers in multiple State locations for immediate use in the event of a nerve agent release. In its review, OIG determined the extent to which nerve agent antidotes were stored at the temperatures required by FDA. OIG also reviewed the extent to which CDC implemented procedures to ensure the quality of nerve agent antidotes and the extent to which antidotes appropriately received extended expiration dates under the Shelf Life Extension Program (SLEP). OIG found that CDC's policies for CHEMPACK drug storage did not meet FDA's temperature and quality requirements and that CDC did not monitor and store containers appropriately. Also, CDC allowed CHEMPACK drugs to inappropriately receive extended expiration dates under SLEP. OIG recommended that CDC revise its policies and procedures regarding CHEMPACK drug storage and SLEP to comply with FDA requirements. CDC concurred with all OIG's recommendations.

Lessons Learned From Real-Life Public Health Emergency Responses

It is important that the public and private sectors prepare for large-scale public health emergencies, and it is equally important that they effectively execute their plans in response to an emergency. Therefore, it is essential that Federal, State, and local entities identify vulnerabilities in, and determine the lessons learned from, responses to real-life public health emergencies.

For example, during the 2009 H1N1 influenza pandemic, OIG conducted onsite evaluations of selected localities' administration of H1N1 vaccine at School-Located Vaccination (SLV) sites. OIG found that SLV programs can be a viable strategy for vaccinating a large number of students in a short time. However, SLV programs require significant planning and resources, and selected localities had difficulty implementing SLV programs. OIG's report identified challenges and lessons learned and provided Federal, State, and local planning considerations for future SLV programs.

After the 2005 Gulf Coast hurricanes, OIG examined selected public health disaster responses to these events to highlight potential vulnerabilities and lessons learned. OIG reviewed the emergency plans of nursing homes in five Gulf Coast States and found that all had problems in implementing their emergency plans or with impromptu decisionmaking. OIG recommended that CMS consider strengthening Federal certification standards for nursing home emergency plans and encourage communication and collaboration between States and localities and nursing homes. CMS concurred with OIG's recommendations and issued Federal guidance and requirements as a result. OIG is conducting a followup evaluation that reexamines nursing home emergency preparedness and evacuation during recent hurricanes, wildfires, and floods. OIG will assess the use of the new tools that CMS developed and now requires as a result of the first OIG report. OIG will also describe the experiences of selected nursing homes, including challenges, successes, and lessons learned when they implemented their plans during natural disasters. (See Management Issue 7 for discussion of preparedness within nursing homes as it relates to quality of care.)

Overall, the Department has made progress in implementing some of OIG's recommendations for improvements to the Nation's preparedness for and response to public health emergencies. However, to mitigate the vulnerabilities noted in this management issue, the Department should continue to focus on providing additional guidance to States and localities to improve their public health emergency preparedness capability.

Management Issue 10: Grants and Contracts Management

MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

In FY 2009, the Department awarded over $364 billion in grants, making it the largest grant-awarding Department in the Federal Government. Almost 71 percent of the money was for health care coverage under Medicaid and CHIP. The remaining 29 percent funded health and social service programs administered by the Administration for Children & Families (ACF), the Health Resources and Services Administration, (HRSA) NIH, CDC, and other Department agencies. The Recovery Act provided $27 billion for the temporary expansion of these health and social service programs for FYs 2009 and 2010.

The size and scope of the Department's grant expenditures make grants management a significant challenge for the Department. New legislative mandates, such as the Recovery Act and the Affordable Care Act, that increase the Department's portfolio of grants and oversight responsibilities exacerbate this challenge. For instance, the Affordable Care Act establishes an $11 billion Community Health Center Fund to be administered through the Department. (See also Management Issue 11 for a discussion of broader departmental challenges related to the oversight and implementation of the Recovery Act and OIG reviews specifically focused on grants management issues related to Recovery Act funding. Broad challenges related to implementation of the Affordable Care Act are discussed in Management Issue 1. Challenges related to the Medicaid and CHIP programs are discussed in Management Issues 2 through 7.)

Adding to this challenge is that the primary responsibility for performance and management of a grant rests with the grantee, with limited Federal involvement in the funded activity. However, the grant-awarding agency retains oversight responsibility for ensuring that funds are awarded and used appropriately and that grantees comply with grant requirements. Recent statutory changes, most notably through the Recovery Act, have increased Federal agencies' responsibilities for grantee oversight. OIG's work in reviewing grant programs administered by ACF, CDC, HRSA, and NIH has highlighted grants management vulnerabilities and opportunities for improvements in the Department's oversight of grant funds and grantee compliance.

In addition to awarding grants, the Department awarded over $20 billion in contracts In FY 2009. The top five products or services purchased with these contracts were drugs and biologics, professional services, information technology and telecommunications, operations of Government facilities, and research. The scope and size of these contracts are significant and

pose a challenge to effective oversight. OIG's work in reviewing the award and management of contracts at NIH and CDC found problems with compliance with appropriations and acquisition laws and regulations.

Grant Oversight

OIG has identified risks related to grantee noncompliance in departmental grants programs at ACF and NIH. Funding from both the Recovery Act and the Affordable Care Act for community health centers increases the challenge HRSA faces in ensuring that Federal grant awards to health centers are used in accordance with Federal regulations. OIG performed a series of audits to assess the financial capability of community health centers receiving Recovery Act funds to account for and manage Federal funds. The assessments identified problems with inventory, cash management, and financial systems controls. In response, HRSA has increased its efforts in monitoring, assisting grantees, and ensuring program integrity.

OIG performed a series of reviews in one State to determine whether the State agency claimed foster care costs to ACF in accordance with Federal regulations. Title IV-E of the Social Security Act, as amended, authorizes Federal funds for States to provide foster care for children under an approved State plan. For children who meet Title IV-E Foster Care requirements, Federal funds are available to States for maintenance, administrative, and training costs. HHS must ensure that costs claimed by a State are in accordance with Federal regulations. In 2008, OIG found that one State agency claimed costs for children in unlicensed facilities and for ineligible services. As of November 2010, ACF had not responded to more than $56 million in questioned costs in this report. In a 2009 review of the same State, OIG found that the State agency inappropriately claimed costs of over $1.6 million for children after they turned 19.

In another example, OIG found that although NIH's National Cancer Institute had implemented processes to ensure the completeness and accuracy of grantees' progress reports, 41 percent of progress reports were received late. OIG also identified deficiencies in NIH's financial oversight of grants, including delays in closing out some grants. NIH agreed with OIG's recommendations to initiate earlier and more frequent followup with grantees to obtain required documents and to improve its grants monitoring, including conducting a pilot study to verify grantees' self-reported fund balances by contacting external sources. OIG is evaluating the NIH National Center for Research Resources' management of the Clinical and Translational Science Awards, which are expected to award 60 grantees with annual funding of $500 million by 2012.

Without proper controls to ensure the appropriate use of Federal funds and to oversee grantees, the Department's grant programs are at risk of fraud, waste, abuse, and ineffectiveness. Expansions in the number and size of grants awarded by the Department magnify grant oversight vulnerabilities facing the programs. OIG will continue to monitor grants management challenges and recommend improvements to the Department's grants oversight, as warranted.

Contract Oversight

OIG conducted a series of contracting audits at NIH and CDC, which found that both improperly funded contracts. CDC administered one contract improperly. An HHS "Tiger Team" initially identified departmentwide concerns about potential improper contracting, including at NIH. A key concern was the improper partial funding of long-term, high-dollar-value research contracts. Federal appropriations statutes require that agency fiscal year funds may be obligated or used only for legitimate needs (including through contracts) of that fiscal year; fiscal year funds cannot generally be used for agency needs of prior or future years. Failure to comply with this statute may result in agencies' not being able to fund or pay outstanding contracts.

OIG is reviewing 21 NIH contracts identified by the Tiger Team to determine whether the contracts were awarded in compliance with Federal appropriations laws. While some of these audits are still in process, OIG's work thus far indicates that at least some of the contracts were improperly funded.

OIG also performed a series of contract audits at CDC. One contract was improperly administered as a personal services contract. In this same contract, CDC was using fiscal year funds after their periods of availability. OIG recommended that CDC determine whether these contract actions violated the Anti-Deficiency Act and take action to correct such violations. OIG plans to continue its contract audit work at CDC, NIH, and throughout the Department.

NIH and CDC stated that they have taken action to correct problems identified in the audit reports. NIH and CDC provided appropriations law training to their acquisition workforce. HHS is developing a training course that specifically addresses the issues identified in the OIG audits. CDC stated that they reviewed all FY 2010 contracts for adherence to contract funding regulations.

HHS acknowledged the appropriations-related acquisition challenges identified by OIG and has informed OIG that it is taking the necessary steps to address those challenges. The Department noted that while achieving full compliance with appropriation law will involve adjustments to its budgetary, program planning, financial, and contracting processes, it is confident that its business process improvement effort will succeed.

PART IV: CROSS-CUTTING ISSUES

OIG has identified three more Departmentwide issues as top management challenges: assessing whether the Department is using Recovery Act funds in accordance with legal and administrative requirements and is meeting the accountability objectives defined by the Office of Management and Budget (OMB); developing and maintaining adequate internal controls over its information systems to protect the security and privacy of health data; and effectively overseeing its ethics program.

Management Issue 11: American Recovery and Reinvestment Act Accountability and Transparency

MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

As the Nation faced what is generally reported to be the most serious economic crisis since the Great Depression, the Recovery Act was enacted in 2009 to promote economic recovery and minimize the impact of the recession. The Congressional Budget Office (CBO) originally projected that the Recovery Act's combined spending and tax provisions would cost $787 billion over 10 years, including more than $499 billion in additional Federal spending and $288 billion in tax relief. The objectives of the Recovery Act include preserving and creating jobs, assisting those most affected by the recession; increasing economic efficiency by investing in technological advances in science and health; investing in transportation, environmental protection, and other infrastructure that will provide long-term economic benefits; and stabilizing State and local budgets.

The Recovery Act provides $141.4 billion to the Department to provide additional Federal assistance for health care, public health and human services programs, and to invest in research and health information technology (health IT), as estimated in the 2011 President's Budget. This amount includes $4.3 billion in the form of reduced contributions for prescription drug costs for additional fiscal relief to the States in addition to the funding in direct provisions from the Recovery Act. The magnitude of expenditures and the potential impact of this funding on the economy, Federal and State budgets, program beneficiaries, and taxpayers make it critical that *Recovery Act* funds be used efficiently and effectively and be protected from fraud, waste, and abuse.

The Department's Recovery Act funding spans a range of agencies and programs. Some of the more significant funding is for:

- **Medicaid** – improving and preserving health care by providing an estimated $84.5 billion temporary increase in the FMAP.
- **Health IT** – accelerating the adoption of health IT by (1) providing the Office of the National Coordinator with $2 billion for Health Information Technology to coordinate Federal health IT policy and programs and foster the electronic use and exchange of health information and (2) by providing CMS with an estimated $25 billion to make incentive payments to encourage physicians and hospitals to adopt "meaningful use" of certified electronic health records starting in 2011. ("Meaningful use" of health IT is the standard established in the Recovery Act, and defined by CMS, that must be met for a hospital or eligible professional to receive incentive payments.)
- **Children and Families** – improving services to children and communities by providing ACF with more than $13.2 billion to temporarily expand the Temporary Assistance for Needy Families Program (TANF), Child Support Enforcement, Foster Care FMAP, Head Start and Early Head Start, Child Care Development, and community services programs.
- **Research** – strengthening scientific research and facilities by providing $10.4 billion to NIH.
- **Health Care** – strengthening community health care services by providing HRSA with $2.5 billion to renovate and construct new centers, to expand health care services, and to train health care professionals.

Most of the Department's Recovery Act funds are increases in Federal funding for existing programs. OIG has conducted extensive work and identified management challenges specific to these programs. (Challenges related to Medicaid are discussed in Management Issues 2 through 7. Challenges related to programs and grants administered by ACF, CDC, NIH, and HRSA are discussed in detail in Management Issue 10. Finally, challenges related to health IT are discussed in Management Issue 12.)

Implementation and oversight to ensure accountability and transparency of Recovery Act funding present significant challenges. Recovery Act funds are to be awarded and distributed within short timeframes to stimulate economic growth and minimize the impact of the recession. Expediting the awards process, however, also creates challenges for the Department in ensuring that funds are distributed to qualified recipients and used appropriately and effectively. Further, creating or expanding programs may increase the number of new recipients that lack experience with Federal requirements for grantees and contractors.

The Recovery Act also established new reporting requirements for the awarding and use of funds to promote transparency and accountability. Challenges associated with the new reporting requirements include developing systems and infrastructure for collecting and reporting the required information, educating recipients about the reporting requirements, validating the reported information, and using the collected information effectively to monitor and oversee Recovery Act programs and performance. The new reporting requirements for Recovery Act funds are in addition to reporting requirements that some grantees must also provide for similar activities funded outside the Recovery Act; this can create multiple and inconsistent reporting rules.

Overseeing and protecting the integrity of Recovery Act funds requires coordination among agencies within the Department and with States and other entities. The Department has established the Office of Recovery Act Coordination, headed by the Deputy Assistant Secretary for Recovery Act Coordination. Department agencies administering programs and activities funded by the Recovery Act are responsible for ensuring the appropriate awarding, distribution, use, and reporting of Recovery Act funds. OIG is charged with overseeing the Department's execution of these responsibilities and with preventing and detecting fraud, waste, and abuse. The Recovery Act also established the Recovery Accountability and Transparency Board (RATB), consisting of 12 Inspectors General, including the HHS Inspector General, to coordinate and conduct oversight of Recovery Act funds; prevent fraud, waste, and abuse; and promote accountability and transparency.

State agencies also have roles in overseeing Recovery Act funds, particularly those that increase Federal contributions to State-administered programs, such as Medicaid, TANF, and Community Services programs. Some States have raised concerns about having adequate funds for the administrative costs associated with meeting Recovery Act oversight and reporting requirements.

At the request of RATB, OIG completed a series of reviews to assess the Department's process, oversight, and effectiveness in performing data-quality reviews of information reported by recipients of Recovery Act funds. OIG found that the Department has designed an adequate process for performing limited data-quality reviews that identify material omissions and significant errors in recipient-reported Recovery Act information. In another RATB-requested review, OIG reviewed the staffing, training, and qualifications of Department personnel responsible for overseeing Recovery Act funds; the overall results of the review based on our findings and those reported by other OIGs concluded that staffing qualifications at the largest Federal agencies, including HHS, were inadequate.

In addition, a series of OIG risk assessments was conducted that covered $72.7 billion of the $76.4 billion allocated to health IT and non-Medicaid programs to determine which Recovery Act programs to review. As a result, OIG performed 127 reviews of grant applicants and new or existing grantees to determine whether the entities were financially viable and had financial management systems in place to adequately manage and account for the additional Recovery Act funds in accordance with Federal regulations. Consequently, OIG identified entities that were not capable of handling Recovery Act grant funds or required increased HHS oversight and guidance. For example, OIG conducted limited-scope audits on 83 Early Head Start applicants for grant funds and based on those audits, ACF decided not to award 15 applicants $31 million in Recovery Act funds. In addition, 60 Early Head Start applicants received funds with increased HHS oversight.

The Recovery Act provided an additional $2.1 billion for the Head Start and Early Head Start programs during FYs 2009 and 2010. OIG has identified risks related to grantee compliance with health and safety requirements at Head Start facilities. OIG initiated a series of reviews to determine whether grantees could provide a safe environment for children. In the multiple reviews performed, OIG found instances of noncompliance with regulations that jeopardized the health and safety of children. OIG has made recommendations to the grantees to address the deficiencies.

As for Recovery Act oversight of Medicaid programs, OIG conducted two reviews to determine whether the Department and CMS had correctly calculated the temporary increase in the FMAP awarded under the Recovery Act, in accordance with the applicable provisions. OIG also conducted 17 reviews of various States and determined that States were generally in compliance with the requirements for Medicaid funding under Section 5001 of the Recovery Act.

OIG has also increased investigative efforts related to programs affected by the Recovery Act. A screening process has been developed to identify applicants for Recovery Act funds that are under investigation by OIG. OIG has developed and implemented processes for addressing allegations related to the fraudulent use of Recovery Act funds and allegations of retaliation against whistleblowers who disclosed instances of the improper use of Recovery Act funds. OIG has also provided training to OIG agents on the Recovery Act and its whistleblower protection provisions.

The Recovery Act provides explicit protections for certain individuals who make specified disclosures relating to these funds. OIG receives allegations of fraud, waste, and mismanagement of Recovery Act funds from various sources, including the RATB and OIG hotline. OIG has received 50 complaints alleging inappropriate use of Recovery Act funds. These complaints have resulted in several investigations and some cases have entered the judicial process. To date, OIG has received one whistleblower-retaliation complaint related to HHS Recovery Act funds.

In addition to steps taken to oversee and protect the integrity of Recovery Act funds, examples of OIG's efforts include reviewing Recovery Act grantees' compliance with the recipient reporting requirements under section 1512 of the *Recovery Act*; reviewing agencies' progress toward implementing Recovery Act incentive payments for electronic health records and other funded health IT initiatives; reviewing CMS policies and procedures for protecting against IT breaches and medical identity theft involving Medicare identification numbers and determining whether responses to any breaches complied with notification requirements; reconciling the CMS-64, the standard form States use to claim FMAP, to claims-level data and identifying high-risk areas and providers for increased audit scrutiny; and performing audits of Recovery Act spending for recipients receiving HHS Recovery Act funding to ensure that awards are being used for authorized purposes and program goals are achieved.

OIG and the Department will continue to work to ensure that the Department meets its Recovery Act responsibilities. The Department continues to face challenges to ensuring the accountability and transparency of Recovery Act funds and ensuring that the funds are used for designated purposes and for the benefit of the beneficiaries served under the programs receiving enhanced resources. Continuing activities include minimizing risk; assessing controls for preventing fraud, waste, and abuse; and ensuring program goals are achieved and Recovery Act funds are accurately tracked and reported. The Department's and OIG's efforts in overseeing the awarding and effective use of funds will have long-term benefits for Department programs beyond the expenditure of Recovery Act funding.

Management Issue 12: Health Information Technology and Integrity of Information Systems

MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

The Health Information Technology for Economic and Clinical Health Act (HITECH Act) established the Office of the National Coordinator for Health Information Technology (ONC) within the Department and tasked it with leading the development of an interoperable national health information network that allows for the electronic exchange of health information while, among other things, protecting the security and privacy of health data. OIG has divided health IT management challenges into two categories: (1) ensuring the integrity of information systems through which health information is transmitted and stored to prevent fraud, waste, and abuse and (2) ensuring the integrity of the Department's programs to promote health IT. Protecting sensitive health data is a challenge because a patchwork of authorities establishes, and agencies oversee, such data.

Within the Department, CMS, ONC, and the Office for Civil Rights (OCR) are responsible for ensuring the privacy and security of health information. One challenge is coordinating among HHS agencies to ensure the privacy and security of health information by enforcing standards and monitoring security controls for health IT at the provider level. Ineffective or inadequate management processes, controls, or IT security put data and systems at risk. With the enactment of the HITECH Act, HHS initiatives promoting the use of health IT include:

- the adoption of interoperability standards by the Secretary;
- payment of Medicare and Medicaid incentives for providers engaged in the "meaningful use" of health IT;
- HRSA grants for the acquisition of health IT;
- ONC programs to facilitate the adoption of health IT through extension center programs; and
- State grants for health information exchange and development of a health IT workforce.

As electronic medical records become more prevalent and the exchange of personal health data over expanding networks becomes more pervasive – and as Federal and State health and human services programs implement the requirement in section 1561 of the Affordable Care Act to facilitate electronic enrollment of beneficiaries – we identify the risk for a rise in medical identity theft. The Department must quickly identify and address vulnerabilities in each of its health IT initiatives. It is also imperative that Recovery Act funds to support the widespread adoption of health IT be used efficiently and effectively. The Department's challenge is to balance the need to meet its health IT development goals with its obligation to oversee the expenditure of Recovery Act funds; an estimated $30 billion over the next several years in pursuit of health IT objectives. Comprehensive guidance to all health care providers is needed to ensure robust IT security that supports health information systems and the underlying network infrastructures to protect health information as it is created, transmitted, and stored.

Integrity of Information Systems

The Department administers its programs through a mix of grants, contracts, and cooperative agreements and as a payer of health benefits through Medicare, Medicaid, CHIP, and IHS. To accomplish its mission, the Department relies on a network environment that includes Federal agencies, State and local governments, grantees and contractors, health care providers, and colleges and universities. A significant challenge for the Department is to establish an information security program that protects critical infrastructure and assets and creates, monitors, and maintains an enterprisewide baseline of core security requirements.

OIG has monitored the ability to meet this challenge by determining whether the Department's information system security controls are adequate. OIG has also examined departmental oversight of health care providers' compliance with the Health Insurance Portability and Accountability Act (HIPAA) Security Rule (the applicability of which the HITECH Act has expanded and enforcement of which has been transferred from CMS to OCR).

OIG has performed dozens of independent audits of departmental agencies, as well as audits of State and local governments, contractors, and hospitals. The audits have identified vulnerabilities in the areas of:

- network access and management;
- security program infrastructure, which includes security program documentation, contingency plan documentation, accuracy of system inventory, and acknowledgment of management responsibilities;
- security training;
- personnel security, such as background checks and user account management;
- contractor oversight; and
- integration of security into major applications, which includes certification and accreditation, contingency plan testing, privacy impact statements, and annual self assessments.

With the push for increased adoption of health IT, there is heightened public concern about the security of personal health information. Accordingly, OIG has increasingly focused on combating medical identity theft. OIG investigations have uncovered a growing number of fraud schemes involving stolen provider and beneficiary identification numbers. In response, OIG issued a consumer education brochure that provides tips and resources to help beneficiaries protect themselves and Medicare from medical identity theft and fraud. OIG is also reviewing CMS's policies and procedures regarding information security breaches and medical identity theft involving Medicare identification numbers. OIG will continue its work in this area and make recommendations to the Department, as appropriate, about safeguards for personally identifiable information.

Integrity of Health Information Technology Programs

Like all grants and contracts, Federal health IT initiatives are susceptible to fraud, noncompliance, and inefficiency. Even before the enactment of the HITECH Act, OIG monitored Federal health IT initiatives. In 2009, OIG assessed Medicare Part D plan sponsors' implementation of CMS-mandated e-prescribing standards. OIG found that most sponsors had implemented some of the standards but that few had implemented all of them. Another study in 2008 examined the State Medicaid agencies' health IT initiatives. OIG recommended that States work with other Federal agencies and offices in developing policies to protect patient privacy and data security and coordinate State Medicaid initiatives with Federal health IT activities to ensure consistency with national goals.

OIG has developed a work plan to ensure that the estimated $49 billion in incentive payments and health IT program funds are used in ways consistent with the requirements in the HITECH Act and the Department's implementing regulations and policies. (See Management Issue 11 for further discussion of challenges associated with the Recovery Act.)

Looking forward, OIG is considering ways in which the design and function of electronic health records and health IT systems can help prevent and detect fraud, waste, and abuse and ways in which these tools can be misused to facilitate fraud, waste, and abuse and impede their detection.

Management Issue 13: Ethics Program Oversight and Enforcement

MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

During the past year, conflicts of interest in the health care system generally, and specifically in the Department, have been the subject of scrutiny, raising the issue of which stakeholders should be responsible for monitoring and managing conflicts of interest: individuals, government, or institutions.

Government Ethics Programs and Conflicts of Interest of Department Employees

Pursuant to Office of Government Ethics (OGE) regulations, the head of each Department and agency appoints a Designated Agency Ethics Official (DAEO) to oversee its ethics program. At HHS, the OIG assists the DAEO, with oversight and enforcement of the Department's ethics program. A key focus is ensuring that employees do not participate in official matters in which they have a conflict of interest or in which there may be impartiality concerns.

Monitoring for conflicts of interest continues to be a challenge for the Department. In December 2009, OIG determined the extent to which CDC and its Special Government Employees (SGE) on Federal Advisory Committees complied with ethics requirements. SGEs on Federal Advisory Committees provide expert advice to the Federal Government on important public health topics, such as breast and cervical cancer, immunization, smoking, tuberculosis, and clinical laboratory improvement. SGEs are temporary Federal employees who are typically involved in work outside the Government in the same areas as their committees' work. SGEs must comply with essentially the same OGE financial disclosure and conflict-of-interest regulations issued by OGE as Federal employees while performing their temporary work. OIG determined that CDC did not require SGEs to disclose their interests completely before participating in meetings, and CDC did not identify or resolve all SGE potential conflicts of interest, even when adequate information identifying a conflict was provided. CDC concurred with all seven of OIG's recommendations. Since the OIG report was issued, CDC has worked with the General Services Administration and the OGC Ethics Division to provide specialized training for all staff with advisory committee responsibilities to address conflict-of-interest issues identified by OIG.

OIG is reviewing HHS waivers and analyzing the extent to which the waivers are being created and used across the Department. Most HHS waivers are limited in nature and contain certain recusal requirements. OIG is examining the HHS waiver process to ensure that recusals within waivers are clear to the employees receiving the waivers and to ensure that higher level managers inform employees not to engage in matters from which they are recused. Another challenge for the Department is monitoring for conflicts of interest in a workforce that has become increasingly reliant on contract workers. For example, a recent audit of a CDC service contract found CDC managers "maintained relatively continuous supervision and control of contractor personnel who worked onsite at CDC," effectively treating these contractors as if they were operating under personal services contracts, which is a prohibited practice. (See also Management Issue 10, for further discussion of this issue as it relates to service contracts.)

In a July 2009 memorandum, the OMB director recognized the formidable task agencies face in appropriately and effectively managing a multi-sector workforce of both Federal employees and contractors to deliver important services. Since December 2007, OIG has maintained hotline posters on its Web site for use by departmental contractors and their employees to encourage reporting fraud to OIG. The OGE is releasing guidance on conflict-of-interest considerations of contractor employees in the workplace and OIG is developing internal training to prepare supervisors to address emerging issues involving contractors.

OIG continues to consult with the Department about the number and quality of conflict-of-interest referrals from divisions in the Department. Since OIG created a form for referrals of conflict-of-interest cases, OIG has seen a significant improvement in the quality of information received on such cases, resulting in reduced evaluation time. OIG's relations with the Office of General Counsel (OGC) Ethics Division, as well as regular interactions by OIG staff with the operating and staff divisions, continue to yield positive results. Departmental management appears to have a greater understanding of what constitutes

potential ethics and conflict-of-interest violations as evidenced by an increase in reporting potential violations, in the quality of the referrals, and in the number of contacts by departmental officials seeking input and guidance on conflict-of-interest matters.

OIG's enforcement efforts are often measured in convictions. In 2009, an employee of the National Library of Medicine at NIH failed to receive required prior approval for outside activities and to report income from them. The employee admitted receiving as much as $500,000 in unauthorized income after testifying as an expert witness on toxicology issues in legal proceedings. As a result, he was sentenced to 1 year of probation and 160 hours of community service and was ordered to pay a $200,000 fine.

As important as convictions are for redressing serious violations, it is more important to prevent employees from violating criminal conflict-of-interest statutes and to protect the integrity of departmental programs. In 2010, in cooperation with the OGC Ethics Division, OIG examined allegations of conflict of interest involving high-level Department officials and determined that no conflict-of-interest violations had occurred. OIG confirmed that the OGC Ethics Division's efforts to work with HHS employees, focusing on incoming high-level officials to reduce and prevent conflict-of-interest violations from occurring, were successful. New employees were encouraged to seek counsel to get advice, and avoid actions that could violate criminal conflict-of-interest statutes.

Oversight of Department Grantee, Researcher and Contractor Conflicts of Interest

In addition to departmental employees and contractors, Federal grantees and non-Federal researchers play important roles in departmental programs, and their conflicts of interest could also bias these programs and ultimately affect the public's health and safety. Eighty percent of NIH research funding goes to extramural grantees, primarily to research universities that undertake grant and contract work. Conflicts of interest among extramural grantees could compromise the integrity of the research that the Department funds. Therefore, in addition to performing work focused on departmental employees, OIG also examined potential conflicts of interest of Federal grantees and non-Federal researchers.

In 2008, OIG identified vulnerabilities associated with NIH's monitoring of conflict-of-interest reports submitted by external grantees for FYs 2004 through 2006. OIG found that NIH's Institutes and the Office of Extramural Research (OER) were unable to provide all the conflict-of-interest reports they received from grantee institutions and did not follow up with grantee institutions about reported conflicts of interest. OIG recommended that NIH increase oversight of grantee institutions and require them to provide details about the nature of financial conflicts of interest and the ways in which they are managed, reduced, or eliminated and ensure that OER's conflict-of-interest database contains information on all conflict-of-interest reports provided by grantee institutions. In July 2009, NIH began requiring that all financial conflict-of-interest reports from grantees be submitted electronically to NIH's system, using a uniform format.

In its followup work, OIG examined the nature of financial conflicts of interest reported by grantee institutions to NIH and the ways in which grantee institutions managed, reduced, or eliminated these conflicts. OIG identified vulnerabilities, including grantee institutions' reliance on researchers' discretion in reporting conflicts, failure to require researchers to report amounts of compensation in financial disclosures, and failure to routinely verify information submitted by researchers. OIG continues to recommend that NIH ask grantee institutions to provide it with details on the nature of all reported financial conflicts of interest and ways in which they are managed, reduced, or eliminated. OIG also recommended that NIH (1) require grantee institutions to collect all information on significant financial interests held by researchers, (2) require grantee institutions to collect from researchers information on specific amounts of equity and compensation, (3) increase oversight of grantee institutions to ensure that financial conflicts of interest are reported and managed appropriately, and (4) develop regulations that address institutional financial conflicts of interest. OIG is undertaking a review to determine what policies and procedures NIH grantee institutions have in place to address researchers' conflicts of interest.

In response to concerns about these vulnerabilities, NIH sought input from the public and from the research community on modifying Federal regulations by publishing an Advance Notice of Proposed Rulemaking (NPRM) on Promoting Objectivity in Research in May 2009. NIH invited public comments on all aspects of potential regulation in this area, particularly on the following issues: (1) expanding the scope of the regulation and the disclosure of conflicts of interest, (2) the definition of "significant financial interest," (3) identification and management of conflicts by grantee institutions, (4) assuring grantee institution compliance, (5) requiring grantee institutions to provide additional information to NIH, and (6) broadening the regulations to address institutional conflicts of interest. The NPRM was published in May 2010 and the comment period closed on August 19, 2010. The NPRM also proposed regulations for revising conflict-of-interest policies for contractors in 45 CFR Part 94.

OIG has also identified departmental conflict-of-interest vulnerabilities affecting other agencies. In 2009, OIG reported on vulnerabilities in FDA oversight of clinical investigators' financial interests. Clinical investigators lead clinical trials, recruit subjects, supervise trials, and analyze and report clinical trial results that are submitted to FDA in new drug applications. OIG identified vulnerabilities in the disclosure process and in FDA's review of the disclosed financial interests. OIG recommended that FDA ensure that new drug sponsors submit complete financial information for all clinical investigators and that FDA consistently review and take action in response to disclosed financial interests. OIG also recommended that sponsors submit financial information for their clinical investigators earlier in the process. In its response to the report, FDA agreed with most of our recommendations. FDA is currently in the process of revising its *Guidance for Industry: Financial Disclosure by Clinical Investigators*. It also updated its *Compliance Program Guidance Manual* chapter on Clinical Investigator Inspections to ensure that clinical investigators submit required financial information to sponsors.

Recent decisions by the Government Accountability Office (GAO) have highlighted the issue of organizational conflicts of interest of Government contractors. GAO sustained two bid protests under the CMS ZPIC program, agreeing that CMS had failed to reasonably consider the awardee's plan to mitigate its impaired objectivity. OIG is also evaluating how CMS oversees potential ZPIC organizational conflicts of interest. In addition, OIG is evaluating the oversight of potential conflicts of interest within the pharmacy and therapeutics committees within Part D plans.

Congress passed conflict-of-interest statutes, and OGE and the Department have promulgated ethics regulations to ensure that Department missions and programs are not compromised by conflicts of interest. Maintaining a heightened focus on ethics in the Department will require continued vigilance by all HHS employees, grantees, contractors, and researchers working with HHS.