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O10 looks forward to continuing to work with the Department to identify and implement strategies to protect the integrity of the Department's programs and the well-being of the beneficiaries of these programs. If you have any questions or comments, please contact me. or your staff may contact Erin Lemire, Acting Director of External Affairs, at (202) 205-9523 or Erin.Lemire@aig.hhs.gov.

A handwritten signature in black ink that reads "Daniel R. Levinson". The signature is written in a cursive style with a large initial 'D'.

Daniel R. Levinson

Attachment

FY 2009 TOP MANAGEMENT AND PERFORMANCE CHALLENGES IDENTIFIED BY THE OFFICE OF THE INSPECTOR GENERAL

Pursuant to the *Reports Consolidation Act of 2000* (P.L. 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 and Human Services (Department) and the Department's progress in addressing those challenges. The top management challenges for fiscal year (FY) 2009 are organized according to three broad categories: (1) integrity of Medicare, Medicaid, and the Children's Health Insurance Program (CHIP); (2) integrity of the Department's public health and human services programs; and (3) cross-cutting issues that span the Department.

PART 1: 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 remediate fraud, waste, and abuse. Based on its extensive experience in combating health care fraud, waste, and abuse, OIG has identified the following five principles that OIG believes should guide the Department's integrity strategy for Medicare, Medicaid, and CHIP. These principles offer a useful framework for implementing programs, as well as designing and implementing integrity safeguards.

- **Enrollment** – Scrutinize individuals and entities that seek to participate as providers and suppliers prior to their enrollment 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 detected fraud, impose appropriate punishment to deter others, and promptly remedy 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 for future generations.

In addition, a sixth management challenge is ensuring that the beneficiaries of Federal health care program receive quality health care. This challenge 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 Issue 1: Integrity of Provider and Supplier Enrollment

MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

The large Federal Government expenditures on the Medicare and Medicaid programs attract certain individuals and entities that seek to exploit the health care system for their own financial gain. Although the vast majority of health care providers and suppliers are honest and well intentioned, the Department faces challenges ensuring the integrity of the programs' provider and supplier enrollment processes. A small percentage of providers and suppliers intent on defrauding these programs have exploited weaknesses in the enrollment process, causing significant harm. These providers and suppliers drain resources that should be spent on providing needed and appropriate care to beneficiaries. Therefore, it is imperative that Medicare and Medicaid provider and supplier enrollment standards and screening processes be strengthened to clarify that participation as a provider or supplier is a privilege, not a right.

OIG's extensive oversight and enforcement work has identified weaknesses in provider and supplier enrollment that enable unqualified, dishonest, and unethical individuals and entities to access a system they can easily exploit. In addition, OIG identified weaknesses in the oversight of provider and supplier eligibility to receive certain payments under Medicare and Medicaid. More rigorous enrollment, screening, and transparency standards would help the Government better know with whom it is doing business. Protecting these programs and their beneficiaries from unqualified, fraudulent, or abusive providers and suppliers up front is more efficient and 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 strengthen the integrity of the Medicare and Medicaid programs. OIG identified certain characteristics that may indicate a provider's increased potential for fraud.

Examples of potential fraud or risk indicators include interest or ownership in other health services 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 other sanctions by State Medicaid agencies or other health care organizations. Current provider enrollment standards and screenings do not use all these fraud indicators to determine a provider's level of risk for fraudulent conduct.

OIG has identified significant vulnerabilities in the enrollment screening of durable medical equipment (DME) suppliers and high rates of noncompliance with enrollment standards. In 2006, OIG conducted unannounced site visits of 1,581 DME suppliers in three south Florida counties and found that 31 percent did not maintain physical facilities or were not open and staffed, contrary to Medicare requirements. Similarly, in 2008, OIG inspected 905 suppliers in Los Angeles County and found that 13 percent did not have physical facilities or were not open during repeated unannounced site visits. In 2008, OIG examined a small random sample of DME suppliers with uncollectible Medicare debt and found that these suppliers were associated with other DME suppliers and home health agencies (primarily through shared ownership, management, or family relationships) that had received approximately \$58 million in Medicare payments. The associations are of interest because Federal investigators suspect, and have found in some cases, that individuals associated with the Medicare debt may omit ownership or management information on enrollment applications and inappropriately receive Medicare payments through businesses publicly fronted by associates or family members.

To address these DME enrollment vulnerabilities, OIG recommended more rigorous screening of provider and supplier applicants. Heightened screening measures for high-risk items and services could include requiring providers to meet accreditation standards; requiring proof of identity and licensure (e.g., fingerprinting, database checks, and in-person interviews); requiring proof of business integrity or surety bonds; periodic recertification and onsite verification that conditions of participation have been met; and full disclosure of ownership and control interests, including disclosure of affiliations with other providers or suppliers with uncollected Medicare or Medicaid debt. As this additional screening would be costly for CMS to conduct, OIG suggested that CMS

consider charging application fees to cover the increased costs. In addition, OIG has suggested that establishing a provisional enrollment period during which new Medicare and Medicaid providers and suppliers would be subject to enhanced oversight, such as prepayment review and payment caps could reduce fraud vulnerabilities.

The Department has made progress in responding to these vulnerabilities with measures aimed at enhancing enrollment standards for DME suppliers. On November 1, 2007, the Centers for Medicare & Medicaid Services (CMS) began a demonstration project requiring DME suppliers in south Florida and southern California to reapply for participation to maintain their privileges. On January 25, 2008, CMS published regulations to clarify and enhance supplier standards. CMS also stated that it would consider seeking legislative authority to impose temporary moratoriums on supplier enrollment. On January 1, 2009, CMS published regulations requiring certain DME suppliers to obtain surety bonds as a prerequisite for enrolling and maintaining enrollment in the Medicare program. OIG recognizes this progress and continues to recommend further improvements to oversight and enforcement of provider enrollment standards.

In other work, OIG investigations identified a fraud scheme involving foreign nationals who obtained Medicare provider numbers that they subsequently 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 subsequently 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 surveyors examine the Employment Eligibility Verification document (Form I-9) for the owner and key employees as part of the accreditation process. Until the vulnerabilities demonstrated by this fraud scheme are addressed, Medicare continues to risk exposure to fraudulent claims by ineligible providers.

The Department also faces challenges stemming from the variation in Medicaid provider and supplier enrollment standards, which can vary both across States and for providers within a State. An OIG evaluation of State Medicaid enrollment requirements for personal care attendants found that State Medicaid programs established multiple sets of provider requirements for personal care attendants that often vary among programs and by delivery models within programs, resulting in 300 sets of provider requirements nation-wide. An OIG audit of Medicaid

personal care services in New York City underscores the importance of enrollment standards and oversight of personal care service attendants to ensure beneficiary safety and quality of care. As part of the audit, OIG interviewed 65 beneficiaries, of whom 40 reported problems with their personal care services attendant or agency or other problems. The reported problems ranged from personal care attendants' engaging in activities unrelated to beneficiary care while on duty to beneficiary abandonment to physical abuse.

In addition, OIG identified challenges related to nursing home ownership transparency. (See also Management Issue 6.) 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. OIG has ongoing work determining whether nursing homes conduct criminal records background checks for employees and whether nursing homes are protecting residents from unqualified or excluded individuals.

Provider and Supplier Eligibility for Certain Payments

Eligibility requirements for certain types of payments help ensure that the providers furnishing items and services to beneficiaries can be relied on to deliver the needed care and meet program criteria. OIG identified instances in which Medicare and Medicaid made payments to providers who were improperly enrolled or were not eligible to receive those payments. These conditions raise concerns about enrollment oversight.

For example, in a review of Medicare capital disproportionate share hospital (DSH) payments made between FYs 2000 and 2006, OIG found that 397 hospitals received \$21.9 million in 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 to receive DSH 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 in-patient psychiatric services because it did not demonstrate compliance with two special Medicare conditions of participation requirements.

OIG audits at two Medicare fiscal intermediaries found that unallowable payments totaling \$890,000 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 and fiscal intermediaries to assess capital DSH eligibility as part of their review process. 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.

Management Issue 2: Integrity of Federal Health Care Program Payment Methodologies

MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

The Federal Government should act as a prudent purchaser of health care. Medicare and Medicaid payment methodologies should ensure access to quality care without wasteful spending. This objective is of paramount importance in maintaining an effective and efficient health care delivery system. The challenges associated with meeting this objective are complex and evolving. Initial payment methodologies must be set to reimburse 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 should anticipate financial incentives and safeguard against fraud risks associated with each payment methodology established.

Setting Initial Payment Methodologies

As Federal health care programs are created, expanded, or revised, it is critical to establish initial payment rates based on the most accurate data available, as well as reasonable assumptions and projections. OIG has identified instances in which issues with the initial data used in payment methodologies have resulted in increased expenditures by both Medicare and its beneficiaries.

For example, aligning Part D payments by Medicare and beneficiaries with plan sponsors' actual costs has been a challenge. Currently, Medicare payments and beneficiary premiums are determined based on bids submitted by plan sponsors and approved by CMS before to the start of the plan year. Ongoing OIG work has found that plans excluded some anticipated rebates from their bids, resulting in a higher net bid amount and therefore higher Medicare payments and beneficiary premiums than if the anticipated rebates had been included. In another review, OIG found that 25 percent of CMS's bid audits of Part D plans for 2006 and 2007 identified at least one material error. Although these audits may influence future bids, they are completed after the bids have been approved for the current plan year. CMS does not adjust a plan's payment amount or beneficiary premiums based on errors

or omissions identified after a bid has been approved. OIG has recommended that CMS hold plans accountable for the accuracy of their bids, and CMS stated that it would consider OIG's recommendation.

In 2006 and 2007, estimated costs in sponsors' bids were higher, in the aggregate, than their actual costs, which resulted in higher Medicare payments and premiums. Medicare recoups a percentage of these higher payments through the reconciliation process following the plan year. Beneficiaries do not recoup any money paid in higher premiums. In 2006, Part D sponsors owed Medicare a net total of \$4.4 billion. In 2007, 154 sponsors owed Medicare a total of \$1.81 billion and 97 sponsors were owed \$1.79 billion from Medicare, resulting in a net total of \$18 million owed to Medicare. Seventy-one percent of sponsors earned unexpected profits in 2007 large enough to trigger risk-sharing payments of \$795 million due to Medicare. Statutory changes to risk sharing that begin with the 2008 reconciliation will decrease the Federal Government's share of sponsors' unexpected profits and losses. Therefore, if sponsors continue to make large unexpected profits in 2008 and beyond, they will return a smaller percentage to the Federal Government. To mitigate this risk, OIG recommended that CMS determine whether changes to the risk sharing are appropriate, and if so, to seek a statutory change.

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. CMS noted, however, that it does not believe that changes to risk sharing are appropriate because plans now have sufficient data on Part D costs to develop bids that are more accurate.

Concerns about the accuracy of Medicare's prospective payments to hospitals also demonstrate the importance of setting appropriate initial reimbursement methodologies. For example, the *Balanced Budget Act of 1997* required CMS to develop a prospective payment system for hospital out-patient department services based on prior claims and cost report data. However, previous OIG work had identified unallowable costs in hospitals' Medicare cost reports and several areas of payment improprieties in Medicare reimbursement for hospital out-patient departments. Because the hospital out-patient prospective payment system is based on data known to be problematic, OIG is concerned that the resulting payments are inaccurate.

OIG reviews have also determined that Medicare payments for certain DME do not accurately reflect the costs of these products. Before 1986, Medicare paid DME suppliers the amounts that the suppliers billed. In 1986, a DME fee

schedule was created, which was based on the average prices that Medicare had paid (i.e., the billed amounts) for each type of equipment. This system has resulted in Medicare payments that do not reflect market prices. For example, OIG found that Medicare allows more than \$7,000 for 36 months of rental payments for oxygen concentrators that cost \$587, on average, to purchase. OIG has recommended that CMS consider working with Congress to reduce the rental period so that Medicare payments more accurately reflect market prices.

CMS's main initiative to reduce beneficiary costs and improve the accuracy of Medicare payments for certain categories of DME is the Competitive Bidding Acquisition Program. Although CMS started to implement the program in 2008, legislation delayed its implementation. CMS plans to restart the program in 2009 in 10 areas, which CMS expects to result in an average 26-percent decrease in the prices of medical equipment in these areas.

Payments to Medicare Advantage organizations may also be higher than necessary. Based on numerous reviews of the Medicare + Choice program (the predecessor to Medicare Advantage), OIG concluded that the data and estimates used as the basis to calculate monthly capitation payments were flawed, resulting in higher payments. This inflated base year data continue to affect the current payments to Medicare Advantage plans, which have not been adjusted to take into account these problems with the underlying data. OIG plans to further examine payments to Medicare Advantage organizations.

Responding to Changes in the Marketplace and Health Care Practices

The Department also faces a substantial challenge to react swiftly and appropriately to changes in the marketplace and medical practices so that the programs continue to effectively reimburse for quality care. OIG has conducted extensive 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 payments for new wound therapy pumps provide one example of the costs of failing to update payments in response to market changes. OIG found that in 2007, Medicare reimbursed suppliers for negative pressure wound therapy pumps based on a purchase price of more than \$17,000, but that suppliers paid, on average, approximately \$3,600 for new models. When Medicare first covered wound pumps, it covered only one model, manufactured and supplied by one company, and Medicare based the payment on that company's purchase price. When Medicare expanded its coverage to several new pump models, it continued to reimburse suppliers for these new pumps based on the original pump's purchase price,

which is more than four times the average price paid by suppliers for new pumps.

OIG has also raised concerns regarding Medicaid and Medicare Part B prescription drug reimbursement. OIG studies have revealed that published prices used to set Medicaid Federal upper limit (FUL) amounts for multiple source (generic) drugs often exceeded prices available in the marketplace. A new FUL reimbursement methodology using average manufacturer price, a sales-based price used in the Medicaid drug rebate program, has been established but not implemented because of a court injunction. Therefore, FUL amounts continue to exceed marketplace prices. In addition, OIG work has demonstrated that Medicare payment rates for some Part B drugs are higher than other prices in the marketplace. Further, the Part B drug reimbursement methodology can result in temporarily inflated payment amounts when newly available generic versions enter the market. To date, no changes have been made to Part B reimbursement as a result of OIG's work.

Payment methodologies for other Medicare benefits also present challenges in responding to marketplace changes. For example, OIG found that Medicare Part B payments for laboratory tests, which were established over 20 years ago, vary within and between Medicare contractors. These variances did not appear to reflect geographic differences in costs. To align payment methodologies, OIG recommended that CMS seek legislation to establish a new process for setting accurate and reasonable payment rates. CMS did not concur with this recommendation. However, CMS stated that it would consider OIG's recommendation as the agency continues to monitor the effects of its current payment policies.

OIG also 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. These misalignments in global eye surgery payments are attributable, in part, to CMS 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.

Payment Incentives and Risks of Fraud and Abuse

Payment methodologies inherently create incentives and risks for fraud. For example, Fee-for-Service (FFS) payments create financial incentives to maximize the number and complexity of services provided, even when such services are not medically necessary. Conversely, under a fixed, prospective payment system, financial incentives encourage fewer services and patients may not receive all of the care that they need and for which the

program is paying. For any payment methodology, it is imperative to identify the incentives and associated risks that it creates and to implement necessary safeguards to remediate the negative incentives and reduce fraud risks. This challenge is compounded by the need to react swiftly to new and unanticipated fraud and abuse schemes that exploit vulnerabilities in established payment methodologies.

OIG's work on Medicare and Medicaid outlier payment highlights the importance of this challenge. Recent investigations have identified abuses of CMS's home health outlier payment methodology, which has resulted in providers' receipt of significant outlier payments to which they are not entitled. Ongoing OIG work is further examining vulnerabilities related to this payment methodology. In response to evidence of abuse of home health outlier payments, CMS proposed a rule in July 2009 that would lower the total amount of home health outlier payments available and would cap outlier payments to individual home health agencies. Implementation of this rule could provide an important safeguard to prevent abuse of the home health outlier payment system.

Similarly, OIG found in prior work that Medicare payment methodologies for in-patient outlier payments had loopholes whereby inflated charges submitted by hospitals and delays in fiscal intermediary financial analysis of hospital data resulted in hundreds of millions of dollars of wasteful spending. Policy changes were subsequently made and financial settlements with selected hospital groups were reached. OIG has also completed work in several States that has shown that if the 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 instance, Medicare had a policy of not paying for pre-admission diagnostic tests within 24 hours of the patient's admission to a hospital. OIG found that in response to this rule, hospitals were performing the tests shortly in advance of the 24-hour period. Although the timeframe was extended based on OIG recommendations to within 72 hours of admittance, subsequent OIG work showed that hospitals responded to this change in payment policy by performing the tests up to 2 weeks before the admittance date so that they could bill separately for those tests.

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 increase Medicaid drug reimbursement have resulted in significant

False Claims Act settlements. For example, in 2007, Aventis Pharmaceuticals, Inc., entered into a \$182.82 million civil settlement to resolve allegations that it falsified price reports and inflated its prices for products that it submitted to 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 involved States' requirements that hospitals return large portions of their disproportionate share payments to the States. This practice is contrary to the program's purpose 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.

Management Issue 3: 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 with program requirements prevents fraud, waste, and abuse in the programs and promotes program efficiency and economy. To ensure compliance, the Department must partner with health care providers. The Medicare program pays for care for 45 million beneficiaries rendered by 1.2 million participating providers and suppliers, including hospitals, physicians, nursing homes, practitioners, DME companies, and others. CMS processes 1.2 billion Medicare FFS claims annually, averaging 4.4 million claims each working day. In 2007, Medicare FFS payments totaled \$431.2 billion. Medicare is required to pay submitted claims within 30 days of receipt, and while all claims are processed electronically, Medicare contractors review fewer than 3 percent of claims before payment is made.

As a result, the Medicare and Medicaid programs rely on providers and suppliers to submit legitimate and accurate claims. 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. Further, a small number of dishonest providers and suppliers attempt to game the system by exploiting or circumventing payment and coverage rules. Effectively combating fraud, waste, and abuse includes ensuring a provider and supplier community that is well informed about the rules and actively engaged in compliance efforts.

The Costs of Noncompliance

Assisting health care providers and suppliers to adopt 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 billing and payment errors; higher quality of care; and 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 2009, improper FFS payments cost Medicare \$24.1 billion (7.8 percent error rate). OIG has identified inappropriate Medicare payments for specific services and products. (See also Management Issues 1, 2, 4, and 5.) For example, OIG found that 63 percent of Medicare-allowed claims for facet joint injections (used to diagnose or treat back pain) did not meet program requirements, resulting in \$129 million in improper payments. In the Medicaid program, OIG found that New York's Medicaid program paid more than \$545.4 million (\$275.3 million Federal share) to providers in New York City for personal care 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 schemes that have resulted in substantial costs to Federal health care programs. For example, investigations of alleged illegal marketing tactics by drug manufacturers have resulted in *False Claims Act* settlements of up to \$2.3 billion. (See Management Issue 8.) Further, 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 6.) 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 these CIAs based on the conduct and circumstances of the 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 preventing noncompliance. However, several factors create challenges to promoting industry compliance with program rules through education efforts. The 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. The 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.

Further, the audience for compliance education is diverse in terms of sophistication, size, and resources. Medicare providers range from sophisticated 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. In addition, 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 multifacility 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 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 CMS-sponsored education programs on requirements of the *Medicare Prescription Drug Improvement and Modernization Act of 2003*). CMS

is also exploring the use of new media, such as podcasts and RSS feeds, to reach provider and supplier audiences.

The Department also partners, and should continue to partner, 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. For example, as noted in Management Issue 6, OIG has worked with nursing home providers through roundtables that focus on how boards of directors can better monitor and ensure quality of care.

A challenge going forward is to determine which tools and approaches are the 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 are another method of fostering an industry culture of compliance and an ongoing 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 program beneficiaries that it serves.

One challenge, however, is that implementation of compliance programs is largely voluntary. Most Medicare and Medicaid providers are not required to adopt compliance programs. Three notable exceptions are Medicaid providers in New York, which are required by the State to implement effective compliance plans as a condition of Medicaid participation; Medicare Part D drug plan sponsors, which are required by statute to implement compliance plans; and individuals and entities that have entered into CIAs with OIG. In addition, several State laws impose 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 are widespread and can be very sophisticated; other sectors have been slower to adopt internal compliance practices and may have fewer resources to devote to compliance.

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

Where compliance programs are required, the Department faces challenges with overseeing adherence to and implementation of program requirements. For example, OIG has found that CMS has not provided sufficient oversight to ensure that Part D sponsors have implemented sufficient compliance plans. Specifically, OIG found that as of January 2006, all prescription drug plan sponsors had compliance plans in place but that only 7 of 79 plan sponsors met all CMS requirements for compliance plans. Sponsors' compliance plans contained only broad outlines of fraud and abuse plans and did not include details or describe specific processes. In its response to OIG's reports on drug plan sponsors' compliance plans, CMS indicated that it planned to conduct routine audits of Part D sponsors' compliance plans beginning in 2007. However, as of July 2009, CMS had conducted only a limited number of compliance plan audits.

Failure to implement effective compliance programs can be a contributing factor that enables fraud and abuse to go unaddressed. In follow-up to its Part D compliance plan review, OIG found evidence suggesting that plan sponsors need to improve the effectiveness of compliance programs in detecting and responding to potential fraud and abuse. Specifically, OIG found that in the first 6 months of 2007, 24 of 86 plan sponsors did not identify any potential fraud and abuse incidents, while a small number of sponsors identified hundreds of incidents. Seven plan sponsors accounted for 90 percent of the incidents identified. Further, OIG found that not all plan sponsors that identified potential fraud and abuse incidents conducted inquiries, initiated corrective actions, or made referrals for further investigation.

Looking forward, the benefits of promoting compliance—and the costs of noncompliance—will grow as beneficiary populations and health care costs increase. The Department faces challenges to effectively assist a large and diverse population of Medicare and Medicaid providers and suppliers in complying with program requirements. However, CMS is implementing several provider education efforts and exploring others. OIG will

also continue to provide compliance tools and resources to the provider community and work with the Department to meet this challenge.

Management Issue 4: Oversight and Monitoring of Federal Health Care Programs

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 trust-based system 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 critically important. However, a tension exists between 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 the Federal health care programs because they are large and complex, with increasing expenditures and growing beneficiary populations. The large size of the programs means that fraud, waste, and abuse in payments can result in substantial financial losses. Additionally, fraud, waste, and abuse schemes have become increasingly sophisticated, and criminals constantly adapt to the latest oversight efforts to avoid detection.

A key method to effectively identify fraud, waste, and abuse is the analysis of claims data. Although each program compiles an enormous amount of data on beneficiaries, providers, and the delivery of services, failing to effectively use these data for oversight and monitoring can result in the loss of scarce Federal health care dollars. Claims-processing and payment systems have traditionally relied upon claim-by-claim review. However, in many cases, fraud or abuse can be detected only by reviewing aggregated claims and billing patterns because each individual 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 prevent, detect, and respond to fraud, waste, and abuse. As discussed in more detail later in this Management Issue, 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 Comprehensive Error Rate Testing (CERT) program, OIG has raised concerns that the Medicare error rates for certain provider types may be

understated. For example, in FY 2006, CMS's CERT contractor estimated the Medicare error rate for DME to be 7.5 percent. However, in our review of the CERT program, we estimated the error rate in the CERT DME sample at 17.3 percent using the same methodology as CMS's CERT contractor. Further, using a different methodology, which entailed reviewing additional documentation, OIG found additional errors and estimated a 28.9-percent error rate of the sample. OIG attributed these review discrepancies to the CERT contractor's inadequate review of available documentation and reliance on clinical inference, CMS's inconsistent policies regarding proof-of-delivery documentation, and the agency's lack of procedures for obtaining information on high-risk DME items from beneficiaries. Similar problems affected the FY 2008 DME error rate. An independent contractor identified 142 additional errors that the CERT contractor had not counted as errors in a sample of 250 claims from the FY 2008 DME CERT sample. CMS reported that to address these problems, it will revise its manuals to clarify requirements and promote uniform interpretation of its policies by Medicare contractors, it has provided direction to the CERT contractor regarding the use of clinical judgment, and it plans to incorporate this clarification into the "Program Integrity Manual."

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.

Error rate reviews can identify important oversight vulnerabilities that result in improper payments. For example, OIG found that for the 6-month period ending June 30, 2006, approximately \$363 million (Federal share) in Medicaid payments and \$67.2 million (Federal share) in CHIP payments were made on behalf of beneficiaries who did not meet Federal and State eligibility requirements in three States. OIG has also identified CHIP eligibility errors outside the PERM process. Children eligible for Medicaid are not eligible for CHIP. OIG estimated that in 2006, at least 4 percent of children enrolled in separate CHIP programs in 36 States were eligible for Medicaid. The Federal matching rate for CHIP is higher than that for Medicaid. Enrollment errors can result in the inappropriate use of Federal matching funds and the expenditure of limited CHIP resources on Medicaid-eligible children.

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 identified numerous examples in which the 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 with monitoring programs for fraud, waste, and abuse.

Claims analysis can reveal providers' improper use of service and diagnostic codes to defraud programs. For example, OIG found that Regenerations, Inc., purportedly a mental-health-counseling agency employing high- and mid-level psychologists and counselors, billed for 84,000 psychotherapy services that were never rendered. Varnador K. Sutton, the sole owner and operator, used the identities of 2,500 Medicaid beneficiaries to defraud the Medicaid program. Sutton usually billed the same service code with the same diagnostic code for all the Medicaid beneficiaries. Once the fraud was detected, the investigation led to Sutton's conviction and sentencing to 10 years in prison and an order to pay \$3.3 million in restitution.

Claims analysis can also reveal instances when providers bill for more services than are physically possible. For example, in one of the largest civil fraud recoveries ever against a single U.S. hospital, Staten Island University Hospital agreed to pay \$88,916,448 in a global settlement resolving allegations that it defrauded Medicare and Medicaid. The OIG investigation identified potential fraudulent billing, among other allegations, of in-patient alcohol and substance abuse detoxification treatment for more beds than the facility was authorized by the State of New York.

Additionally, claims analysis can detect erroneous place-of-service or discharge codes, and implementing claims edits can reduce inappropriate payments resulting from such miscoding. In 2003, OIG identified over \$100 million in improper payments made to hospitals for erroneously coded claims that indicated patients were discharged to home when they actually were transferred to post-acute care. Medicare makes higher payments to hospitals on behalf of patients who are discharged to home compared to those on behalf of patients discharged to other settings, such as skilled nursing facilities. Consistent with OIG's recommendation, CMS implemented an edit to detect transfers improperly coded as discharges. In follow-up work, OIG determined that such overpayments were substantially lower following CMS's implementation of this edit.

Further, claims analysis can identify particular service areas in which providers submit questionable claims. For example, OIG found that in 2007, 20 counties that had only 6 percent of Medicare beneficiaries accounted for 16 percent of Medicare Part B spending on ultrasound services, suggesting possible fraudulent billing by

providers in these counties. Further, nearly one in five ultrasound claims nation-wide had characteristics, such as the lack of a prior office visit or other service claim from the physician who ordered the ultrasound service, that raise concern about whether the claims for \$403 million in Part B charges were appropriate. CMS concurred with OIG's recommendations to increase its monitoring of ultrasound claims and to further review questionable claims.

Through use of historical program data, OIG has identified improper Medicare and Medicaid payments and associated program vulnerabilities and recommended corrective actions. For instance, OIG found that five State Medicaid programs had claims from providers for more than 24 hours of personal care services in a day. Other recent findings include personal care services inappropriately billed during institutional stays, duplicate Medicare and Medicaid home health payments for medical supplies and therapeutic services, and improper FFS payments for services covered by capitated Medicaid managed care.

Challenges To Using Data Effectively

In some cases, program data are insufficient to support effective oversight and monitoring. For example, OIG found that Medicare data are insufficient to determine consistently whether Medicare Part B chemotherapy administration payments are appropriate. Specifically, 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. Additionally, OIG found that hospice claims do not collect information needed to determine whether hospice agencies comply with the requirement that they not be reimbursed for more than 5 consecutive days of respite care at a time. In another example, CMS and States do not maintain a primary level-of-care designation for nursing homes that could facilitate accurate claim submission by suppliers and proper claim adjudication by payment contractors.

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 with respect to DME, and OIG is looking into potential vulnerabilities in prescriber identifiers in Medicare Part D records. An OIG study found that Medicare allowed over \$6 million for DME claims with invalid Unique Physician Identification Numbers (UPIN) in 2007 of referring physicians. OIG also found that Medicare 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 National Provider Identification (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 new NPI system. In ongoing work, OIG is also examining whether prescription drug event records representing Medicare Part D claims include valid prescriber identifiers.

The Medicaid program has unique data challenges because key functions of program operations occur in States, rather than on a national level. The Medicaid Statistical Information System (MSIS) is currently the only source of nation-wide Medicaid claims information, and weaknesses in MSIS data limit its usefulness for oversight and monitoring of the program. For example, OIG found that CMS accepted submissions to MSIS from 15 State Medicaid agencies that lacked required managed care encounter data. Encounter data are the primary record of Medicaid services provided to beneficiaries enrolled in capitated Medicaid managed care. Further, 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. Moreover, 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.

OIG has also identified opportunities for State Medicaid agencies to improve their monitoring and oversight of claims. For example, in 2006 OIG found that providers in 8 of 10 audited States received an estimated total of \$27.3 million in Medicaid overpayments, which the States never recovered, for services claimed to have been provided after beneficiaries' deaths. Prepayment screening by some States did not successfully identify the overpayments because the States did not use all available information sources to identify deceased beneficiaries and their payment systems had data entry, matching, and processing problems.

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 both Medicare and Medicaid. Additionally, CMS has plans to enhance data systems available for use by these contractors.

For Medicare, CMS is transitioning program safeguard functions from its current Program Safeguard Contractors

and Medicare Drug Integrity Contractors 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 (Medicare Advantage health plans); and Part D (prescription drug data) and for coordinating Medicare-Medicaid data matches (Medi-Medi). As of October 2009, CMS had awarded four ZPIC contracts, with three additional contracts planned. While CMS expects that the new ZPIC model will have advantages over the previous model, transitioning from one model to another presents implementation challenges in contracting and in transferring data and responsibilities from one contractor to another.

In 2003, Congress authorized the Department to establish a demonstration program for Recovery Audit Contractors (RACs) for the purpose of identifying underpayments and overpayments and recouping 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 nation-wide and permanent basis. These RACs will cover all 50 States by 2010. CMS reported that the RAC demonstration project successfully returned almost a billion dollars to Medicare, represented a new mechanism for detecting improper payments, and provided CMS with a tool for preventing future improper payments. CMS will require RACs to help develop plans designed to address vulnerabilities identified during their reviews. OIG is determining whether the demonstration RACs have referred cases to law enforcement. OIG and CMS are working together to ensure appropriate referrals of suspected fraud under the permanent RAC program.

As part of the Medicaid Integrity Program, CMS has recently hired contractors to perform data analysis to detect aberrant billing patterns and to audit claims to identify improper payments. In addition, the Medicaid Integrity Group is working to develop a Medicaid data engine to combine State Medicaid claims data to facilitate detection of fraud, waste, and abuse. Further, CMS plans to enhance the data available to monitor payment accuracy and integrity across the Medicare and Medicaid programs. To this end, CMS is working to develop an Integrated Data Repository (IDR), which would warehouse data on Medicare Parts A, B, and D and DME, as well as Medicaid. To this end, in 2007 CMS began developing an Integrated Data Repository (IDR), which CMS indicates will eventually contain all Part A, Part B, DME, HHA, and key Part D data, as well as Medicaid. The prospect of such a comprehensive data warehouse holds considerable

promise for detecting and preventing fraud, waste, and abuse; however, the system is still under development.

Despite the progress described and plans for future enhancements, the Department needs to make continued improvements in oversight and monitoring to meet the challenges identified. 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 5 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 draw and analyze claims and provider data across Medicare Parts A, B, C, and D and Medicaid.

Management Issue 5: 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 upon an extensive range of regulations, program requirements, and payment methodologies, which 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. Similarly, Medicaid and CHIP have their own unique systems and contractors. Further, the programs collectively 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 an identified vulnerability, which can result in significant monetary losses before an appropriate remedy or sanction is applied.

OIG's work has identified fraud and vulnerabilities across many areas of the Department's health care programs. See also Management Issues 1-4. 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 moved virally through communities and across the country. Law enforcement may respond with criminal prosecutions in one jurisdiction only to see the scheme transplanted and 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 the Federal health care programs. In the face of this significant management challenge, the Department brings to bear a law enforcement response through OIG and a programmatic response through CMS.

Law Enforcement Response

On May 20, 2009, the Secretary and the Attorney General for the United States Department of Justice announced the creation of the Health Care Fraud Prevention and Enforcement Action Team (HEAT) joint task force to combat health care waste, fraud, and abuse. Among other activities, HEAT is building on the successful Medicare Fraud 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 to identify criminals operating as health care providers and detect emerging or migrating fraud schemes.

One goal of the Strike Forces is to decrease the time between the Government's detection of a fraudulent scheme and the arrest and prosecution of the offenders. The Strike Force model is designed specifically to address the challenges to quick response and has proven to be particularly effective against schemes that have been spread quickly and virally in local communities, where criminals have discovered how to circumvent program controls and then quickly replicate the schemes. By creating organized teams of prosecutors and Federal, State, and local, the Strike Force brings a high level of coordination among law enforcement authorities. This increased coordination, combined with rapid Medicare billing analysis and close relations with financial institutions, is intended specifically to accelerate the Government's response to fraud schemes. Equally important, the Strike Force attempts to identify program weaknesses and lessons drawn from these cases and to communicate rapidly those program vulnerabilities, along with recommendations for improvement, to CMS. Strike Force teams are operating in Miami, Los Angeles, Detroit, and Houston. As of September 30, 2009, Strike Force efforts have resulted in the filing of charges against 423 individuals or entities, 187 convictions, and \$226 million in investigative receivables.

The Strike Force model provides significant benefits and has produced substantial results and return on investment; yet, even this model continues to face challenges in responding quickly and effectively to fraud. For example, the success of a Strike Force depends upon having timely access to claims data, which enables law enforcement to respond quickly to stop fraudulent billing and recover stolen funds before the perpetrators have fled. However, in some cases, timely access to data has been impeded by variations between how quickly contractors can respond, contract limitations, competing data requests, and other operational challenges. In some cases, data may not exist in a usable form across different service areas, making it harder to identify fraud schemes. Although efficient, the Strike Forces depend upon having prosecutors and agents available to pursue the cases and resources are limited.

In addition, not all types of fraud may lend themselves to a Strike Force model of enforcement. The model appears most effective when fraud is concentrated geographically and among particular services and provider types. This tends to occur among providers/services with low barriers to entry, such as DME, home health, physical/occupational therapy, and infusion therapy, and often includes fraudulent schemes, such as billing for services not rendered and kickbacks to providers or beneficiaries. Yet law enforcement responds to many other types of health care fraud and vulnerabilities, including complex corporate frauds; document-intensive cases against pharmaceutical manufacturers for false claims arising from off-label drug marketing and other violations; serious quality-of-care violations; cases involving difficult issues of medical necessity; and cases arising in rural, as well as urban, areas across the country.

Federal Health Care Program Responses

Law enforcement alone will not eliminate fraud and abuse; yet even where vulnerabilities are accurately identified, it can be a significant challenge for the Department to respond effectively and ensure that the problems are corrected. For example, during the 2007 unannounced site visits to DME suppliers in south Florida (described in Management Issue 1), OIG found that 491 of the suppliers failed to meet Medicare standards; CMS revoked these suppliers' 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 have subsequently had their privileges revoked, and some individuals connected to reinstated suppliers have been indicted. OIG found that because there are no criteria regarding the types of evidence necessary to reinstate providers' billing privileges, hearing officers made their decisions based on a variety of evidence. CMS agreed that it should consider establishing consistent guidelines regarding the evaluation

of evidence that a hearing officer will review during the appeal process, and this will be a challenge for the Department going forward. OIG intends to assess other Medicare contractors' use of enrollment screening mechanisms and post-enrollment monitoring activities 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 in this area.

In a 2007 review, OIG found that CMS had limited success in controlling the aberrant billing practices of south Florida infusion therapy providers. CMS and its contractors have used multiple approaches, but none has proven effective over time. CMS may take action against a particular provider billing number, such as a payment suspension, billing number revocation, or requirement for prepayment review. Each of these tools has limitations with respect to its administrative burden and its ability to prevent payment for fraudulent claims. One limitation of all these tools is that they apply to specific provider billing numbers; however, fraudulent providers often bill using multiple billing numbers, sometimes steal billing numbers from legitimate providers, and may reapply for new billing numbers using false information (see related discussions in Management Issues 1 and 4). Further, claims-processing edits have been effective in responding to aberrant billing in the short term but have not had lasting effects. Although edits have reduced payments for particular codes, aberrant billers tend to switch to new codes, undermining the edits' overall effectiveness.

Another challenge for the Department is to respond to detected vulnerabilities by suspending payments to providers upon credible evidence of fraud. Payment suspension must be used judiciously with safeguards to protect the rights of providers while also protecting the programs. This is critical in an environment where claims are submitted electronically and paid electronically and large sums of money may be paid by the Government in a very short period of time if the payment suspension is not implemented in a timely manner. This challenge is heightened because when defendants challenge CMS's legal authority to suspend payments, the Government often cannot reveal the source of its investigative information to the target in the midst of the fraud investigation.

The Department, including OIG, must continue to work with its many partners to respond to vulnerabilities in the current 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 known vulnerabilities and weaknesses. OIG's "Compendium of Unimplemented Recommendations" includes many significant

vulnerabilities and recommended responses requiring action by the Department or Congress. The Department, including OIG, must also continually identify new risks posed by the changing dynamics of Federal health care programs and the evolving nature of fraud and abuse schemes as well as effective responses to remediate those risks.

Management Issue 6: 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 of the Federal health care programs do not receive substandard care and are not subject to abuse and neglect. The Department also faces challenges in adopting tenets of the patient safety movement, which focuses on improving care delivery systems through quality improvement initiatives, measurement, and reporting.

Oversight of Compliance with Existing Quality Standards

Overseeing compliance with existing quality standards through certification and accreditation processes represents a challenge for the Department. Ensuring that hospitals, skilled nursing facilities, and home health agencies, among other provider types, meet those standards is an enormous undertaking, but necessary to afford the public some external assurances about the adequacy of care practices, systems, and physical facilities.

Ensuring quality care for nursing home residents continues to be a significant challenge. For example, in 2008, OIG determined that over 90 percent of nursing homes surveyed for compliance with Federal regulations were cited for deficiencies, most commonly for quality of care, resident assessment, and quality of life. OIG is currently conducting a related study looking at skilled nursing facilities' compliance with regulations regarding resident assessment, care planning, and discharge planning. In other ongoing work, OIG is examining atypical antipsychotic drugs that are prescribed for nursing home residents.

In addition, OIG is examining quality of care issues in home and community-based settings. In 2008, OIG reviewed home health agencies with patterns of noncompliance. Fifteen percent of home health agencies were cited for the same deficiency on three consecutive surveys. OIG also found that CMS oversight could be improved by using historical information about

deficiencies to identify at-risk home health agencies. OIG is currently reviewing whether Medicaid-funded home- and community-based waiver programs and assisted living facilities comply with State and Federal requirements to ensure the health and welfare of service recipients.

The Department has made some progress in ensuring that providers comply with existing quality standards. For example, CMS continues to expand its Special Focus Facility (SFF) program and plans to increase the number of SFF nursing homes beginning in FY 2010. Under the SFF program, nursing homes with the worst survey performance undergo enhanced monitoring. OIG plans to review CMS oversight of poorly performing nursing homes, including SFFs. CMS has also tasked its Quality Improvement Organizations (QIO) to work with providers on improving their performance on specific clinical measures related to patient safety and disease prevention. The agency is rolling out a revised nursing home survey process, called the Quality Indicator Survey. CMS reports that 16 States are using this enhanced, data-driven survey process. CMS also reports that it has drafted a proposed rule that will establish requirements for unannounced, standard, and extended surveys of home health agencies and provide for various intermediate sanctions

Protecting Beneficiaries From Substandard Care and From Abuse and Neglect

Protecting beneficiaries of Federal health care programs from substandard care and from abuse and neglect by providers is an ever-present challenge for the Department. Identifying and addressing instances of substandard care is a central part of this challenge.

OIG investigations and enforcement cases demonstrate that some beneficiaries receive substandard care or are abused and neglected by providers. To illustrate, in August 2008, Grant Park Care Center, a skilled nursing facility in the District of Columbia, agreed to pay \$2 million to resolve OIG allegations that it failed to provide basic nursing care to many residents, resulting in serious patient harm. In June 2008, OIG alleged that Ivy Ridge Personal Care Center in Pennsylvania physically abused residents and denied them necessary food and medicine. As a result of OIG's investigation, the home was closed and OIG excluded the owner from participating in Federal health care programs.

Complex ownership arrangements that include multiple layers of entities present a particular challenge for holding nursing home owners accountable for substandard care. OIG investigations have found instances in which nursing home owners have used such arrangements to avoid accountability for failing to provide necessary and required care. Through these complex corporate structures, owners divert funds from resident care. While investigating

nursing homes for substandard care, OIG found 1 facility with as many as 17 limited liability companies that played a role in the facility's operations and ownership.

The Department's primary program for addressing substandard care is Medicare's QIO program. The QIO program includes, among other things, medical review of beneficiary complaints and quality improvement activities. However, in a 2007 report, OIG found that only 11 percent of cases reviewed by QIOs were for quality-of-care concerns and that QIOs rarely initiated sanction activity after confirming a quality-of-care concern. Moreover, in OIG's experience, QIOs routinely fail to respond to OIG referrals regarding beneficiary care.

The Department has several other programs and initiatives to help ensure that beneficiaries are free from abuse and neglect. The Department relies, in part, on the State Medicaid Fraud Control Units, which are funded on a 75-percent matching basis by the Department, to investigate and address abuse and neglect in State-regulated Medicaid facilities. In addition, Congress recently renewed and expanded CMS's seven-State Background Check Pilot Program, which is intended to identify efficient, effective, and economical procedures for checking the backgrounds of employees with direct access to patients. OIG is currently evaluating whether and to what extent nursing facilities employ individuals with criminal convictions.

The Patient Safety Movement and Incentives for Quality Improvement

The Department faces challenges in adopting tenets of the patient safety movement, which focuses on quality improvement, measurement, root cause analysis, and public reporting, in a manner consistent with its own mission and responsibilities as a purchaser of health care.

OIG's recent work underscores the significance of this challenge. For example, OIG reported on the extent to which States have established adverse event reporting systems, finding that only half the States have adopted systems. Further, States collect different types of events and lack consistent definitions, which create substantial challenges to compiling State data to develop benchmarks. In a case study of two counties, OIG found that about 15 percent of hospitalized Medicare beneficiaries experienced adverse events that resulted in harm. OIG is currently expanding this work to calculate a national incidence rate of adverse events for the Medicare population and will examine the incidence of adverse events for Medicaid recipients. OIG is also assessing issues associated with public disclosure of adverse event information and reviewing the early implementation of CMS's nonpayment policy for select hospital-acquired conditions.

The Department also faces a challenge in working with various types of health care providers to ensure that they are knowledgeable about and consistently implement quality improvement processes. Recent OIG efforts promoted providers' incorporation of quality assurance and improvement into voluntary compliance programs. For example, OIG sponsored two roundtables, one with the long-term care industry and one with the hospital industry, to explore how best to involve boards of directors and trustees in quality matters. For providers with multiple locations, OIG's work has stressed the importance of company-wide and corporately driven quality assurance and improvement systems, as opposed to relying solely on facility-based programs.

The Department has implemented a number of programs as part of the ongoing challenge to become a more prudent purchaser of quality health care. For example, CMS's value-based purchasing initiative links enhanced payments to reporting quality measures. To report these measures publicly and move toward rewarding providers based on performance, however, CMS must ensure that reported data are complete and accurate. Looking forward, OIG will examine hospitals' controls regarding the accuracy of data reported to CMS. OIG will also begin to review CMS's pay-for-performance initiatives, which are unfolding in varied settings. As an increasing number of States implement pay-for-performance systems in Medicaid, OIG will also determine whether States have sufficient controls to ensure appropriate incentive payments in Medicaid programs aimed at rewarding high-quality care.

CMS is also conducting demonstrations to improve care for individuals with chronic diseases, to improve the quality of transitional care, and to prevent unnecessary hospital readmissions. Looking forward, OIG will analyze hospital readmissions.

The Department continues to play a leadership role in making quality-related data, such as hospital, nursing home, and dialysis ratings, available to consumers. In 2009, CMS began posting its Five-Star Quality Rating System on the Nursing Home Compare Web site, which rates nursing homes on a variety of quality measures. In addition, QIOs provide technical assistance concerning quality improvement processes and best practices to different providers. The Agency for Healthcare Research and Quality (AHRQ) has also made considerable progress in implementing Patient Safety Organizations, which will play an important role in collecting and studying data regarding adverse events. CMS reports that in Medicaid and CHIP, CMS is working with AHRQ to increase the quality and transparency of information available regarding

children's health care and identifying children's measures that can be reported from a hospital setting.

Future Challenges

The population is aging and the delivery of health care is evolving because of new technologies and evolving payment methodologies. As a result, ensuring that beneficiaries receive quality care in all settings will become even more complex in the years ahead. The increased use of health information technology and electronic health records also holds promise to improve the quality of care within and across settings. CMS reports that health information technology and electronic health records are a focus for Medicare, Medicaid and CHIP. However, these developments may also present their own unique challenges that have yet to be identified. For more information on issues associated with health information technology, see Management Issue 11.

PART 2: INTEGRITY OF THE DEPARTMENT'S PUBLIC HEALTH AND HUMAN SERVICES PROGRAMS

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

Management Issue 7: Emergency Preparedness and Response

MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

Events like Hurricanes Katrina and Rita, and more recently 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 public health emergencies. The ability to effectively prepare for and respond to a public health emergency requires planning, coordination, and communication across a wide 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 organizational structures poses unique and unprecedented demands on the Department.

Since 2002, the Department has provided over \$8 billion to States and localities through various programs to enhance their emergency preparedness activities and to better enable them to respond to large-scale, natural or man-made public health emergencies, such as acts of bioterrorism or

infectious disease outbreaks. (See Management Issue 8 for discussions of preparedness for and response to food-borne illness and related emergencies.) In its January 2009 Pandemic Influenza Preparedness Spending Report to Congress, the Department cited its progress in enhancing the Nation's pandemic preparedness by making strides in the development and production of vaccine antigen and new adjuvants for avian influenza (H5N1), which was the focus of pandemic influenza planning prior to the April 2009 outbreak of the H1N1 virus. The Department has also continued to work with States to improve their preparedness. However, OIG work assessing preparedness as recently as summer of 2008 shows both progress and the need for significant improvements to the public and private sectors' preparedness and response to public health emergencies.

State and Local Emergency Preparedness Planning

The Department provides guidance to States and localities on the development of emergency preparedness plans. Documented emergency preparedness plans that are cohesive and contain sufficient detail are critical for ensuring that States and localities are prepared for a public health emergency. However, variations in State and local health department structures and the size of populations they serve make it difficult to provide Federal guidance to prepare for an event, such as an influenza pandemic.

In its evaluation of the Nation's pandemic influenza preparedness, OIG found that the majority of States and localities OIG reviewed had begun emergency preparedness planning efforts; however, more planning is needed. For example, in its evaluation of the States' and localities' medical surge preparedness, OIG found that most of the selected localities had not identified guidelines for altering triage, admission, and patient care during a pandemic, as recommended. In its evaluation of preparedness to distribute and dispense vaccines and antiviral drugs during a pandemic, OIG found that selected localities had not addressed in their planning documents most of the items identified in Department guidance. Based on the findings from its pandemic influenza preparedness work, OIG recommended that the Department work with States to help localities improve their preparedness. In response to these recommendations, the Office of the Assistant Secretary for Preparedness and Response (ASPR) stated that it has undertaken a number of activities to improve States' and localities preparedness including updating its Medical Surge Capacity and Capability Handbook to further assist State health care system planning efforts in the event of a pandemic.

Some States and localities have established adequate planning documents; however, they vary in the extent to which they exercise their emergency plans and address lessons learned. For instance, in its review of States' and

localities' medical surge readiness, OIG found that all of the selected localities conducted medical surge exercises; however, none consistently documented the lessons learned from these exercises. OIG had similar findings in its review of vaccine and antiviral drug distribution and dispensing. As a result, OIG recommended that the Department ensure that States and localities consistently document their exercises and lessons learned from the exercises to improve their preparedness. ASPR stated in FY 2009 that it implemented a new standardized reporting template to improve health care system exercise documentation and data collection.

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

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 response. These threats include anthrax, influenza, nerve agents, and food-borne 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, findings from OIG's work reveal potential vulnerabilities in the Nation's preparedness to respond to these biological and chemical threats.

For example, weaknesses exist in our 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.

Additionally, OIG reviewed Department and external laboratories for 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 many laboratories did not adequately safeguard the agents against theft or loss. Further, in its audits at universities, as well as public, private, and Department laboratories, OIG found problems with recordkeeping, access controls, or training, among other findings. Moreover, through its authority to impose civil monetary penalties against entities that violate select agent regulations, OIG has collected approximately \$1.8 million in civil monetary penalties for violations, such as conducting unauthorized research with select agents, taking inadequate precautions in shipping select agents, storing toxins in an unsecured area before transfer, and allowing unauthorized individuals access to select agents.

OIG is currently reviewing CDC's CHEMPACK project, which places nerve agent antidotes in monitored storage containers in cities and States for immediate use in the event of a chemical emergency. In its review, OIG will determine the extent to which nerve agent antidotes were stored at the temperatures required by the Food and Drug Administration (FDA). OIG will also review the extent to which the CDC implemented procedures to ensure the quality of nerve agent antidotes in the CHEMPACK project.

Lessons Learned From Real-Life Events

It is important that both the public and private sectors prepare for large-scale public health emergencies, and it is equally important that they 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 events.

For example, as efforts continue in restoring the health care infrastructure in and around New Orleans after the Gulf Coast hurricanes, OIG continues to examine the Department's disaster response to these events to highlight potential vulnerabilities and lessons learned. OIG reviews of the response to the Gulf Coast hurricanes revealed weaknesses in certain health care entities' ability to respond to a public health emergency. For instance, OIG's review of nursing homes in five Gulf Coast States found that all the nursing homes reviewed experienced problems with implementing emergency plans or impromptu decision making. Specifically, problems in the nursing homes arose because of ineffective emergency planning or failure to execute the emergency plans properly. Administrators and staff from selected nursing homes did not always follow emergency plans during hurricanes during our period of review because plans were not up-to-date or did not include instructions for particular circumstances. Further, plans often lacked components suggested by Department guidance. 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. OIG is currently conducting a follow-up evaluation of this study.

Similarly, in its review of the United States Public Health Service Commissioned Corp's response to Hurricanes Katrina and Rita, OIG found that the Corps provided valuable support to the States but that it could improve its response to public health emergencies. Particularly, OIG found that many deployed officers met Corps readiness standards but lacked experience, effective training, and familiarity with response plans. OIG recommended that the Corps stagger deployments to ensure that experienced officers were in the field. OIG also recommended that the Corps implement more training for Corps officers. As of March 2009, the Corps had implemented all the recommendations noted in this evaluation, including developing more effective officer training programs and staggering deployments to ensure continuity of operations.

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 regarding this management issue, the Department should provide additional guidance to States and localities to improve their public health emergency preparedness.

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

MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

Ensuring the safety and security of the Nation's food supply, human and veterinary drugs, and medical devices represents a significant challenge for the Department. That challenge includes responding to emergencies related to food safety, which often involves multiple State and Federal public health agencies. It also includes protecting the rights, safety, and well-being of human subjects who participate in clinical trials conducted here and abroad for the products the Department regulates. It also includes ensuring that medical products, once proven to be safe and effective, and foods that are safe and lawful, are labeled and advertised appropriately. The increasingly globalized market for food, drugs, and medical devices elevates the significance of these challenges.

Oversight of Food Safety

OIG reports have underscored the challenges that FDA faces in tracing food through the distribution chain during a food emergency and in monitoring food recalls. For

example, OIG conducted a food traceability exercise and found that only 5 of the 40 products that OIG purchased could be traced through each stage of the food supply chain back to the farm or border. In addition, 59 percent of selected food facilities did not comply with FDA's recordkeeping requirements, and those requirements were insufficient to ensure the traceability of the food supply. In another review, OIG found that FDA lacks the statutory authority to require manufacturers to initiate pet food recalls and did not always follow its procedures in overseeing the recall of pet food tainted with melamine. Furthermore, FDA's procedures were not always adequate for monitoring recalls as large as those required in the pet food incident. These challenges related to recordkeeping, traceability, and recalls are significant because more than 300,000 Americans are hospitalized and 5,000 die yearly after consuming contaminated foods and beverages. In a food emergency, FDA is responsible for finding the contamination source and overseeing the voluntary removal by the manufacturers of the food products from the supply chain.

Looking forward, OIG is reviewing FDA's inspections of food facilities, its oversight of contractors that conduct those inspections, its oversight and operations related to imported food and feed products, its recall procedures for human food, and the extent to which it tested human food for contamination from melamine and other contaminants.

The Department has made progress toward ensuring the safety of our Nation's food supply, and toward that end, in March 2009, the President created the Food Safety Working Group. The group, chaired by the Secretaries of this Department and the Department of Agriculture, will foster coordination throughout the Government and work toward modernization of food safety laws for the 21st century by building collaborative partnerships with consumers, industry, and regulatory agencies. Among its priorities is establishing an incident command system to link relevant agencies in emergencies. In addition, 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.

Oversight of Drugs and Medical Devices

OIG's recent work highlighted the challenges FDA faces in reviewing generic drug applications in a timely manner. Generic drug applications increased at more than double the rate of FDA's review resources in the last 5 years. In a 2008 report, OIG found that FDA disapproved 96 percent of original generic drug applications under review in 2006 because they did not meet FDA review standards. Furthermore, FDA exceeded the 180-day review for nearly half of the original generic applications. FDA has implemented some changes that are consistent with OIG recommendations to improve the generic drug approval

process. Specifically, FDA recently published a final rule that required all its review divisions to review generic drug applications and describe all deficiencies to the applicant within 180 days and issued additional guidance on what information to include in their applications.

Other OIG work relates to the Department's challenge in ensuring that drugs, once determined to be safe and effective, are marketed appropriately. For example, in September 2009, Pfizer, Inc. and its subsidiary Pharmacia & Upjohn, Inc. (Pfizer), agreed to pay \$2.3 billion to resolve criminal and civil liability arising from alleged illegal promotion of certain drugs. Pharmacia & Upjohn, Inc. agreed to plead guilty to a felony violation of the *Food, Drug, and Cosmetic Act* for misbranding Bextra, an anti-inflammatory drug pulled from the market in 2005, with the intent to defraud or mislead. The criminal fine and related forfeiture total \$1.3 billion. Pfizer agreed to pay \$1 billion in a civil settlement to resolve allegations of illegal promotion of Bextra and three additional drugs. As part of the settlement, Pfizer also has agreed to enter into an expansive CIA with OIG. That agreement requires the implementation of procedures and reviews to avoid and promptly detect similar conduct.

In another example, in January 2009, Eli Lilly and Company (Lilly) entered a \$1.4 billion global criminal, civil, and administrative settlement to resolve allegations that it illegally marketed its antipsychotic drug Zyprexa. In its plea agreement, Lilly admitted that from September 1999 to March 31, 2001, it promoted Zyprexa for unapproved uses in elderly populations as treatment for dementia, including Alzheimer's dementia. Lilly entered into a 5-year CIA with OIG.

The scope of potential off-label marketing violations is vast. OIG is currently 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. In addition, 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 mitigate against off-label marketing.

OIG's work has also increasingly focused attention on how the Department oversees the safety of medical devices. FDA receives about 200,000 adverse event reports each year regarding medical devices. In a 2009 report, OIG found that FDA does not use these reports in a systematic manner to detect and address safety concerns about medical devices. In future work, OIG will review FDA's

oversight of medical device post-marketing surveillance studies.

Oversight of Human Subject Protections in Clinical Trials

The Department's ability to protect human subjects enrolled in clinical trials remains a challenge that OIG continues to monitor. OIG is determining the extent to which drugs marketed in the United States are approved based on data from foreign clinical trials. That work is also determining the extent to which FDA oversees those trials. 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 the FY 2000-2005 period. FDA has taken steps to improve its oversight of clinical trials by recently finalizing rules to establish a registry for institutional review boards.

As the agency tasked with ensuring the safety and efficacy of food, cosmetics, drugs, biological products, medical devices, and products that emit radiation, FDA faces important challenges with respect to these increasingly globalized markets. Despite the progress described, and plans for future enhancements, FDA needs to make continued improvements in oversight and monitoring with respect to food safety, medical devices, and clinical trials to meet the challenges identified. Looking forward, the Department will be further challenged by its new authority to regulate the content, marketing, and sale of tobacco products. FDA will need to collaborate with public health leaders to develop and implement an effective public health strategy that reduces the burden of illness caused by tobacco products.

Management Issue 9: Grants Management

MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

The Department is the largest grant-awarding agency in the Federal Government. In FY 2008, the Department awarded \$264 billion in grants. Almost 70 percent of the money was for health care coverage under Medicaid and CHIP. The remaining 30 percent funded health and social service programs administered by the Administration for Children and Families (ACF), the Health Resources and Services Administration (HRSA), the National Institutes of Health (NIH), and other Department agencies. Moreover, the *American Recovery and Reinvestment Act of 2009 (Recovery Act)* provided a total of \$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. (See also Management Issue 10 for a discussion of broader

departmental challenges related to the oversight and implementation of the *Recovery Act*. Challenges related to the Medicaid and CHIP programs are discussed in Management Issues 1 through 6.)

Adding to this challenge is the fact that unlike other Government expenditures, the responsibility for performance and management of a grant rests primarily with the grantee, with limited Federal Government 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, HRSA, and NIH has highlighted grants management vulnerabilities and opportunities for improvements in the Department's oversight of grant funds and grantee compliance.

Improper Payments

Ensuring the appropriate use of grant funds is a challenge for the Department. OIG has identified improper payments made under ACF's Temporary Assistance for Needy Families (TANF) and foster care programs, as well as HRSA's Ryan White *Comprehensive AIDS Resources Emergency (CARE) Act* program.

The Office of Management and Budget (OMB) lists TANF as one of the programs that may be susceptible to significant erroneous payments. To assist ACF and the Department in establishing an improper payment rate as required by the *Improper Payments Information Act of 2002 (IPIA)*, OIG statistically selected eight States to review in FY 2008. The improper payment rates for seven of these States ranged from 6 to 29 percent of the Federal dollars expended for the 1-year audit period, and OIG estimated that improper payments totaled \$190 million. The eighth State did not cooperate with OIG, and negotiations between that State, OMB, and the Department to conduct the improper payment review in 2009 failed. As a result, the Department will not be able to report an improper payment rate in the *FY 2009 Agency Financial Report* or comply with *IPIA* requirements for the TANF program.

Similarly, OIG has identified improper payments within the foster care program. At the beginning of FY 2009, for example, OIG and ACF officials recommended that the Department disallow \$409.1 million in foster care payments to one State. This amount included:

- \$78.4 million in unallowable maintenance payments claimed for unlicensed facilities or ineligible children that OIG identified for the period October 1997 through September 2002;
- \$111.9 million related to issues with the per diem rates used to charge the Federal Government for providing foster care services. The time period for this disallowance was October 1997 through September 2002; and
- \$218.8 million in a projection made by ACF for the period October 2002 through June 2008, based on disallowed amounts between October 1997 and September 2002.

The Department agreed that the State should repay the \$409.1 million in disallowed costs. However, as of August 2009, the disallowance letter to the State has not been sent.

OIG has also identified improper payments made under HRSA's *Ryan White CARE Act* program. During a 2008 pilot review of a single territory, OIG determined that over \$24 million in services paid for with Ryan White grant funds should have been covered by other health insurance. OIG extended this review to eight more States, and the combined draft and final results from 2009 have uncovered an additional \$10.2 million in overpayments for a 2-year period.

Other Grants Oversight Challenges

In addition to ensuring the appropriate use of grant funds, the Department is responsible for ensuring the integrity of the grants award processes and grantee compliance with program requirements. However, OIG has identified vulnerabilities in these areas.

For example, OIG conducted risk assessments as part of its work with the Department to ensure that agencies meet their *Recovery Act* responsibilities. OIG's risk assessment of ACF highlighted the need for greater internal controls for TANF. OIG's interim results indicate that the program may be vulnerable to States manipulating caseloads to qualify for additional assistance. Furthermore, the recent breakdown in controls in New York State's release of TANF emergency funds for school supplies indicates that administrators may not have a full understanding of *Recovery Act* requirements, nor have they implemented suitably designed processes to ensure that clear guidance is provided to recipients and *Recovery Act* funds are appropriately used.

OIG has also identified risks related to grantee noncompliance. For 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 and delays in closing out some grants. NIH agreed with OIG's recommendations to initiate earlier and more frequent follow-up with grantees to obtain required documents and to improve its grants monitoring, including by annually verifying grantees' self-reported fund balances with external sources. In another example, OIG is concerned about whether Head Start and Early Head Start program grantees can provide safe environments, as required, as the number of enrolled children increases through the *Recovery Act* expansions of these programs. OIG is initiating reviews in eight States to assess this issue.

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 will only magnify grant oversight vulnerabilities. OIG will continue to monitor grants management challenges and recommend improvements to the Department's grants oversight, as warranted.

PART 3: CROSS-CUTTING ISSUES

OIG has also identified three other Department-wide issues that are top management challenges. These include assessing whether the Department is using *Recovery Act* funds in accordance with legal and administrative requirements and is meeting the accountability objectives defined by OMB; developing and maintaining adequate internal controls over its information systems; and effectively overseeing its ethics program.

Management Issue 10: 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 to promote economic recovery and ameliorate the impacts of the recession. The *Recovery Act's* combined spending and tax provisions are expected to 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 maintaining jobs, assisting those most affected by the recession, increasing economic efficiency by investing in technological advances in science and health, and stabilizing State and local budgets.

The *Recovery Act* provides \$166.6 billion to the Department to provide additional Federal assistance for health care, public health, and human services programs, as

well as to invest in research and health information technology (health IT). 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 are used efficiently and effectively and are protected from fraud, waste, and abuse.

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

- improving and preserving health care by providing an \$87.5 billion temporary increase in the Medicaid Federal Medical Assistance Percentage (FMAP);
- accelerating the adoption of health IT through (1) the Office of the National Coordinator for Health Information Technology (\$2 billion) to coordinate Federal health IT policy and programs and foster the electronic use and exchange of health information and (2) CMS (\$44.7 billion) to make incentive payments to encourage physicians and hospitals to adopt and use certified electronic health records in a meaningful way;
- improving children and community services by providing ACF with over \$12.3 billion to temporarily expand the TANF, child support, Head Start, child care development, and community services programs;
- strengthening scientific research and facilities by providing \$10.4 billion to NIH; and
- strengthening community health care services by providing HRSA with \$2.3 billion to construct and renovate new centers, to expand health care services, and to train health care professionals.

The majority of the Department's *Recovery Act* funding increases 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 detail in Management Issues 1 through 6 of this document. Challenges related to programs and grants administered by ACF, NIH, and HRSA are presented in Management Issue 9. Finally, challenges related to health IT are discussed in Management Issue 11.

Implementation and oversight to ensure accountability and transparency of *Recovery Act* funding present significant management challenges. The *Recovery Act* funds are to be awarded and distributed within short timeframes. Awarding and distributing funds quickly is important to the *Recovery Act's* objectives to stimulate economic growth

and ameliorate the impacts of the recession. Expediting the awards process, however, also creates challenges for the Department in ensuring that funds are distributed to qualified recipients and are used appropriately and effectively. Further, creating or expanding programs may increase the number of new recipients that may lack experience with Federal requirements for grantees and contractors.

The *Recovery Act* also established new reporting requirements related to the awarding and use of funds to promote transparency and accountability. Challenges associated with the new reporting requirements include developing the 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. These new reporting requirements are in addition to the information that some recipients of *Recovery Act* funds must also provide for similar activities funded outside the *Recovery Act*, creating multiple and inconsistent reporting requirements.

Overseeing and protecting the integrity of *Recovery Act* funds is a shared responsibility requiring coordination among agencies within the Department and with States and other entities. The Department has established the Office of *Recovery Act* Coordination (ORAC), headed by a 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. In addition, the *Recovery Act* established the Recovery Accountability and Transparency Board (RATB), consisting of 12 Inspectors General, including the HHS Inspector General, to coordinate and conduct oversight of funds distributed pursuant to the *Recovery Act* to prevent fraud, waste, and abuse and promote accountability and transparency. The RATB administers the Government's Recovery.gov Web site. State agencies also have essential 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.

Together, OIG and the Department are working to ensure that the Department meets its *Recovery Act* responsibilities. Ongoing activities include minimizing risk; assessing controls for preventing fraud, waste, and abuse; and ensuring program goals are achieved and stimulus funds

are accurately tracked and reported. Initial steps, for example, include:

- outlining the process for obtaining meaningful coverage by single audits (the financial and compliance audits required of all recipients of \$500,000 or more in Federal funding) to assist in determining whether the accountability objectives are met (i.e., that the recipients, uses, and benefits of all funds are transparent to the public; funds are used for authorized purposes; and instances of fraud, waste, error and abuse are mitigated);
- reviewing the spending plans for each *Recovery Act* initiative with a focus on the purpose of funding, means of execution, method of selection, intended recipients, and accountability measures;
- conducting a risk assessment covering \$72.7 billion of the \$76.4 billion allocated to Health IT and non-Medicaid programs;
- reviewing the Department and State controls to ensure that the temporary increase in the FMAP is implemented as intended by the *Recovery Act*;
- reviewing training and qualifications of Departmental personnel responsible for overseeing *Recovery Act* funds;
- reviewing the implementation plans for *Recovery Act* initiatives or programs with a focus on objectives, performance measures, monitoring and evaluation, transparency, accountability, and barriers to effective implementation; and
- developing a screening process to identify applicants for *Recovery Act* funds that are under investigation by OIG.

In addition, the *Recovery Act* requires OIG to investigate alleged instances of retaliation against whistleblowers who disclose the potential misuse of *Recovery Act* funds. OIG is preparing for a possible influx of complaints by updating its hotline and tracking systems and training agents on the evaluation and investigation of such whistleblower complaints.

Although the Department faces challenges in ensuring the accountability and transparency of *Recovery Act* funds, the Department's and OIG's efforts underway, including the use of risk assessments, may have long-term benefits for Department programs even beyond the expenditure of *Recovery Act* funding.

Management Issue 11: Health Information Technology and Integrity of Information Systems

MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

Over the past decade, the development and implementation of interoperable health IT has become a national priority. The Federal Government has recognized the potential for health IT to revolutionize the delivery of medical care by both improving quality and lowering costs. In 2004, the President issued Executive Order 13335 to create the Office of the National Coordinator for Health IT (ONC) within the Department of Health and Human Services. ONC was tasked with the goal of achieving access to an interoperable electronic medical record for most Americans by 2014. Since then, the public and private sectors have worked together to advance the vision of the nation-wide adoption of interoperable health IT, which includes the use of electronic health records (EHR) and electronic prescribing (e-prescribing).

The Department must balance the need to meet these goals with its obligations to oversee the expenditure of Federal funds in pursuit of health IT objectives. For example, the *Health Information Technology for Economic and Clinical Health (HITECH) Act*, as part of the *Recovery Act*, includes a wide array of mandates, contracts, grants, loans, incentives, and penalties aimed at promoting the widespread and secure use of interoperable health IT. The *HITECH Act* also tasks the Department, with ONC as the lead, with adopting standards and establishing a governance mechanism for the nation-wide health information network (NHIN), through which health data, such as EHR and e-prescriptions, will be exchanged. The goals of these provisions are also supported by unprecedented funding to encourage the adoption of health IT—an estimated \$49 billion in spending over the next several years.

Achieving the widespread use of electronic medical records is an ambitious target, and it is imperative that *Recovery Act* funds to support this goal be used efficiently and effectively. The success of this massive undertaking, like that of any Government initiative, can be threatened by vulnerabilities created or overlooked during planning, funding, and implementation. In addition, with the push for increased adoption of health IT, there is also heightened concern among the public regarding the privacy and security of their personal health information. Therefore, the Department must identify and address to the fullest extent possible, and as early as possible, such vulnerabilities with respect to each of its health IT initiatives.

The Department's health IT management challenges identified by OIG can be divided into two broad

categories: ensuring the integrity of the Department's programs to promote health information technology and ensuring the integrity of information systems through which health information is transmitted and stored.

Integrity of Health Information Technology Programs

Like any of the Department's grants programs or contracts, Federal health IT initiatives are susceptible to potential fraud, noncompliance, and inefficiency. Even before the enactment of the *HITECH Act*, OIG was engaged in monitoring Federal health IT initiatives. For example, in 2009 OIG initiated an assessment of Medicare Part D plan sponsors' implementation of CMS-mandated e-prescribing standards. OIG found that most plan sponsors had implemented some of the mandated standards but that few had completely implemented all required standards. Another study, completed 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.

With the enactment of the *HITECH Act*, Federal initiatives to promote the use of health IT now 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; and ONC programs to facilitate the adoption of health IT through health IT extension programs, State grants for health information exchange, and development of an HIT workforce. OIG has developed a work plan to provide oversight to these areas 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 10 for further discussion of challenges associated with the *Recovery Act*.

Integrity of Information Systems

The Department administers its wide array of programs through a mix of grants, contracts, and cooperative agreements and as a payor of health benefits. As such, to accomplish its mission, the Department relies on a distributed network environment that includes Federal agencies, State and local governments, grantees and contractors, health care providers, and colleges and universities. This environment presents a significant

challenge for the Department to establish an information security program that protects critical infrastructure and assets and creates, monitors, and maintains an enterprise-wide baseline of core security requirements.

OIG has monitored the Department's ability to meet this challenge by determining whether the Department's information system security controls are robust, as well as examining its oversight over health care providers' compliance with the *Health Insurance Portability and Accountability Act of 1996 Security Rule* (the applicability of which the *HITECH Act* has expanded and whose enforcement been transferred from CMS to the Department's Office for Civil Rights). OIG has performed dozens of independent audits of key departmental agencies, as well as audits of State and local governments, contractors, and hospitals. These 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 the integration of security into major applications, which includes certification and accreditation, contingency plan testing, privacy impact statements, and annual self-assessments.

The *HITECH Act* will present a challenge to the Department's processes for ensuring the confidentiality, integrity, and availability of critical systems and data. In response, OIG will use the results of its risk assessments to target its oversight and monitoring of the security controls of the Department's networks, as well as those of its contractors and grantees.

Because of increasing recognition of the scope and detrimental consequences of identity theft, OIG is increasing its focus on medical identity theft, which can result from breaches in information security. OIG investigations have uncovered an increasing number of fraud schemes involving stolen provider and beneficiary identification numbers. In response, OIG issued a consumer education brochure providing tips and resources to help beneficiaries protect themselves and Medicare from medical identity theft and fraud. OIG will continue its work in this area and make recommendations to the Department, as appropriate, regarding safeguards for personally identifiable information.

Management Issue 12: Ethics Program Oversight and Enforcement

MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

The year 2008 marked the 30th anniversary of both the *Inspector General Act of 1978* and the *Ethics in Government Act of 1978*, which established the Office of Government Ethics (OGE). Both statutes set the stage for a more robust framework and mechanism for ensuring the integrity of the Federal workforce and Federal programs.

Government Ethics Programs and Conflicts of Interest of Department Employees

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

Monitoring for conflicts of interest continues to be a challenge for the Department. For example, OIG currently has a study underway that will determine the extent to which the CDC and its Special Government Employees (SGE) on Federal advisory committees complied with ethics requirements. OIG is also planning to conduct similar reviews of other Departmental agencies.

The Department has recently implemented some model practices, such as expanding oversight by monitoring the financial disclosure systems and the ethics training program department wide, providing instructor-led initial ethics orientation to departmental employees, and providing instructor-led annual ethics training to political employees. The Department also provides face-to-face initial ethics orientation for incoming scholars and SGE advisory committee members.

Another challenge for the Department is monitoring for conflicts of interest of a workforce that has become increasingly reliant on contract workers. A recent revision under the Federal Acquisition Regulation requires contractors to have a written code of ethical conduct and to post information on how to report fraud. In response, OIG created an OIG hotline poster for use by Department contractors. Also, as OGE releases guidance on conflict-of-interest considerations of contractor employees in the workplace, OIG is developing internal training on this topic to prepare for emerging issues involving contractors working in the Department. To examine the scope of this challenge, OIG has plans to assess CMS’s process for

oversight and monitoring of contractors’ conflicts of interest.

OIG has also identified the lack of uniform procedures for resolving allegations of improper conduct as a management challenge within the Department. In 2008, OIG issued a report on how NIH handles allegations about employee activities that might be criminal or improper. OIG’s evaluation found a lack of uniform procedures for handling allegations and recommended that NIH develop a formal written policy for handling allegations. OIG also recommended that NIH maintain documentation detailing how allegations are ultimately resolved. NIH concurred with the recommendations and has since implemented them in a new chapter of the “NIH Policy Manual.”

OIG also consulted with the Department regarding the number and quality of conflict-of-interest referrals that it was receiving from across the various divisions in the Department. To improve the quality of referrals, OIG created a comprehensive form for the DAEO and other departmental ethics officials to use when referring conflict-of-interest cases. OIG’s ongoing relations with the Office of General Counsel (OGC) Ethics Division, as well as regular interactions by OIG staff with the operating and staff divisions, have yielded positive results with an increase in the quality of the referrals, an increase in the number of referrals from various departmental components, and an increase in departmental officials seeking input and guidance on conflict-of-interest matters. For example, OIG’s enforcement efforts in 2009 included the conviction of an employee of the National Library of Medicine, NIH, who was sentenced to 1 year probation and 160 hours of community service and ordered to pay a \$200,000 fine as punishment for a felony violation relating to conflict-of-interest regulations by failing to receive approval and failing to report finances from his outside activities. The employee admitted to receiving as much as \$500,000 in unauthorized income from testifying as an expert witness on toxicology issues in legal proceedings.

Oversight of Department Grantee and Researcher 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 bias these programs and ultimately affect the public’s health and safety. For example, 80 percent of NIH research funding goes to extramural grantees, primarily to research universities that undertake work pursuant to grants and contracts. Conflicts of interest among extramural grantees could compromise the integrity of the research that the Department funds. Therefore, in addition to performing our work focused on departmental employees, OIG has also examined potential

conflicts of interest relating to Federal grantees and non-Federal researchers.

In a January 2008 report, OIG identified vulnerabilities associated with NIH's monitoring of conflict-of-interest reports submitted by external grantees in FYs 2004 through 2006. OIG found that NIH's Institutes and the Office of Extramural Research (OER) were unable to provide all the actual conflict-of-interest reports they received from grantee institutions and did not follow up with grantee institutions regarding reported conflicts of interest. OIG recommended that NIH increase oversight of grantee institutions and require grantee institutions to provide details regarding 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. Beginning in July 2009, NIH began requiring all financial conflict-of-interest reports from grantees to be submitted electronically using a uniform format in their systems.

In its follow-up, 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 request grantee institutions to provide it with details regarding the nature of all reported financial conflicts of interest and the ways in which they are managed, reduced, or eliminated. OIG offered additional recommendations, including that NIH (1) require grantee institutions to collect all information on significant financial interests held by researchers and not just those deemed by researchers to be reasonably affected by the research; (2) require grantee institutions to collect information on specific amounts of equity and compensation from researchers; (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.

With regard to the last recommendation, OIG is currently undertaking a review to determine what policies and procedures NIH grantee institutions have in place to address institutional conflicts of interest.

In considering potential changes to the Federal regulations that would address some of the current vulnerabilities, NIH sought to gain input from the public and research community on whether modifications are needed to Federal regulations addressing grantee conflicts of interest. In May 2009, NIH published an Advanced Note of Proposed Rulemaking on Promoting Objectivity in Research. 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.

OIG has also identified research conflict-of-interest vulnerabilities in other Department agencies. For example, in 2009, OIG reported on vulnerabilities in FDA's 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. The OIG report highlighted 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. Finally, OIG recommended that sponsors submit financial information for their clinical investigators earlier in the process. In its response to the report, FDA stated that it will consider making changes to 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. However, FDA did not agree that sponsors should submit financial information for their clinical investigators earlier as part of the pretrial application process.

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

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DEPARTMENT'S RESPONSE TO THE OIG TOP MANAGEMENT AND PERFORMANCE CHALLENGES

Date: November 16, 2009

To: Daniel R. ~~Levinson, Inspector Gen~~
From: Richard J. Turman, Acting As ~~Assistant Secretary~~ for ~~Financial~~ Resources and Chief Financial Officer

Subject: FY 2009 Top Management and Performance Challenges Identified by the Office of the Inspector General

This memorandum is in response to OIG's *FY 2009 Top Management and Performance Challenges*, which summarized the top management and performance challenges that the Department has faced over recent years.

We concur with OIG's findings concerning the HHS top management and performance challenges. In response to OIG's report, we are providing the attached table which includes a brief summary of the top management challenges, management's response, and future plans to address these challenges during FY 2010.

Our management is committed to working toward resolving these challenges, and looks forward to continued collaboration with OIG to improve the health and well-being of the American people through our efforts.

FY 2009 Top Management and Performance Challenges Summary

Part I: Integrity of Medicare, Medicaid, Children’s Health Insurance Program

Management Challenge Identified by the OIG	OIG Progress Assessment	Management Response	Future Plans to Address the Challenge
1. Integrity of Provider and Supplier Enrollment	CMS has made progress in responding to enrollment vulnerabilities, including implementing some measures aimed at enhancing enrollment standards for durable medical equipment (DME) suppliers; additional measures would further improve integrity of provider and supplier enrollment.	We agree with OIG’s assessment and are making progress to respond to enrollment vulnerabilities. CMS implemented new durable medical equipment, orthotics, prosthetics, and supplies (DMEPOS) suppliers Accreditation Standards and has also established a surety bond requirement for all DMEPOS suppliers.	Medicare administrative contractors and fiscal intermediaries are being directed to review capital disproportionate share hospital (DSH) payments in support of provider and supplier eligibility. CMS is confident it has the necessary tools to ensure that future DSH payments comply with all applicable Federal provider and supplier requirements.
2. Integrity of Federal Health Care Program Payment Methodologies	CMS is working to ensure that payments are based on accurate data, respond to changes in the marketplace and medical practice, and limit the risk of fraud and abuse; however, many the payment issues identified by OIG have not yet been resolved.	CMS is making progress on issues with data used in payment methodologies that have affected both Medicare and its beneficiaries. CMS agrees it must be a prudent purchaser of health care and must work to ensure that the Medicare and Medicaid payment methodologies allow access to quality care without wasteful overspending.	The Department is reacting to changes in the marketplace and medical practices so that the programs continue to effectively reimburse for quality care, while ensuring payment incentives limit the risks of fraud and abuse.
3. Promoting Compliance with Federal Health Care Program Requirements	CMS is partnering with providers and suppliers in adopting practices and promoting compliance with program coverage, payment, and quality requirements. This includes education and guidance efforts, including continued participation in the Provider Partnership Program.	CMS continues to participate in the Provider Partnership Program, and is partnering with providers and suppliers in education and guidance efforts.	Medicare and Medicaid providers are being encouraged to implement compliance programs. CMS is creating an education, training, and outreach campaign, which is designed to improve the plan sponsor’s compliance with Medicare program requirements.

Part I: Integrity of Medicare, Medicaid, Children's Health Insurance Program (Continued)

Management Challenge Identified by the OIG	OIG Progress Assessment	Management Response	Future Plans to Address the Challenge
4. Oversight and Monitoring of Federal Health Care Programs	CMS has efforts underway, including developing oversight tools such as the Integrated Data Repository, to make needed improvements to oversight and monitoring of Federal health care programs.	Progress continues as CMS contracts with outside entities to perform oversight and monitoring functions for both Medicare and Medicaid. Improving the integrity of Medicare fee for service payments is a top priority at CMS.	CMS has plans to enhance data systems available for use by the contractors. CMS is committed to continuously improving the Payment Error Rate Measurement (PERM) program.
5. Response to Fraud and Vulnerabilities in Federal Health Care Programs	HHS is making progress in responding to fraud through law enforcement (through OIG, in partnership with the Department of Justice) and by addressing program vulnerabilities (through CMS). The Health Care Fraud Prevention and Enforcement Action Team (HEAT) is a collaborative initiative focused on fraud prevention and response.	In conjunction with accurately identified vulnerabilities, CMS revoked suppliers' billing privileges that failed to meet Medicare standards. CMS agrees that responding to fraud and program vulnerabilities requires a high degree of coordination and collaboration between Federal and State agencies.	CMS will continue to work with its partners to respond to health care waste, fraud, and abuse.
6. Quality of Care	CMS has made some progress in ensuring that providers comply with quality standards, developing initiative to protect beneficiaries from abuse or neglect, and implementing payment incentives linked to quality.	CMS continues to operate its Special Focus Facility (SFF) program, monitoring nursing homes with the worst survey performances. CMS agrees that there are significant opportunities for improvement in the Beneficiary Protection Program and has launched a redesign of the program.	Quality Improvement Organizations (QIO) will work with providers on improving their performance on specific clinical measures related to patient safety in all States.

Part II: Integrity of the Department’s Public Health and Human Services Programs

Management Challenge Identified by the OIG	OIG Progress Assessment	Management Response	Future Plans to Address the Challenge
7. Emergency Preparedness and Response	The Department working with State and local health officials has made progress in preparing for and responding to public health emergencies. They continue to work together in the development of emergency preparedness and detection plans for pandemic influenza, bioterrorist attacks, and natural disasters.	The Department provided guidance to States and localities on the development of a tiered health care response structure, and seamless emergency preparedness plan development and integration for all-hazards health care system preparedness. In addition, an update to the Medical Surge Capacity and Capability Handbook was completed.	Progress continues toward health care system preparedness, which requires exercise and evaluation strategies, including evaluations of all tiers within the health care system.
8. Oversight of Food, Drugs, and Medical Devices	FDA has made progress in ensuring the timely approval and oversight of drugs and medical devices. In FY 2009, the Food Safety Working Group was created to help ensure the safety of our Nation’s food supply however; FDA continues to face challenges in tracing food during food emergencies.	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.	FDA will continue to improve its generic drug approval process in addition to its oversight of clinical trials.
9. Grants Management	HHS made progress in developing consistent policies and procedures to oversee Federal grantees and has taken a key leadership role in the temporary expansion of health and social service programs under the Recovery Act, due to the Department’s significant grant expenditures as the largest grant-awarding agency in the Federal Government.	The Department continued to establish practices regarding the integrity of grant data and its use, including grantee reporting and closeout procedures. NIH created a new centralized processing center for the receipt of closeout documents, and reminds grantees of their ability to submit closeout reports in the electronic research administration (eRA) Commons Closeout Module.	Focus will continue on the timely financial closeout of ended projects.

Part III: Cross-Cutting Issues that Span the Department

Management Challenge Identified by the OIG	OIG Progress Assessment	Management Response	Future Plans to Address the Challenge
10. <i>American Recovery and Reinvestment Act.</i>	The <i>Recovery Act</i> provided an estimated \$167 billion over 10 years to the Department to provide Federal assistance for health care, public health, and human services programs, as well as to invest in research and health information technology (health IT). It is critical that <i>Recovery Act</i> funds are used efficiently and effectively and are protected from fraud, waste, and abuse.	HHS established the Office of Recovery Act Coordination (ORAC) for ensuring the appropriate awarding, distributing, use, and reporting of <i>Recovery Act</i> funds. In addition the <i>Recovery Act</i> established the Recovery Accountability and Transparency Board (RATB), including the HHS Inspector, to prevent fraud, waste, and abuse, while promoting accountability and transparency.	The OIG and the Department will work together to ensure we meet our <i>Recovery Act</i> responsibilities. In addition, we will continue to prepare for a potential influx of complaints by updating our OIG hotline and tracking systems, and training agents on the evaluation and investigation of such whistleblower complaints.
11. Health Information Technology and Integrity of Information Systems	The Department continues to make progress in ensuring the integrity of the Department's programs to promote health information technology, in addition to ensuring the integrity of information systems through which health information is transmitted and stored.	The Office of the National Coordinator for Health IT (ONC) provided national leadership in health IT adoption and electronic health information exchange. The <i>Health Information Technology for Economic and Clinical Health (HITECH) Act</i> highlighted ONC's leadership by providing significant funding and authority for the Department to promote the use of health IT.	Under the guidance of ONC, the Department will continue to improve health care quality, safety, and efficiency by establishing new policies, and fostering the nation-wide health information network (NHIN). The Department will continue to collaborate with partners with regards to privacy, security, and data stewardship for electronic individually identifiable health information.
12. Ethics Program Oversight and Enforcement	NIH and FDA have implemented additional measures to strengthen their processes for reviewing and approving outside activities. The OGC Ethics Division continues its ethics program oversight.	The OGC Ethics Division has responsibility for administering the Department's ethics program as it pertains to HHS employees (including special Government employees). It continued to conduct internal reviews of OPDIV and STAFFDIV ethics programs to ensure that these programs function effectively and that conflicts of interest on the part of HHS employees are identified and resolved.	HHS will adopt a number of model practices to ensure the continued efficacy of the agency's ethics programs, and will continue to work closely with the OIG in the handling of referrals of conflict of interest violations.