
FY 2008 TOP MANAGEMENT AND PERFORMANCE CHALLENGES IDENTIFIED BY THE OFFICE OF THE INSPECTOR GENERAL

Management Issue 1: Oversight of Medicare Part D

MANAGEMENT CHALLENGE:

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) established Medicare Part D, a voluntary outpatient prescription drug benefit available to all Medicare beneficiaries. The program took effect on January 1, 2006, and as of January 2007, nearly 24 million beneficiaries were enrolled in Part D and almost 7 million additional beneficiaries were enrolled in employer-sponsored plans that receive the Retiree Drug Subsidy (RDS). According to the "2008 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds," Part D expenditures for 2007 totaled \$49.5 billion. The magnitude of expenditures and the impact of this benefit on beneficiaries, from both health and financial perspectives, make it critical that Medicare Part D operate efficiently and effectively and be protected from fraud and abuse.

The structure and operation of the Part D benefit contain features that present significant management challenges. Part D coverage is provided by private entities, known as drug plan sponsors, that contract with the Centers for Medicare & Medicaid Services (CMS) to provide Part D drug benefits. Qualified employer-sponsored plans may also receive the RDS to maintain drug coverage for their Medicare-eligible retirees. Within the Department, CMS bears primary responsibility for implementing and administering Part D. However, administration and oversight of Medicare Part D depend upon extensive coordination and information sharing among Federal and State government agencies, drug plan sponsors, contractors, health care providers, and third-party payers.

OIG has identified concerns about limited oversight of Part D, particularly with respect to implementation of internal controls to ensure payment accuracy and program safeguards to prevent and detect fraud, waste, and abuse. These vulnerabilities can have significant consequences for Medicare and beneficiaries. For example, inaccurate bids by some plan sponsors have resulted in Medicare paying higher subsidies and beneficiaries paying higher premiums. We have also examined and continue to monitor beneficiary protections to ensure access to drugs, appropriate cost sharing, and access to accurate information. Limited oversight of plan sponsors' marketing materials and tracking of beneficiaries' drug spending, which affects their cost-sharing obligations, are among the concerns that we have identified.

Payment Accuracy and Internal Controls

Payments to drug plan sponsors based on bids, risk adjustments, and reconciliations add to the complexities and challenges of the benefit. Medicare and beneficiaries share the cost of Part D drug coverage. Medicare pays prospective monthly subsidies to plans and beneficiaries pay monthly premiums. The subsidy and premium amounts are based on plan bids, which plan sponsors submit and CMS approves prior to the plan year. Subsequently, Medicare reconciles its payments to plans through a multistage process that begins 6 months after the plan year ends. As part of reconciliation, CMS determines whether risk-sharing payments are required. Risk sharing requires the Federal Government to share in sponsors' unexpected profits and losses, based on risk corridors defined by the MMA. OIG reviews have raised concerns related to the adequacy of CMS's and sponsors' internal controls to ensure the accuracy of payments by Medicare and beneficiaries.

In 2007, OIG analyzed preliminary reconciliation amounts and estimated that plan sponsors owed Medicare a net total of \$4.4 billion for 2006. Most of the funds that sponsors owed were profits that were subject to risk-sharing requirements. In general, these payments owed to Medicare were caused by sponsors overestimating their net costs in their bids. CMS does not have mechanisms in place to adjust prospective payments or to collect funds prior to reconciliation. As a result, sponsors had the use of over

\$4 billion owed to Medicare for a significant length of time. Further, sponsors' overestimates also resulted in higher beneficiary premiums; however, beneficiaries do not recoup money paid in higher premiums. OIG is currently reviewing reconciliation amounts owed to Medicare for 2007.

Additionally, OIG has identified vulnerabilities in CMS's oversight of bids and plan sponsors' support for their bids. CMS uses bid audits, which focus on the actuarial assumptions underlying bids, as part of its oversight of sponsors' bids. OIG found that one-quarter of bid audits completed for plan years 2006 and 2007 identified at least one material finding, which CMS defines as a significant issue that, if corrected, would change the bid. Both Medicare payments and beneficiary premiums are affected when bid amounts are not calculated appropriately. However, CMS has not adjusted plan sponsors' bid amounts based on bid audit material findings because of timing issues and because some material findings are not quantifiable. Instead, CMS uses bid audits to influence the submission, review, and audit of future bid amounts. Although CMS intends to supplement its bid oversight with information from financial audits, as of April 2008, only 4 percent of the required financial audits of plan year 2006 had begun.

OIG is also auditing drug plan bids to determine whether estimates of price concessions were supported. Price concessions include discounts, direct or indirect subsidies, rebates, and other forms of direct or indirect remuneration (DIR). Part D plan sponsors are required to report all negotiated price concession data and rebates in full in their bids. Including price concessions in drug plan bids results in lower Medicare payments and beneficiary premiums. However, our ongoing audit work has preliminarily identified some anticipated rebates that were excluded from the bids we reviewed. Further, because CMS's bid audit protocol focuses on actuarial assumptions and not the accuracy of data, we are concerned that CMS's bid audits would not identify rebates that have been inappropriately excluded.

In addition, OIG has found deficiencies in internal controls over RDS payments for employer-sponsored coverage. An OIG audit determined that an employer-based sponsor's gross retiree costs for 2006 included retirees who were not qualified for the RDS, resulting in an overstatement of reported gross retiree costs. The sponsor did not establish sufficient controls to prevent such incorrect reported costs.

OIG is conducting additional work on Part D payment accuracy and internal controls, including: examining the nature and extent of price concessions received by selected plan sponsors and reported by sponsors in their bids and DIR reports; auditing plan sponsors' support for their reported DIR; comparing drug reimbursement amounts by Part D plans to those by State Medicaid programs; and examining controls to prevent duplicate payments by Medicaid and Part D, Medicare Parts A and D, Medicare Parts B and D, and by multiple Part D plans.

Program Safeguards

CMS and drug plan sponsors share responsibility for protecting the Part D program from fraud, waste, and abuse. CMS is responsible for oversight and implementation of safeguards to protect the integrity of the Part D benefit. In an initial review, OIG found that as of October 2006, CMS's safeguard activities needed further development and application. Although CMS has made progress since then, some of the concerns identified in 2006 have not been fully addressed. For example, we found that in 2006, neither CMS nor the Medicare Drug Integrity Contractor (MEDIC) in operation at that time had conducted any significant data analysis for fraud detection. In August 2007, the MEDICs gained access to Part D claims data, but as of June 2008, they had not yet analyzed claims data to detect aberrant billing patterns or potential fraud. CMS and the MEDICs have continued to rely largely on incoming complaints to identify fraud and abuse. In addition, in 2006, we found that CMS had let a contract to develop the financial audit program, with an expectation that the first audits would begin in January 2008. However, we found that as of April 2008, only 4 percent of the required financial audits of plan year 2006 had begun, and CMS had contracted for less than half the required number of audits.

Additionally, Part D plan sponsors are required to implement compliance plans that include comprehensive plans to detect, correct, and prevent fraud, waste, and abuse. 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 of CMS's requirements for compliance plans. Plan sponsors' compliance plans contained only broad outlines of a fraud and abuse plan and did not include details or describe specific processes. In follow-up work, OIG reviewed CMS's oversight of plan sponsors' implementation of compliance plans. We found that as of August 2008, CMS had conducted only one focused audit of a drug plan sponsor's compliance plan and none of CMS's routine audits had included compliance plan reviews. In response to our findings in 2006, CMS instructed all plan sponsors to include a compliance plan self-assessment. However, CMS's self-assessment tool did not include all of the requirements for compliance plans and CMS did not verify plan sponsors' responses.

In other work, OIG found evidence suggesting that additional focus on fraud and abuse detection and response by plan sponsors is needed. Specifically, we found that in the first 6 months of 2007, 24 of 86 plan sponsors did not identify any potential fraud and abuse incidents. Seven plan sponsors accounted for 90 percent of the incidents identified, and most incidents were associated with pharmacies. 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.

OIG's investigations related to Part D have included cases of alleged fraud involving beneficiaries, providers, and plan sponsors. Specific allegations include drug diversion, forgery/falsification of benefit applications, and billing for services not rendered.

Beneficiary Protections

OIG also focuses significant attention on beneficiary protections to ensure access to drugs, appropriate cost sharing, and access to accurate information. In June 2008, OIG issued a report that assessed the availability of Part D drugs to dual-eligible nursing home residents (dual eligibles are beneficiaries eligible for both Medicare and Medicaid). According to nursing home administrators, medical directors, and long-term care (LTC) pharmacy directors, almost all dual-eligible residents are receiving all necessary Part D drugs. However, many respondents expressed concerns that Part D formularies may not meet the needs of nursing home residents, that the prior authorization process to obtain plan approval for certain drugs was burdensome, and that some dual-eligible residents were incorrectly identified as required to pay copayments. OIG also raised concerns about the lack of transparency with respect to incentives created by LTC pharmacy rebates. We found that LTC pharmacies often make recommendations that influence physicians' prescribing decisions for nursing home residents. However, LTC pharmacies generally do not disclose to physicians information about rebates that they receive from drug manufacturers. This is a concern because rebates may create incentives for pharmacies to recommend certain drugs over others based on financial considerations as opposed to clinical considerations. We plan to conduct additional work on LTC pharmacy rebates.

OIG also examined pharmacy participation in and experiences with Medicare Part D, with a focus on independent community pharmacies. We found a high rate of pharmacy participation in 2006—96 percent of independent pharmacies in nonmetropolitan areas participated in at least one Part D plan. However, community pharmacies expressed a high rate of dissatisfaction regarding plan sponsors' contract terms and processes. OIG will continue to monitor beneficiary access to pharmacies participating in Part D.

In addition, OIG has raised concerns about accurate tracking of beneficiaries' true out-of-pocket costs (TrOOP), which is critical to ensuring that beneficiaries are charged the correct amounts for cost sharing. We found that in 2006, CMS conducted limited oversight of sponsors' tracking of TrOOP and relied primarily on sponsors to self-report noncompliance with TrOOP requirements.

OIG has also identified challenges to outreach to Medicare beneficiaries who may qualify to receive assistance with their Part D premiums and copayments through the low-income subsidy. CMS does not have access to a comprehensive source of income data to accurately identify potentially eligible beneficiaries who need to apply for the subsidy. CMS has worked with the Social Security Administration and many State and local partners to educate beneficiaries about the subsidy. However, such efforts could

be more efficiently targeted if CMS had income data and could focus outreach on the pool of likely eligible beneficiaries.

To make informed decisions, beneficiaries need access to accurate information about available drug plans, as well as the rules of Medicare Part D that govern enrollment and termination, among others. However, we have identified deficiencies in drug plan marketing materials and information on plan sponsors' Web sites. Eighty-five percent of drug plans' marketing materials for 2007 that we reviewed failed to meet all CMS guidelines, in part because CMS's model documents were not consistent with its guidelines. These deficiencies ranged from omitting required information about PDP benefits and rules to not using the required font size for footnotes. Examples of some more significant deficiencies include omissions of required information on the low-income subsidy, explanations that enrollment in a drug plan automatically disenrolls the beneficiary from any other Medicare drug plan or managed care plan, and statements regarding access to network pharmacies. In another review, OIG found that a third of plan sponsors' Web sites did not contain all federally required content about receipt and use of Part D benefits. Further, 85 percent of these sponsors' Web sites did not meet at least one of the Federal requirements for Web site accessibility for individuals with disabilities. These problems could affect beneficiaries' access to needed information.

Ongoing OIG work assesses the accuracy of selected Part D plans' drug prices provided on the Medicare Prescription Drug Plan Finder (Plan Finder), a Web-based tool that enables beneficiaries to compare drug prices and costs across drug plans. We are comparing plans' retail drug prices as posted on Plan Finder to actual drug costs on corresponding prescription drug event claims. OIG is also investigating cases of potential fraud in Part D marketing.

ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

Payment Accuracy and Internal Controls

With respect to reconciliation amounts owed in 2006, CMS believes that the variance between prospective and reconciled payments will markedly decrease over time as actual program data become available to CMS and drug plan sponsors, thus eliminating this as an issue. Preliminary estimates indicate that amounts plan sponsors owe to Medicare for 2007 will be significantly lower than amounts owed for 2006. CMS also stated that it has no legal authority to implement an interim reconciliation process.

CMS agreed with OIG's recommendation that the data collected from the 2006 and subsequent plan years be used in the review of future bid submissions. Bids for 2008 were the first bids for which base year data from 2006 were available. CMS has made some progress regarding its use of bid audits. In particular, beginning with the plan year 2008 bid, bid reviewers are instructed to ensure that issues identified in prior bid audits were addressed and not repeated.

To strengthen the bid audit process, CMS stated that it will consider using the authority it has to ensure that Part D sponsors comply with Part D operational requirements. With respect to financial audits, CMS reported that funding challenges prevent it from carrying out the statutory requirement to complete financial audits on one-third of plan sponsors annually. Because of these financial constraints, CMS stated that it is revising the audit protocols to conduct financial audits in the most efficient manner possible.

Program Safeguards

CMS has demonstrated progress in protecting Medicare Part D from fraud and abuse, but further implementation of safeguards is needed. Many safeguard activities are to be conducted by CMS's MEDICs. MEDIC responsibilities include responding to and investigating beneficiary complaints, proactively analyzing Part D data to identify suspicious activities, making referrals to OIG, and fulfilling data requests from law enforcement. To carry out these responsibilities, MEDICs require access to Part D data. In the summer of 2007, MEDICs were granted interim access to the Integrated Data Repository, which houses prescription drug event data. Access to Part D data has enabled MEDICs to follow up on

complaints and fulfill data requests; however, MEDICs have not conducted data analysis to identify potential fraud.

CMS has entered into a contract to develop a centralized data repository, known as One Program Integrity System Integrator (One PI). This database is intended to warehouse data on Medicare Parts A, B, and D and on Medicaid. The primary purpose of One PI is to establish an enterprise resource that will provide a single source of information for all CMS fraud, waste, and abuse activities. When developed, One PI is expected to offer powerful data analysis and fraud detection tools. However, the target implementation date for One PI has been delayed and CMS has not provided a new expected timeframe for completion and operability.

In 2007, CMS commenced its routine compliance audits of drug plan sponsors. According to CMS, it is working on strengthening its oversight of Part D sponsors by improving its method for identifying sponsors for compliance audits. Its strategy is to identify the appropriate level of effort that the agency must undertake to ensure implementation of and adherence to program oversight controls. By utilizing the Part D reporting requirements, input from the plan managers, and Part D data analysis, CMS identifies organizations and program areas representing the greatest compliance risks to Medicare beneficiaries and the Government.

In its response to OIG's 2006 report on drug plan sponsors' compliance plans, CMS indicated that it planned to conduct routine audits of PDP sponsors' compliance plans beginning in 2007. However, CMS conducted only one focused audit of a drug plan sponsor's compliance plan in 2007. As of early August 2008, CMS had not conducted any routine audits of PDP sponsors' compliance plans. In response to OIG's 2008 follow-up report, CMS stated that it will begin audits of Part D sponsors' compliance plans in the near future. These audits will consist of a limited number of desk audits; however, CMS stated that as more resources become available, it would include more audits, additional onsite reviews, and other more comprehensive fraud prevention activities.

In response to OIG's report on plan sponsors' identification of potential fraud incidents, CMS stated its intentions to follow up with the MEDICs, revise reporting requirements, and provide guidance to plan sponsors on incident tracking. CMS also concurred with our recommendation to determine whether the sponsors that identified potential fraud and abuse initiated inquiries and corrective actions, as required, and made referrals for further investigation.

In addition, effective January 2009, as part of their required compliance plans, Part D sponsors will be required to provide to their contractors (first tier, downstream, and related entities) appropriate fraud, waste, and abuse training. In October 2008, CMS issued a memorandum to Part D sponsors providing details about this requirement and stating that CMS is working with associations to assist industry in developing a training program that meets these requirements.

At the time of our 2006 review of CMS safeguards, CMS had released only five chapters of the "Prescription Drug Benefit Manual." Although this manual is still incomplete, as of October 2008, CMS had issued 10 chapters (at least 18 chapters are anticipated). The guidance provided in these chapters addresses marketing; enrollment and disenrollment; creditable coverage; benefits and beneficiary protections; formulary requirements; medication therapy management and quality improvement; fraud, waste, and abuse; coordination of benefits; and enrollee grievances, coverage determinations and appeals; as well as general provisions.

Beneficiary Protections

In response to concerns regarding availability of Part D drugs to dual-eligible nursing home residents, CMS stated that it will work with its partners and monitor complaints regarding formularies, adjust the formulary review process as necessary, and consider our recommendations as it constructs the formulary review checks for calendar year 2009. CMS also agreed to continue to work with sponsors to improve the prior authorization process. In addition, CMS indicated that it would update its guidance in the next revision of Chapter 6 of the "Prescription Drug Benefit Manual" and ensure that beneficiaries in nursing

homes have access to an emergency supply of drugs anytime during the plan year. Further, as CMS continues to work with LTC partners and providers, it will emphasize protections available to beneficiaries in nursing homes. CMS is also taking a number of steps to ensure that dual-eligible nursing home residents are not inappropriately charged copayments for Part D drugs. CMS disagreed with OIG's recommendation that it should consider methods to encourage LTC pharmacies to disclose to physicians information about drug rebates because it does not have the authority to require such disclosures. CMS noted that it requires plan sponsors to collect and review information regarding rebates received by their network LTC pharmacies.

With respect to oversight of plan sponsors' tracking of TrOOP, CMS indicated that it will continue to use sponsors' self-reports to identify noncompliance. In addition, CMS reported its intent to use Part D claims data to review TrOOP accumulation after reconciliation activities for 2006 have been completed. CMS also stated that the financial audits of drug plans would include an examination of how Part D plans track TrOOP costs. However, as discussed, these financial audits have been slow to materialize.

Management Issue 2: Medicare Integrity

MANAGEMENT CHALLENGE:

Because of the size and scope of the Medicare program, errors in payment can quickly add up to billions of dollars in losses to the Trust Fund and to taxpayers. In fiscal year (FY) 2007, Medicare benefit payments totaled about \$413 billion for services provided to approximately 44 million beneficiaries. The 2008 Annual Report of the Board of Trustees projects that by the year 2017, Medicare expenditures will have more than doubled, to \$881 billion, and the number of Medicare beneficiaries will have grown to close to 57 million.

With increasing dollars at stake and a growing beneficiary population, the importance and the challenges of safeguarding this program are greater than ever. Additionally, fraud, waste, and abuse schemes have become increasingly sophisticated and constantly adapt in response to the latest oversight efforts by Congress, CMS, OIG, and our law enforcement partners.

To ensure both the solvency of the Trust Fund and beneficiaries' continued access to quality services, correct and appropriate payments must be made for properly rendered services. OIG's work in this area is aimed at identifying and recommending methods to minimize inappropriate payments; holding accountable unscrupulous providers who defraud the program; identifying ways to close loopholes being exploited; and examining payment and pricing methods to ensure that Medicare, its beneficiaries, and taxpayers realize value for program expenditures. For example, OIG has recently focused oversight efforts in the areas of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS); infusion services; Part B prescription drugs; inpatient services; and physician and other health professional services. Additionally, OIG continues to monitor the adequacy of CMS's internal controls and oversight activities that are designed to ensure that payments are made properly and funds are properly accounted for, and to protect the program against fraudulent activity. OIG's activities related to ensuring the integrity of the Medicare Part D prescription drug benefit and quality of care are discussed in Management Issues 1 and 4, respectively.

Payment Error Rate

The Improper Payments Information Act of 2002 (IPIA) requires the heads of Federal agencies with any program or activity that has estimated improper payments exceeding \$10 million to report to Congress the agency's estimates of the improper payments and the actions the agency is taking to reduce those payments. Prior to the enactment of IPIA, OIG developed and reported on the annual Medicare fee-for-service paid claims error rate (FYs 1996 through 2002). In FY 2003, CMS assumed responsibility for conducting the Medicare Fee-For-Service error rate process under its Comprehensive Error Rate Testing (CERT) program and Hospital Payment Monitoring Program and reporting the national error rates to Congress for each fiscal year in accordance with IPIA. From 2004 through 2006, the error rate declined

from 10.1 percent for FY 2004, to 5.2 percent for FY 2005 and 4.4 percent for FY 2006. In its 2007 financial report, CMS reported a gross paid claims error rate (overpayments plus underpayments) of 3.9 percent (\$10.8 billion) for the fiscal year.

Although the overall Medicare fee-for-service payment error rate has decreased in recent years, the increasing size and scope of the Medicare program means that even a lower error rate still has a significant fiscal impact. Additionally, OIG is concerned that the error rates for certain provider types may be understated. Specifically, through the review of additional medical records and interviews with beneficiaries and providers, an OIG audit of the CERT DMEPOS error rate determination for FY 2006 found a 28.9-percent error rate in the CERT DMEPOS sample. OIG has recently initiated a similar audit of the home health error rate computation.

Specific Program Area Vulnerabilities

Improper payments and problems in specific parts of the program continue to be identified by OIG audits, evaluations and investigations. These reviews have revealed payments for unallowable services, improper coding, and other types of improper payments. Improper payments range from reimbursement for services provided but inadequately documented and inadvertent mistakes to outright fraud and abuse. OIG has also determined that, for certain items and services, Medicare's reimbursement rate is too high, thus potentially resulting in wasteful expenditures.

Durable Medical Equipment Suppliers and Infusion Services

OIG continues to identify significant vulnerabilities related to Medicare payments for DMEPOS, including (1) DME suppliers circumventing enrollment and billing controls and defrauding the program, (2) high improper payment rates for certain types of DMEPOS, and (3) inappropriate payment rates for certain DMEPOS.

From 2002 to 2007, OIG excluded from the Medicare and Medicaid programs 135 DMEPOS companies and 544 individuals associated with DMEPOS. During this same period, OIG's investigations resulted in 373 criminal prosecutions of DMEPOS suppliers, and 115 civil settlements or judgments were imposed. Together, these criminal convictions and civil adjudications have resulted in more than \$1 billion in restitution, fines, and penalties.

OIG and our law enforcement partners have concentrated our recent efforts in geographic areas at high risk for Medicare fraud, including South Florida and Los Angeles. To help combat DMEPOS fraud in South Florida, OIG, in conjunction with the U.S. Attorney's Office for the Southern District of Florida, the Federal Bureau of Investigation, and the Department of Justice (DOJ) launched a Medicare Fraud Strike Task Force (Strike Force) in March 2007. The Strike Force is identifying, investigating, and pursuing enforcement actions against DMEPOS suppliers and infusion clinics suspected of Medicare fraud. As of July 2008, our South Florida initiatives resulted in 92 convictions, 76 civil actions, and \$144.7 million in receivables and judgments. Building on the success of the South Florida strike force, in March 2008, DOJ and OIG created a second strike force in Los Angeles.

In related work, OIG has identified weaknesses in Medicare's supplier enrollment process and oversight activities intended to ensure that only qualified suppliers participate in Medicare. In 2007, OIG found that 31 percent of DMEPOS suppliers in three South Florida counties 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.

OIG also found that CMS has had limited success controlling aberrant billing by infusion clinics. In the second half of 2006, the claims originating in three South Florida counties accounted for 79 percent of the amount submitted to Medicare nationally for drug claims involving HIV/AIDS patients and constituted 37 percent of the total amount Medicare paid for services for beneficiaries with HIV/AIDS. However, only 10 percent of Medicare beneficiaries with HIV/AIDS lived in these three counties. Other metropolitan

areas exhibited aberrant billing, but to a lesser extent than South Florida. OIG is currently reviewing aberrant claim patterns for inhalation drugs in South Florida.

In additional work, OIG identified strategies that DMEPOS suppliers have used to circumvent billing controls and defraud the program. Medicare regulations require DME suppliers to provide the Medicare provider identifier of the physician who ordered the equipment on the claim. Until May 23, 2008, Medicare used unique provider identification numbers (UPIN) and then switched to national provider identifiers (NPI). Requiring the UPIN (or NPI) on claims is intended to indicate that a physician has verified the need for the DMEPOS and to enable CMS to determine who prescribed the DMEPOS as part of any postpayment reviews. OIG studies have uncovered: (1) the use of invalid or inactive UPINs, (2) the use of UPINs that belonged to deceased physicians, (3) the improper use of surrogate UPINs, and (4) the use of legitimate UPINs that were associated with an unusually large number of claims. OIG testified before Congress about our concerns that UPIN vulnerabilities, as well as other challenges, may affect the integrity of the new NPI system. Therefore, OIG has planned additional work to examine the accuracy and completeness of NPIs.

OIG has also found that certain types of DMEPOS are particularly vulnerable to improper payments. For example, an investigation of a large wheelchair supplier found that the company submitted false claims to Medicare and Medicaid, including claims for power wheelchairs that beneficiaries did not want, did not need, or could not use. In 2007, the company agreed to pay \$4 million and relinquish its right to approximately \$13 million in claims initially denied for payment by CMS. Nationally, in 2004, OIG estimated that Medicare and its beneficiaries paid \$96 million for claims that did not meet Medicare's coverage criteria for any type of wheelchair or scooter and spent an additional \$82 million in excessive payments for claims that could have been billed using a code for a less expensive mobility device.

Prior OIG work has also identified that Medicare pays too much for certain pieces of DMEPOS and related supplies such as power wheelchairs, hospital beds, diabetic supplies, and home oxygen equipment. For example, in a 2006 report, OIG found that Medicare allowed, on average, \$7,215 for the rental of an oxygen concentrator that costs about \$600 to purchase new. Additionally, beneficiaries incurred \$1,443 in coinsurance charges. We determined that if home oxygen payments were limited to 13 months rather than the current 36 months, Medicare and its beneficiaries would save \$3.2 billion over 5 years. In other work related to Medicare pricing, OIG is currently conducting work to examine the appropriateness of prices that Medicare pays for wheelchairs by comparing Medicare prices to supplier purchase prices.

Part B Prescription Drugs

Consistent with OIG recommendations to address the serious flaws in Medicare's prior Part B drug reimbursement methodology, the MMA instituted a new drug reimbursement methodology for Part B based on average sales prices (ASP), which took effect in 2005. Congress also mandated that OIG monitor Part B drug reimbursement and certain market prices for Part B covered drugs on an ongoing basis and provided the Secretary authority to adjust reimbursement amounts when OIG identifies drugs with ASPs that exceed market prices by a certain threshold. Although the new reimbursement methodology has lowered the previously inflated Part B drug reimbursement amounts, OIG's work has identified a number of drugs for which the Medicare reimbursement amounts may still be higher than certain other prices in the marketplace. In addition, OIG found that the Part B reimbursement methodology can result in temporarily inflated payments for drugs with newly approved generic versions. For example, in March 2008, the Medicare payment amount for irinotecan was more than double the OIG calculated average manufacturer sales price, primarily because Medicare's reimbursement calculation did not yet take into account sales of a newly approved, lower priced generic irinotecan. OIG estimates that had the Medicare payment amount for irinotecan been based on the average manufacturer sales price, Medicare expenditures for this drug would have been reduced by \$6.5 million in that month alone. Because of the two-quarter lag in the ASP system, the Medicare payment amount will not reflect any sales of lower priced irinotecan until the third quarter of 2008.

OIG is also concerned that Medicare reimbursement for end stage renal disease (ESRD) drugs may be too high. In 2007, OIG found that the average acquisition costs for the two most widely used ESRD drugs, epoetin alfa (Epogen) and darbepoetin alfa (Aranesp), were approximately 10 percent below Medicare's reimbursement amount. Although the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) requires that ESRD drugs be bundled into the ESRD composite rate by 2011, in the meantime, financial incentives may lead to overutilization of these drugs, thus raising both financial and quality concerns. OIG is conducting additional work to determine whether claims submitted for Epogen administered at dialysis facilities are supported and billed in accordance with Medicare requirements.

Inpatient Services

Expenditures for inpatient services, including those provided by inpatient hospitals and skilled nursing facilities, account for one-third of all Medicare expenditures. Even small vulnerabilities can translate into large dollar losses. OIG therefore continues to focus efforts on reviewing the appropriateness of billings and accuracy of cost reporting in these types of facilities. To illustrate, in a series of audits, OIG found that 21 hospitals reported in their Medicare cost reports a total of \$377.9 million in inaccurate hospital wage data. Under the acute care hospital inpatient prospective payment system, CMS adjusts the Medicare base rate paid to participating hospitals by the wage index applicable to the area in which the hospitals are located. Therefore inaccurate wage data can affect the accuracy of future Medicare payments. OIG is continuing its reviews of hospital and Medicare controls over the accuracy of the hospital wage data, and similarly is examining the methodology used to update hospital capital payment rates and the appropriateness of the associated payment levels.

To promote access to hospital care for patients with substantial medical needs, CMS makes additional payments called outlier payments. OIG found that a major hospital chain took advantage of the Medicare outlier payment system by billing for and receiving hundreds of millions of dollars in outlier payments by merely increasing its charges for services. In 2006, the hospital chain agreed to pay the Government more than \$900 million to settle allegations concerning the improper outlier payments and allegations that it paid illegal kickbacks to doctors for patient referrals and used improper billing codes to receive inflated payments.

In reviews of nursing homes, OIG continues to find significant improper payments related to Part B claims for beneficiaries who were in Part A-covered skilled nursing facility stays, for which the Part B services are reimbursed as part of the Part A payment. In a 2008 report, OIG found that Medicare Part B made \$106.9 million in potential overpayments to suppliers of outpatient hospital, laboratory, and radiology services on behalf of beneficiaries in Part A covered skilled nursing facility stays before edits to prevent such overpayments were fully operational. After the edits were fully operational, OIG identified potential overpayments of \$22.7 million and estimated that fiscal intermediaries and carriers had not recovered approximately \$17.9 million of these overpayments. OIG has also pursued enforcement actions against providers who defraud Medicare in this manner. For example, in 2007, an Illinois laboratory agreed to pay more than \$700,000 and be excluded from participation in Medicare and Medicaid for 5 years to settle allegations of fraudulently billing Medicare Part B for services rendered to beneficiaries residing in skilled nursing facilities. OIG is conducting reviews related to the appropriateness of Medicare Part B payments for nursing home residents during Part A stays and plans to review the accuracy of Medicare payments to skilled nursing facilities.

OIG continues to be concerned that providers of inpatient services may be potentially gaming prospective payment reimbursement systems by discharging or transferring patients to other facilities for financial rather than clinical reasons. In 2007, OIG assessed services provided to beneficiaries with consecutive Medicare stays involving inpatient and skilled nursing facilities and found that 35 percent of consecutive stay sequences were associated with quality-of-care problems and/or fragmentation of services for which Medicare paid an estimated \$4.5 billion.

In other work, OIG is reviewing the extent to which hospitals improperly claim provider-based status for inpatient and outpatient facilities to receive higher payment rates, and determining whether bad debt

payments claimed by various types of inpatient facilities were properly used to reduce the cost of beneficiary services for the period in which the recoveries were made.

Physician and Other Health Professional Services

OIG continues to identify areas of vulnerability related to certain types of services provided by physicians and other health professionals, including services related to advanced imaging, pain management, and mental health. For example, advanced imaging services, such as magnetic resonance imaging (MRI), positron emission tomography, and computed tomography, have proliferated rapidly in ambulatory settings. In a 2007 report, OIG found that from 1995 to 2005, expenditures for advanced imaging paid under the Medicare Physician Fee Schedule grew more than fourfold, from \$1.4 million to \$6.2 million. Services provided by independent diagnostic testing facilities (IDTFs) accounted for nearly 30 percent of this growth. Previous OIG work has found problems with IDTFs, including noncompliance with Medicare requirements and billing for services that were not reasonable and necessary. Although this growth in advanced imaging has the potential to increase convenience and improve health outcomes for beneficiaries, it also raises concerns about the potential for the inappropriate use of services, which can be costly for both Medicare and its beneficiaries. In a 2008 report, OIG reviewed how MRI services paid under the physician fee schedule were provided, and noted that the complexity of and limited transparency in the relationships among those ordering and those providing the services warrants continued attention to ensure that the services provided are reasonable, necessary, and compliant with Medicare statutes and regulations.

OIG is also monitoring the increase in utilization of and billing for interventional pain management procedures, which include such things as facet joint injections, nerve removal, and spinal cord stimulation. Facet joint injections are an interventional pain management technique used to diagnose or treat back pain. From 2003 to 2006, the number of Medicare claims for facet joint injections increased by 76 percent and payments for facet joint injections increased from \$141 million to \$307 million. OIG found that 63 percent of Medicare facet joint injection services in 2006 did not meet program requirements, resulting in approximately \$96 million in improper payments to physicians and \$33 million to facilities.

OIG has also identified vulnerabilities resulting in substantial improper Medicare Part B payments for mental health services. For example, OIG determined that 47 percent of the Part B mental health services allowed by Medicare in 2003 did not meet program requirements, resulting in a projected \$718 million in improper payments. Miscoded and undocumented services accounted for the greatest number of payment errors, and violations of the "incident to" rule resulted in an estimated \$72 million in improper payments. We recommended that CMS revise, expand, and reissue its 2003 Program Memorandum on Part B mental health services with an increased emphasis on proper documentation coding and the requirements for services billed "incident-to." In related ongoing work, OIG is determining whether Medicare payments for psychiatric services were reasonable and necessary.

In other ongoing work, OIG is reviewing whether claims for services provided by clinical social workers were appropriately separately billed to Medicare Part B, whether physicians properly coded the places of service on claims for services provided in ambulatory surgical centers and hospital outpatient departments, the extent to which services billed "incident-to" were medically necessary, and the extent to which physicians reassign their benefits to other entities and are aware of billing for services rendered. Future work will examine the reasonableness, medical necessity, and proper documentation associated with claims for physical therapy services provided by independent therapists in an outpatient setting.

Internal Controls

Medicare relies on extensive information systems operations at CMS and at Medicare contractor sites to administer the Medicare program and to account for Medicare expenditures. Effective internal controls must be in place and utilized to ensure the proper processing of transactions and the integrity of stored data. However, OIG's FY 2007 financial statement audit report for CMS identified a material internal control weakness in Medicare claim-processing controls related to direct update access to Medicare claims data, controls over edit settings in application systems, and lack of CMS oversight. Effective controls over

the use of direct update access to claims and changes to edits within major Medicare claims processing systems is imperative to ensure the accuracy of claims processing.

Specifically, the audit determined that a significant number of Medicare contractor employees had been granted direct access to Medicare claims data, but these employees did not require access to perform their job responsibilities and this access did not undergo comprehensive review or logging. The ability to directly change claims without comprehensive review increases the likelihood of intentional or unintentional payment errors. In addition, management could not provide reports to document the volume and nature of claims that bypassed the Common Working Files (CWF), and controls over changes to edits and proper edit settings were not always in use by the contractors. The CWF is a system that uses localized databases, maintained by host contractors, to validate and approve prepayment of Medicare claims and to coordinate Medicare Part A and B benefits. Only in special circumstances should Medicare claims be paid without being processed through CWF edits as this can result in payment errors. The audit also determined that CMS lacked sufficient processes and procedures to track compliance with requirements of claim-processing controls.

OIG is conducting additional work to assess the extent to which Medicare claims are processed and paid without the CWF editing controls and to determine the impact on the completeness of the National Claims History (NCH) file. The NCH File contains information on all claims made on behalf of Medicare beneficiaries and is used to support regulatory, reimbursement, and policy functions performed by CMS and its contractors.

Program Oversight

Section 202(b) of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) authorized CMS to contract with entities to fulfill program integrity functions for the Medicare program and required a competitive process for awarding contracts. These contractors, called program safeguard contractors (PSC), perform investigative work on Medicare payments to deter fraud and abuse. When they identify overpayments that have been made to Medicare providers, they refer them to Medicare claims processors for collection. In 2006, OIG found that PSC performance evaluation reports issued by CMS from 1999 to 2004 contained minimal information about PSC achievements related to detecting and deterring fraud and abuse under benefit integrity task orders. In a 2007 report, OIG determined that PSCs differed substantially in the number of new investigations and case referrals to law enforcement; some had minimal activity in these primary workload categories. We also found that most PSCs had minimal results from proactive data analysis and we found no consistency across PSCs regarding the level of detail about proactive data analysis include in the monthly status reports. We recommended that CMS review PSCs with especially low volumes of activity in investigations and case referrals for Medicare Parts A and B. In addition, we recommended that CMS require PSCs to provide more detailed explanations of their investigations, case referrals to law enforcement, and proactive data analysis.

OIG is continuing work to examine the effectiveness of the PSCs and is currently reviewing the extent to which PSCs referred overpayments to claims processors for collection in 2007 and identify the procedures that PSCs and claims processors use to identify and track possible fraud and abuse related to overpayments. Also, despite high rates of fraud within the DMEPOS area, we noted that only a small number of suppliers have had their payments suspended; therefore, OIG will review Medicare contractors, including PSCs', use of payment suspensions and other administrative sanctions intended to prevent payments to providers and suppliers suspected of fraud. Additionally, OIG plans to review CMS's oversight and monitoring of recovery audit contractors (RAC), who are responsible for detecting and collecting Medicare overpayments, to determine whether they meet their contractual requirements outlined in the RAC Task Orders.

ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:**Payment Error Rates**

The FY 2007 gross paid claims error rate of 3.9 percent reported by CMS is 0.5 percentage point lower than the 4.4 percent error rate it reported the previous year. CMS has demonstrated continued vigilance in monitoring the error rate and is developing appropriate corrective action plans. For example, CMS has worked with the health care provider community to clarify reimbursement rules and to impress upon providers the importance of fully documented services. CMS also has taken a number of steps to improve compliance with Medicare coverage and reimbursement requirements to curb inappropriate payments, including working with contractors to assist providers in submitting sufficient documentation to support billed services.

Specific Program Area Vulnerabilities

To address the potential improper payment exposure for durable medical equipment, the Secretary of the Department of Health and Human Services (HHS) announced a 2-year effort aimed at stopping fraudulent billing to the Medicare program and protecting beneficiaries and taxpayers. Under the initiative, on November 1, 2007, CMS began a demonstration project requiring DMEPOS suppliers in South Florida and Southern California to reapply for participation in the Medicare program to maintain their billing privileges. In August 2007, CMS also announced a demonstration project in South Florida focused on infusion therapy. Under this demonstration, currently enrolled infusion therapy clinics located in the targeted area are required to immediately submit new enrollment applications and will undergo mandatory site visits.

To address OIG recommendations that CMS revise claims-processing edits to ensure that UPINs listed on DME claims are valid and active, and to emphasize to suppliers the importance of using accurate UPINs when submitting claims to Medicare, CMS indicated that it had developed instructions, system changes, and edits that would reject claims listing a deceased physician's UPIN. CMS also stated that it planned to expand the edits to include all invalid and inactive UPINs. In November 2001 and April 2002, CMS issued instructions to its carriers stating that DME claims listing a deceased physician's UPIN would be denied. We are unaware of any further CMS action taken to address the presence of invalid and inactive UPINs on DME claims. Therefore, we continued, through 2007, to promote our recommendations addressing the invalid and inactive UPIN issue by including them in our annual publications listing unimplemented OIG recommendations.

In response to OIG recommendations related to payments for power wheelchairs, CMS has developed a plan of action to ensure that Medicare payments are made only for power wheelchairs that are reasonable and necessary. OIG is currently conducting work to determine whether these changes have affected the level of improper payments for power wheelchairs. CMS also continues to support efforts by Congress and the Administration to reduce the rental period for oxygen concentrators consistent with OIG's recommendation. For example, the President's Budget Proposal for FY 2009 included a provision that would reduce the rental period for most oxygen equipment from 36 to 13 months. Additionally, CMS issued regulations that addressed OIG's recommendations regarding costs for nonroutine maintenance and servicing, as well as for portable oxygen after patients reached the 36-month cap on rental payments. Finally, the MMA required that CMS establish a DMEPOS competitive bidding program to replace the current fee schedule payment amounts for specified DMEPOS items with payment rates established by the bidding process. However, MIPPA has delayed implementation of this program.

The Secretary has the authority to lower Medicare payment amounts based on the results of OIG studies comparing ASPs to AMPs and widely available market prices; however, CMS has yet to make any changes as a result of OIG's pricing comparisons. In response to the OIG report highlighting the vulnerability in Part B payment for drugs with newly approved generic versions, CMS expressed its commitment to ensuring accurate payments for drug products under the ASP methodology. CMS also noted that in the

4 months since OIG collected the data specific to the irinotecan study, the ASP-based payment limits had fallen and that this decline demonstrates that the ASP methodology reflects market-based prices over time.

CMS stated that it had increased its efforts to educate providers about the need to properly document wage data, and stated that it will continue to encourage hospitals to ensure that the methodologies used to develop wage data and the documentation maintained meet CMS requirements. In addition, CMS noted that OIG's recommended adjustments were used in calculating the FY 2007 wage index. In its response to OIG's 2007 report on consecutive Medicare stays, CMS stated that it would place greater emphasis on continuity-of-care issues in all settings and on measuring the rate of events, such as readmissions. The Ninth Statement of Work for the Quality Improvement Organization (QIO) program, effective August 1, 2008, made some significant changes in the way that CMS and the QIOs approach quality improvement. For example, QIOs will work in 14 States to coordinate care and promote seamless transitions among settings, including transitions from hospital to skilled nursing care.

CMS agreed that the complexity of MR services warrants continued attention and has taken regulatory steps to curb overutilization of diagnostic testing services including expanding the antimarkup provision to the professional component of services and seeking public comment on the in-office ancillary exception to the physician self-referral law. CMS also stated its commitment to examining the relationship between the utilization of advanced imaging services and the entities that order and bill for them. With respect to Medicare mental health services, CMS reported to us in 2008 that it was considering changes to ensure more accurate payment policies. Guidance on "incident to" services is available in the "Benefits Policy Manual" (Pub. 100-02, Chapter 15, section 60.1); however, we continue to recommend that CMS reissue the 2003 Program Memorandum with the additional guidance cited in our recommendations.

Internal Controls

CMS received an unqualified opinion on its FY 2007 financial statements. CMS continued to improve its financial management performance in FY 2007 in many areas and indicated that it has developed a corrective action plan to address the audit issues identified. Specifically, CMS has worked to establish and document consistent controls over the use of direct update access to claims data and control over edits in a variety of financial information systems. However, progress is challenged by the ongoing modernization of the claims processing applications and the contractor transition process related to the MMA requirement to competitively procure claims administration contractors to replace fiscal intermediaries and carriers by 2011. According to CMS officials, the CMS modernization program to centralize data processing and reduce the number of data centers represents a long-term solution to simplify the application software code and change controls needed for more robust security. Additionally, CMS is in the process of implementing significant changes to its claims administration contracting environment, which is expected to consolidate and reduce the number of contractors and data centers.

Program Oversight

In response to our 2007 report on PSCs, CMS indicated that direct comparisons between PSC task orders are difficult to make and stated that it has revised the monthly reporting system to collect more information and improve reporting consistency across PSCs. CMS indicated that quantifying results may create perverse incentives; however, we continue to recommend that CMS include a combination of qualitative and quantitative results information, including activities required in PSC task orders, in the PSC evaluation report.

Management Issue 3: Medicaid and SCHIP Integrity

MANAGEMENT CHALLENGE:

Medicaid is a joint Federal-State program that provides medical assistance to an estimated 50 million Americans with low incomes or disabilities. In 2007, the Medicaid program accounted for nearly

\$350 billion in health care spending, of which the Federal share was almost \$191 billion. This represents an increase of almost \$100 billion from the \$91 billion in Federal Medicaid expenditures in 1997. From 1997 to 2007, Medicaid enrollment also grew from 40.6 million to 49.1 million beneficiaries. At the Federal level, CMS administers the Medicaid program. However, Medicaid is structured such that the States have flexibility to design and administer their programs within Federal parameters. The Federal Government pays the States a statutorily determined matching rate for Medicaid payments, currently ranging between 50 and 83 percent.

The State Children's Health Insurance Program (SCHIP) provides coverage to uninsured low-income children who do not qualify for Medicaid. SCHIP provides an allotment of Federal matching funds to help States expand health care coverage to uninsured children and, in 2007, assisted roughly 7.5 million low-income children at a Federal cost of \$6 billion. Similar to Medicaid, States design and administer their SCHIP programs within Federal parameters.

The magnitude and growth of health care expenditures, combined with the health and financial impacts of Medicaid and SCHIP on vulnerable populations, make it critical that these programs operate efficiently and effectively and be protected from fraud and abuse. States and the Federal Government share in this responsibility. Coordination among multiple Federal and State entities with oversight and enforcement responsibilities, including CMS, OIG, State Medicaid agencies, State Medicaid Fraud Control Units (MFCU), and others, is crucial to efficient and effective Medicaid oversight. This shared oversight responsibility, as well as the diversity among Medicaid and SCHIP programs in size, structure, and administration, create significant challenges to program oversight and to ensuring Medicaid and SCHIP integrity.

Payment Integrity and Oversight

Payment Error Rates

Because Medicaid and SCHIP are Federal-State matching programs, improper payments by States lead to corresponding improper Federal payments. However, identifying payment errors, their causes, and other vulnerabilities in the Medicaid and SCHIP programs is particularly challenging because of the diversity of State programs and the variation in their administrative and control systems. Lack of information about payment error rates in Medicaid and SCHIP can present a substantial vulnerability in preventing and detecting fraud, waste, and abuse.

CMS's Payment Error Rate Measurement (PERM) program was designed to measure error rates in compliance with the Improper Payments Information Act of 2002. The PERM program includes error rates for three components of Medicaid and SCHIP: fee-for-service, managed care, and eligibility. To produce the managed care and fee-for-service error rates, CMS is using a national contracting strategy; and, as part of ongoing monitoring and oversight, OIG conducted a review of the FY 2006 PERM process for the Medicaid fee-for-service component.

For the 6-month period ending June 30, 2006, approximately \$363 million (Federal share) in Medicaid payments and \$67.2 million (Federal share) in SCHIP payments were made on behalf of beneficiaries who did not meet Federal and State eligibility requirements in these three States. OIG will continue to monitor and oversee the PERM program by reviewing the error rate processes for Medicaid and SCHIP fee-for-service, managed care, and eligibility.

Home- and Community-Based Care

The provision of long-term care (LTC) is increasingly shifting from institutional settings, such as nursing homes, to home- and community-based settings. In 2007, CMS awarded \$1.4 billion in grants to 31 States to support the transition of 37,731 individuals out of institutional settings over a 5-year demonstration period. CMS estimates that Medicaid expenditures for home- and community-based care and personal care services will total approximately \$26 billion in FY 2008. With this shift come challenges for ensuring program and payment integrity. OIG evaluations have found inappropriate Medicaid payments for home

health services and supplies that were paid for by Medicare (Medicaid is the payer of last resort). OIG has also identified a number of challenges, such as limitations in data, which hinder States' abilities to prevent such inappropriate payments for home health services and supplies. In addition, OIG has identified inappropriate Medicaid payments by five States for personal care services (PCS) billed during periods of beneficiary institutionalization. Three of these States allowed PCS providers to bill for services using date ranges that can include days on which no services were provided, making it difficult to determine whether claims that overlapped with institutional claims were paid in error. After completing our analysis of overlapping PCS and institutional claims, we further analyzed the PCS claims to identify claims that exceeded 24 hours per day. OIG identified paid claims for PCS that were billed in excess of 24 hours per day in four of the five States, indicating possible payment errors that may not have been identified by existing State controls. OIG is conducting additional work to identify the appropriateness of Medicaid payments for PCS.

OIG has also investigated fraud perpetrated by home health and personal care service providers and has successfully pursued enforcement actions. For example, a home health agency in Georgia and two of its administrators have agreed to pay \$475,000 to resolve allegations that the home health agency upcoded initial certification diagnoses and then continually certified home health care episodes for patients who either did not need the services or who were not homebound. In another example, a woman in Oregon was sentenced to 39 months' imprisonment and ordered to pay \$108,000 in restitution after evidence showed that she engaged in a scheme wherein she claimed to be providing in-home care to her codefendant, a Medicaid recipient, who was actually only pretending to be disabled. For 7 years, the women billed Medicaid for services that were never provided and then split the Medicaid payments.

OIG will continue to monitor home- and community-based services, including reviewing qualifications of personal care service providers, oversight of Medicaid funding to assisted living facilities, safeguards for home- and community-based services, payments to Medicaid-funded adult day health services, and community transition services waivers.

Prescription Drugs

CMS estimates that net prescription drug payments for FY 2008 will total approximately \$10 billion. Medicaid's net payments for prescription drugs comprise two components: States' reimbursement to pharmacies and rebates that drug manufacturers are required to pay to States. OIG has identified systemic vulnerabilities as well as specific fraud schemes related to Medicaid drug reimbursement, marketing, and drug rebates.

OIG audits and evaluations have consistently found evidence that Medicaid drug reimbursement exceeds pharmacies' drug acquisition costs, primarily because States lack access to accurate pharmacy drug cost data. Most States rely on published average wholesale prices (AWP) or wholesale acquisition costs (WAC), which do not necessarily reflect actual sales transactions. The Federal Upper Limit (FUL) program limits Medicaid reimbursement for drugs with generic equivalents. The Deficit Reduction Act of 2005 (DRA) required CMS to change its FUL calculation to base these limits on average manufacturer price (AMP), a sales-based price by January 2008; however, in December 2007, a Federal district court issued a preliminary injunction that prevented CMS from implementing these new FULs. Additionally, in July 2008, Congress enacted Public Law 110-275 delaying the implementation of the new FULs and prohibiting public disclosure of AMP until October 2009. Therefore, FULs are calculated using the prior formula based on the lowest published price (i.e., AWP or WAC), which OIG has found to result in inflated payments.

Further, OIG investigations have uncovered fraud schemes related to Medicaid reimbursement and marketing of prescription drugs. OIG has pursued cases in which pharmacies have switched the drugs prescribed to patients to exploit Medicaid reimbursement rules and receive higher payments. We have also investigated and pursued enforcement actions in cases in which drug manufacturers have fraudulently inflated their reported AWP to increase providers' reimbursement for their drugs as a marketing tactic. Other illegal marketing tactics identified by OIG investigations include kickbacks and

off-label promotion, which are addressed in Top Management Issue 6: Oversight of Food, Drugs, and Medical Devices.

OIG is also concerned that State Medicaid programs may not be receiving all drug rebates to which they are entitled. We have identified internal control weaknesses in several States, which may have resulted in these States not collecting all of the rebates due to their Medicaid programs. Medicaid rebates are based on a statutory formula that includes manufacturer-reported AMPs and best price. However, OIG has identified problems with AMP data, including late or incomplete AMP submissions and inconsistent interpretations of how to calculate AMPs. OIG investigations have also uncovered schemes in which drug manufacturers have defrauded Medicaid by misreporting best price data to lower their rebate obligations.

In a recent civil settlement, the Bristol-Myers Squibb Co. (BMS) and its wholly owned subsidiary, Apothecon, Inc., agreed to pay \$499 million plus interest to resolve allegations that BMS fraudulently set and maintained inflated prices for a wide assortment of oncology and generic drug products, paid various forms of illegal kickbacks to physicians and pharmacies, promoted off-label uses of the antipsychotic drug Abilify, and knowingly misreported its best price for the antidepressive drug Serzone. BMS entered into a 5-year corporate integrity agreement (CIA) with OIG, which is a contract that imposes systems, monitoring, and reporting requirements designed to prevent future misconduct in exchange for OIG's agreement not to seek BMS's exclusion from participation in Federal health care programs.

Other Medicaid Services

Other Medicaid services that are particularly vulnerable to inappropriate payments include school-based health services, disproportionate share hospital (DSH) payments, case management services, and dental services. For example, OIG has consistently found that schools have not adequately supported the claims submitted to States for school-based health services. In particular, OIG identified significant overpayments involving speech therapy and transportation claims in New York. In 2004 and 2005, OIG issued four reports questioning unallowable Federal funds to the New York Medicaid program totaling more than \$721 million. Findings included payments for services not sufficiently documented, services not authorized, and services rendered by unqualified providers. In a 2006 report, OIG also identified a State Medicaid agency that claimed Federal funding totaling \$86 million for unallowable targeted case management services. Contrary to Federal regulations, the targeted case management claims included social workers' salary costs related to direct social services, such as child protection and welfare services. In another example, OIG found that in 9 of the 10 DSH programs reviewed, States made DSH payments that exceeded the hospital-specific limits by approximately \$1.6 billion (\$902 million Federal share). In addition, OIG reviewed Medicaid payments for pediatric dental services in five States and found that 31 percent of services did not meet Federal and State requirements, resulting in improper Medicaid payments of approximately \$155 million (\$96 million Federal share) in 2003. Further, OIG is investigating alleged Medicaid fraud and patient abuse in a national chain of pediatric dental clinics.

Data Accessibility

One continuing challenge to Federal oversight of the Medicaid program is the lack of sufficient Medicaid data at the national level to assist in the detection of fraud and abuse. CMS requires States to submit specific Medicaid beneficiary-level claims and eligibility data, including detailed individual managed care enrollee encounter data, which CMS compiles and validates in the Medicaid Statistical Information System (MSIS). An ongoing OIG evaluation is reviewing whether MSIS data are sufficiently current, accurate, and comprehensive for detecting Medicaid fraud, waste, and abuse. In addition, as more than 60 percent of the Medicaid population receives all or some services through Medicaid managed care, OIG is evaluating the extent to which States are reporting Medicaid managed care encounter data to CMS.

National Medicaid claims data are limited in their capacity to support program integrity and oversight activities. Limitations include the following: some essential data elements, such as provider identification information, are not captured; data are updated quarterly, limiting the ability to analyze national data in real time; and CMS's process for collecting and validating the MSIS files can take as long as 2 years, making

the final data too old for certain program integrity activities. These limitations can increase the time and costs for CMS to conduct certain Medicaid oversight and program integrity activities, such as analyzing claims across States to detect aberrant billing patterns. OIG has also encountered these data challenges in conducting Medicaid investigations, audits, or evaluations that involve multiple States.

Appropriateness of Federal and State Cost-Sharing

OIG has identified a number of State financing arrangements and other revenue maximization tactics that inappropriately increase Federal Medicaid payments to States. Using such arrangements, States have obtained more Federal Medicaid dollars with fewer State dollars, resulting in an effective match rate that is higher than the statutorily determined match rate.

Intergovernmental Transfers

For years, OIG has reported on significant problems in State Medicaid financing arrangements involving the use of intergovernmental transfers (IGT). Specifically, OIG found that six States inflated the Federal share of Medicaid by more than \$3 billion by requiring providers operated by units of government, such as county-owned nursing homes, to return Medicaid payments to State governments through IGTs. Once the payments are returned, funds cannot be tracked and may be used by the States for purposes unrelated to Medicaid. This practice shifts the cost of Medicaid to the Federal Government, contrary to Federal and State cost-sharing principles. Although this practice can occur with any type of Medicaid payment to facilities operated by units of government, OIG identified serious problems involving supplemental payments to public hospitals and LTC facilities available under the upper payment limit (UPL) rules, DSH payments, and payments for school-based services.

State Oversight of Consultants

Some States employ consultants to assist them in navigating Medicaid rules and regulations. However, some consultants provide questionable or improper advice about ways to inappropriately maximize the State's Federal health care revenue. Contingency fee contracts can exacerbate the risk of questionable or improper advice. These contracts make the consultant's payment contingent on the amount of Federal Medicaid dollars a State receives, which increases the consultant's incentives to generate additional payments that may or may not be due to the State. We have found several instances in which States have failed to properly review the advice they are given and thus submitted improper claims. For example, as of June 2008, we have completed reviews in five States and questioned approximately \$197 million in improper Federal payments made as a result of advice given by contractors. We found that the States generally failed to ensure the accuracy of the claim submitted for Federal reimbursement and instead relied solely on the advice of the contractors. We have work ongoing in five additional States.

OIG is also working closely with DOJ to investigate and prosecute False Claims Act cases concerning fraudulent billing based on the advice of revenue maximization consultants. In July 2007, the Federal Government entered into an agreement with Maximus, Inc., for \$42.6 million to settle allegations that Maximus caused the District of Columbia to submit false claims for targeted case management services that were never provided. As part of the settlement, Maximus also entered into a CIA with OIG that contained several unprecedented provisions. Under the CIA, OIG will review Maximus' contracts and require dissemination of any negative review findings to Maximus' clients.

State Children's Health Insurance Program

OIG is statutorily required to determine every 3 years whether Medicaid-eligible children are inappropriately enrolled in separate SCHIP programs. States receive a higher matching rate for SCHIP than for Medicaid, thus creating incentives for States to inappropriately enroll Medicaid-eligible children in SCHIP. Most recently, OIG found that an estimated 4 percent of children enrolled in separate SCHIP programs were eligible for Medicaid in 2006, representing an increase over the 1-percent error rate found in 2003. Additionally, 4.5 percent of cases lacked sufficient documentation to enable OIG to make a determination regarding Medicaid eligibility.

ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

Section 6034 of the DRA established the Medicaid Integrity Program to combat fraud, waste, and abuse. CMS created the Medicaid Integrity Group (MIG) to implement this program. Pursuant to the DRA, CMS issued a 5-year Comprehensive Medicaid Integrity Plan in 2006, in consultation with OIG and other stakeholders, and has updated it annually. The primary goals of MIG are to promote the proper expenditure of Medicaid program funds, improve program integrity performance nationally, ensure the operational and administrative excellence of the Medicaid Integrity Program, demonstrate effective use of Medicaid Integrity Program funds, and foster collaboration with internal and external stakeholders. Among other activities, in summer 2008, MIG is commencing mandated audits of Medicaid providers.

OIG has worked closely with MIG and our Federal and State law enforcement partners to coordinate related activities and maximize our collective effectiveness in fighting Medicaid fraud, waste, and abuse. In addition, OIG and MIG have been working closely with State Medicaid agencies and MFCUs to improve communication and encourage collaboration within States. For example, in followup to a 2007 OIG report that raised concerns about the variation in and low volume of suspected fraud referrals from State Medicaid agencies to MFCUs, in September 2008, CMS issued performance standards for referrals of suspected fraud from State Medicaid agencies to MFCUs and guidance on best practices for Medicaid Program Integrity Units' interactions with MFCUs. In addition, OIG has implemented several improvements to the process State Medicaid Agencies use to refer to OIG providers that the State has excluded from Medicaid participation. These improvements include increased outreach and communication between OIG and State Medicaid Agencies, the creation of an exclusions referral guide, and improvements to the electronic tracking program for exclusion referrals. In 2007 and 2008, OIG sponsored 13 Medicaid integrity conferences throughout the Nation to foster communication and collaboration among Federal and State oversight and law enforcement entities and to highlight the integrity issues of greatest concern in each region.

Payment Integrity and Oversight*Payment Error Rates*

The FY 2007 Performance and Accountability Report (PAR) included a preliminary national Medicaid fee-for-service error rate based on a sample of States and of claims within those States for the first two quarters of FY 2006. The final national Medicaid fee-for-service error rate for FY 2006 will be reported in the FY 2008 Agency Financial Report, as will the national Medicaid and SCHIP fee-for-service, managed care, and eligibility error rates for FY 2007. CMS expects to be fully compliant with the Improper Payments Information Act of 2002 reporting requirements by FY 2008.

Home- and Community-Based Care

In response to OIG's report on personal care services, CMS indicated that it will explore various ways to incorporate information regarding these personal care service vulnerabilities as part of the technical assistance and support it provides to States. In addition, CMS reported that by FY 2009, it plans to start educating providers on payment and billing integrity as well as quality-of-care issues related to personal care services. In responding to our report on duplicate Medicaid and Medicare home health payments, CMS indicated that it will clarify policy on coverage of routine medical supplies under Medicare's home health prospective payment system.

Prescription Drugs

On July 17, 2007, CMS published a final rule with comment period (72 FR 39142) that (1) implements the provisions of the DRA pertaining to prescription drugs under the Medicaid program; (2) adds to existing regulations Medicaid rebate policies, including clarifying certain aspects of AMP calculations; and (3) solicits public comments on the FUL outlier and AMP sections of the rule. Pursuant to the DRA, the rule includes requirements related to State plans, Federal financial participation for drugs, and the

payment for covered outpatient drugs under Medicaid. The rule was scheduled to take effect on January 1, 2008. However, in December 2007, a Federal judge issued a preliminary injunction prohibiting CMS from implementing provisions of this rule. Additionally, in July of 2008, Congress enacted Public Law 110-275, which prevents CMS from releasing AMP data and from implementing FULs based on AMP until October 2009. Therefore, FULs continue to be calculated using the prior formula based on the lowest published price (i.e., the AWP or the WAC), which OIG has found to result in inflated payments.

Other Medicaid Services

CMS is finalizing regulations to clarify policies regarding reimbursement for school-based services, DSH payments, and targeted case management. In December 2007, a final regulation was promulgated to eliminate Medicaid reimbursement for school administration expenditures and costs related to the transportation of children between home and school. However, section 206 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 delayed implementation of these changes. In addition, section 7001 of the Supplemental Appropriations Act of 2008, P.L. No. 110-252, extended this moratorium until April 2009.

In August 2005, CMS published a Notice of Proposed Rulemaking to implement the new Medicaid DSH payment reporting and auditing provisions of section 1001(d) of the MMA. An interim final rule involving targeted case management was published in the Federal Register on December 4, 2007. The rule clarifies the definition of covered case management and implements section 6052 of the DRA, which redefined the scope of allowable case management services. However, section 7001 of the Supplemental Appropriations Act of 2008, P.L. No. 110-252, established a moratorium to delay its implementation until April 2009.

Data Accessibility

CMS's MIG is working to address data limitations by creating a new database to store Medicaid data from all States and exploring options to increase the number of data elements and frequency of data submissions from the States. MIG is working with OIG and other key stakeholders to make Medicaid data more accessible and useful for program integrity activities.

Additionally, two CMS projects under way are meant to ensure the availability of Medicaid data for program integrity activities. CMS has entered into a contract to develop a centralized data repository, known as One PI, which is intended to warehouse data from Medicare Parts A, B, and D and Medicaid. One PI is expected to offer powerful data analysis and fraud detection tools. The Medicaid Information Technology Architecture (MITA) initiative is intended to foster integrated business and IT transformation across the Medicaid enterprise to improve the administration of the Medicaid program. If successful, this would result in an increased availability of accurate and timely data.

Appropriateness of Federal and State Cost-Sharing

Intergovernmental Transfers

To curb abuses in State Medicaid financing arrangements, CMS promulgated final regulations (effective March 13 and November 5, 2001, and May 14, 2002) that modified UPL regulations pursuant to the Benefits Improvement and Protection Act of 2000. The rules created three aggregate UPLs: one each for private, State, and non-State government-operated facilities. The new regulations were gradually phased in and became fully effective on October 1, 2008. However, when fully implemented, these regulatory changes will limit, but not eliminate, the risk of Medicaid monies being returned by public providers to the State and then used for non-Medicaid purposes because the regulations do not require the provider to keep and use the enhanced funds to provide medical services to Medicaid beneficiaries.

In addition, in May 2007, CMS published a Final Rule with Comment Period, CMS-2258-FC (Cost Limit for Providers Operated by Units of Government and Provisions To Ensure the Integrity of Federal-State Financial Partnership) in the Federal Register (May 29, 2007; 72 FR 29748) that would modify Medicaid reimbursement. Consistent with OIG recommendations, this regulation codifies existing statutory authority that health care providers retain the total Medicaid payments received. This change, in addition to the UPL regulatory changes, will help ensure that Medicaid funds are used to provide necessary services

to beneficiaries. However, Public Law 110-28 prohibited implementation of the regulation for 1 year following the date of enactment, May 25, 2007. In addition, section 7001 of the Supplemental Appropriations Act of 2008, P.L. No. 110-252, blocks CMS from implementing the regulation until April 1, 2009. Also, on May 23, 2008, a Federal court vacated and remanded the Final Rule back to CMS because the Final Rule was improperly promulgated.

State Children's Health Insurance Program

Throughout the latter part of 2007 and early 2008, CMS's focus has centered on SCHIP reauthorization. SCHIP was funded through 2007 and must be reauthorized by Congress for Federal funding to continue. Although reauthorization legislation was vetoed by the President, the program is being funded through a continuing resolution. We will continue to monitor CMS's implementation of OIG's recommendations related to SCHIP.

Management Issue 4: Quality of Care

MANAGEMENT CHALLENGE:

Ensuring the quality of care provided to beneficiaries of Federal health care programs continues to be a high priority of OIG. Much of OIG's enforcement work is focused on ensuring that resources are not improperly diverted from patient care, as well as preventing providers from withholding needed care or rendering unnecessary or even harmful services. OIG works with DOJ, MFCUs, and other State and local law enforcement offices to investigate and prosecute instances of substandard care that led to patient harm. OIG also promotes quality through significant compliance initiatives. Additionally, OIG has produced a large body of work related to quality of care in a variety of settings, such as hospitals, home care, hospice, and nursing facilities. This work has included examining factors that may affect care, including incentives stemming from the structure of reimbursement systems; the effectiveness of oversight and enforcement mechanisms, including survey and certification systems; and the mechanisms used to screen potential health care employees.

OIG Enforcement and Compliance Efforts

OIG, together with our law enforcement partners, has with increasing frequency used the False Claims Act, the Federal Government's primary civil enforcement tool for fraud, to address poor quality of care. These cases often involve allegations of widespread failures that result in patient harm. In cases involving nursing facilities, systemic problems we have identified that have resulted in substandard care include staffing shortages; improper use of restraints; failure to implement medical orders or services identified on the care plan; failure to provide proper nutrition; failure to ensure that residents are protected from falls, physical abuse, and medication errors; and failure to prevent facility-acquired conditions such as infections and pressure ulcers. In many instances, as part of settling alleged violations of the False Claims Act, OIG has required providers to adopt Corporate Integrity Agreements (CIA) under which providers are required to implement compliance programs that focus on quality of care and retain external quality-of-care monitors selected by OIG. The external quality-of-care monitor plays a consultative role, assessing the effectiveness, reliability, and thoroughness of the provider's internal quality control systems; the provider's response to quality of care issues; the provider's development and implementation of corrective action plans; and the provider's proactive steps to ensure quality care. These CIAs include effective enforcement remedies for breach of the CIA, such as specific performance of CIA provisions, stipulated penalties, and exclusion. OIG currently has in place 28 CIAs with quality-of-care provisions covering about 265 facilities.

To illustrate OIG's use of the False Claims Act to address poor quality of care, OIG found that Ciena Healthcare Management, Inc., which manages 32 skilled nursing facilities in Michigan, had failed to provide adequate nutrition, medication management, fall prevention, and pressure ulcer care to its residents. Under the terms of the settlement reached in August 2007, Ciena paid \$1.25 million to resolve

liability under the False Claims Act. Ciena now operates under a CIA that promotes the provision of safe and appropriate care to residents at all Ciena facilities.

During investigations of nursing homes for the provision of substandard care, OIG has encountered nursing facilities with as many as 17 limited liability companies that play a role in the facility's operations. In such ownership structures, often the entity that acts as the facility operator does not own any assets and uses the facility under a sublease, and the operating entity usually contracts with a management/administrative services company to perform the day-to-day operations of the facility. OIG has found that these complex structures and the associated lack of transparency in a facility's ownership and management create challenges for ensuring accountability and greatly complicate law enforcement's investigations, and that at times profit-seeking investors compete against patient care for resources.

OIG has authority to hold hospitals accountable for failure to provide required emergency services. Specifically, under the Emergency Medical Treatment and Labor Act (EMTALA), 42 U.S.C. § 1395dd, OIG is authorized impose a civil monetary penalty against a participating hospital if the hospital has an emergency department and fails to provide a medical screening examination to individuals who present to the emergency department for treatment, or, if the individual has an emergency medical condition, to provide stabilizing treatment. In 2007, the OIG settled 13 cases and collected almost \$300,000 in civil monetary penalties under EMTALA. For example, in 2007, a hospital in Indiana paid \$40,000 to resolve allegations that it failed to treat a man who arrived at the emergency department by ambulance in an unresponsive state; the man was transferred more than 180 miles without stabilizing treatment and arrived at the second hospital "brain dead." As of May 2008, OIG had settled four EMTALA matters, collecting \$162,500 in civil monetary penalties.

To hold responsible individuals accountable and to protect additional beneficiaries from harm, OIG excludes from participation in Federal health care programs individuals and entities whose conduct results in poor care. In enforcement actions against corporate entities, such as nursing facilities and chains, OIG places particular emphasis on higher level officials, such as owners and chief executive officers. For example, recently the owner of a chain of personal care facilities agreed to be permanently excluded from participating in the Medicare and Medicaid programs because of her responsibility for the egregious conditions in her company's facilities, including insufficient food and nutrition, inadequate oversight of the administration of medication, failure to seek medical treatment when needed, unclean clothing and bedding, and structurally unsafe buildings.

The troubling failures of care in the long-term care industry uncovered by OIG enforcement activities have prompted OIG to undertake compliance promotion initiatives to help long-term care providers avoid problems that may endanger the vulnerable populations they serve. For example, on September 30, 2008, OIG issued a Supplemental Compliance Program Guidance for Nursing Facilities, updating the original Compliance Program Guidance issued in 2000 by identifying additional potential vulnerabilities and offering suggestions to promote quality of care. OIG also published a Resource for Health Care Boards of Directors on Corporate Responsibility and Health Care Quality in September 2007. This guidance document serves as an educational resource to help the leaders of health care organizations improve the quality of care provided at their institutions and, ultimately, the overall quality of the Nation's health care system. OIG also hosted a Government/industry roundtable entitled "Driving for Quality in Long-Term Care: A Board of Directors Dashboard", on December 6, 2007. At the roundtable, long-term care professionals and Government representatives engaged in a productive exchange of ideas, sharing strategies to improve quality in long-term care facilities. OIG published a report outlining key points from the roundtable so that providers throughout the long term care industry could learn from the roundtable. In recent testimony, OIG also recommended that Congress work with CMS to establish and provide resources for demonstration projects to explore different approaches to the implementation of compliance programs in nursing homes.

Survey and Certification

Through periodic facility inspections and individual complaint investigations, CMS and State agencies assess the performance of various types of providers to determine whether to certify them for participation in the Medicare and Medicaid programs. In 2003 and 2006 reports, OIG identified deficiencies in the State survey and certification and complaint investigation processes used to assess the performance of nursing facilities. In more recent work, OIG has continued to examine the effectiveness of survey and certification processes, as well as the enforcement mechanisms used when facilities are found to be out of compliance for designated time periods or have deficiencies that place program beneficiaries at serious risk of harm.

After an initial survey, home health agencies are subject to surveys at a minimum of every 36 months to continue their participation in the Medicare program. Previous studies have shown that many home health agencies that fail to comply with program standards still maintain their Medicare certification, serve Medicare beneficiaries, and receive Medicare funding. A Government Accountability Office (GAO) study identified a common pattern whereby an agency is cited for a deficiency, takes corrective action for a short time to maintain certification, but then slips back into noncompliance by the next survey. Following these cycles of noncompliance and temporary improvement, deficient home health agencies maintain Medicare certification indefinitely. When problematic facilities are recertified without meaningful intervention, poor quality may persist. In a 2008 report, OIG studied patterns of cyclical noncompliance of Medicare certified home health agencies to identify conditions that contribute to cyclical noncompliance. OIG's study found that 15 percent of home health agencies received the same deficiency citations across three consecutive surveys. OIG's study also explored the sanction process and how CMS ensures that appropriate sanctions are imposed upon noncompliant home health agencies. OIG recommended improvements in CMS oversight, such as enhanced use of existing survey data to identify deficiency patterns and at-risk home health agencies and implementation of intermediate sanctions.

Another 2008 report related to enforcement mechanisms to ensure compliance with conditions of participation for nursing homes. OIG evaluated CMS's use of a sanction that prevents noncompliant nursing homes from receiving payment for new admissions. Effective use of this sanction encourages substandard nursing homes to improve and, until such time as the homes meet Federal standards, encourages prospective residents to find superior alternative sources of care. OIG offered CMS several recommendations, including suggestions to enhance communications with CMS contractors and to deny payments for new admissions more effectively.

In a 2007 report, OIG found that hospices are assigned a lower priority for survey and certification inspections than other health care organizations. The report also found that, as of July 2005, 14 percent of hospices were past due for certification and, on average, had not been surveyed for 9 years—3 years longer than the CMS standard at that time. Finally, OIG found that health and safety deficiencies were cited for 46 percent of hospices surveyed, most frequently for patient care planning and quality deficiencies. OIG recommended that CMS provide guidance to State agencies and CMS regional offices regarding analysis of existing data to target "at-risk" hospices for certification surveys. OIG also recommended that hospices be included in Federal comparative surveys and annual State performance reviews and that CMS seek legislation to establish additional enforcement remedies for poor hospice performance.

Other Oversight

OIG work continues to focus on identifying specific quality-of-care problems in a variety of health care settings, as well as identifying opportunities for improving the effectiveness of other mechanisms designed to promote and ensure quality of care.

For example, in a report issued in May 2007, OIG assessed the extent to which QIOs identify quality-of-care concerns through medical record reviews and what interventions they undertake in response to confirmed concerns about quality of care. The study revealed that only about 11 percent of cases reviewed by QIOs entailed evaluations for quality-of-care complaints, and in 19 percent of those reviews the QIO confirmed a quality-of-care concern. In 72 percent of those cases with confirmed quality concerns, the QIO

recommended a corrective action, which generally entailed the two mildest corrective actions (i.e., the QIO offered advice or suggested that the provider should consider an alternate approach in the future) and rarely initiated sanction activity. In 28 percent of cases where a quality-of-care concern was confirmed, the QIO did not recommend any corrective action. OIG recommended that CMS consider revisiting its guidance to QIOs on classifying confirmed quality concerns and appropriate corrective actions.

In an additional report, issued in June 2008, OIG assessed the effectiveness of external quality reviews for Medicaid managed care. State Medicaid agencies that offer Medicaid managed care programs must contract with External Quality Review Organizations (EQROs) to monitor the quality of managed care plans. EQROs examine Medicaid managed care plans' strengths and weaknesses with respect to quality, timeliness, and access to care. OIG's study of EQROs found that most States are using the results of EQRO reviews. However, many EQRO reports did not include all required information and most States cited concerns with the external quality review process. OIG offered recommendations, such as improving the information made available to the State Medicaid programs, to improve the external quality review process and, ultimately, improve the quality of Medicaid managed care.

In another report, issued in January 2008, OIG evaluated physician-owned specialty hospitals' ability to manage medical emergencies. Among other things, we found that not all hospitals had nurses on duty and physicians on duty or on call, as required by the current Medicare Conditions of Participation. We also found that some hospitals lacked basic information in their written policies for managing medical emergencies. OIG offered CMS several recommendations, including suggestions to ensure that hospitals meet the current Medicare Conditions of Participation, which require a registered nurse to be on duty 24 hours a day, 7 days a week, and a physician to be on duty or on call if one is not onsite.

OIG is continuing to evaluate systemic issues that directly affect patient care. For example, studies are currently ongoing or planned to examine: (1) staffing levels and other quality-of-care indicators in investor-owned nursing homes, (2) use of atypical antipsychotics by elderly nursing home residents, and (3) appropriate dosing of erythropoiesis-stimulating agents in dialysis patients. OIG is also undertaking a congressionally mandated review of serious medical errors, referred to as "never events," such as a physician performing surgery on the wrong patient.

ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

Progress continues to be made in strengthening oversight of the quality of care paid for by the Medicare and Medicaid programs. For example, CMS is taking steps to improve its enforcement of nursing home quality requirements. Recognizing the need to focus more attention on facilities that historically provided poor care to residents, CMS operates a Special Focus Facility (SFF) program that involves enhanced monitoring of about 135 facilities. CMS selects nursing homes for the SFF program by reviewing 3 years' of deficiency data, thereby targeting facilities with a history of noncompliance. CMS strengthened its enforcement for SFFs by requiring immediate sanctions for facilities that failed to significantly improve their performance from one survey to the next, and by requiring termination for facilities with no significant improvement after three surveys over an 18-month period. In November 2007, CMS began publishing the names of the SFFs that failed to improve significantly. In February 2008, CMS began publishing lists of SFFs in a format that enables consumers to distinguish between those that have improved and those that have not, thereby providing SFFs a powerful incentive to improve. CMS also proposes making additional technical assistance available to SFFs to help them improve quality.

Because many more than the 135 homes in the SFF program could benefit from quality improvement, other efforts designed to improve nursing home quality include a voluntary program that CMS established in 2004 to help nursing homes improve the quality of care provided to residents. QIOs worked for 12 months with one to five nursing homes with significant quality problems in each of 18 States to help them redesign their clinical practices. CMS also completed a seven-State pilot program on criminal background checks for prospective direct patient access employees in September 2007. The evaluation of the pilot, issued in

August 2008, contained a number of recommendations regarding appropriate procedures and mechanisms for a national background check program.

CMS has also made progress in promoting quality by collecting and publishing quality-related data on nursing homes and hospitals. CMS offers consumers and the nursing home industry a good base of information on the quality of nursing homes, primarily through its Nursing Home Compare Web site. Nursing Home Compare includes information on inspection results, including identified deficiencies; facility characteristics, such as number of beds and type of ownership; nursing home staffing levels; and quality measures based on the clinical and functional status of a nursing home's residents. This information can be used by consumers to select and monitor performance in nursing homes and by providers to serve as the basis for quality improvement efforts. Additionally, CMS announced that it had enhanced Nursing Home Compare to identify the nursing facilities that are or have been on the CMS Special Focus Facility List. CMS also publishes data on hospital quality, providing beneficiaries with information they may use in selecting hospitals. As of 2008, CMS's Hospital Quality Initiative provides consumers with information on quality, patient satisfaction, and pricing for specific procedures, among other information. The initiative relies on a variety of tools that aim to stimulate and support improvements in hospital quality of care.

In its response to the OIG study on "Deficiency History and Recertification of Medicare Home Health Agencies," CMS noted that it had recently adopted changes to combat the problem of cyclical noncompliance. The steps CMS has taken include: (1) issuing identifiers for home health agency branch locations to facilitate oversight, (2) enhancing the Outcome and Assessment Information Set reports to provide information to surveyors to help them determine areas to examine during surveys, (3) increasing training to provide more tools to surveyors, (4) identifying a targeted sample of home health agencies for oversight, and (5) developing and strengthening a State Performance Standards System.

In May 2008, CMS published new Hospice Condition of Participation requirements that are designed to raise the performance standards for hospices. CMS also indicated that it aims to improve hospice oversight by improving the survey process. CMS also proposes to amend the hospice section of the "State Operations Manual" to enable State surveyors to make more consistent decisions regarding compliance with Medicare regulations.

Management Issue 5: Emergency Preparedness and Response

MANAGEMENT CHALLENGE:

The ability to effectively prepare for and respond to a public health emergency requires planning, coordination, and communication across a wide range of entities that includes 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 HHS, as the Federal agency tasked with the responsibility of coordinating the Nation's health response in the event of a disaster. Since 2002, HHS has provided over \$7 billion to States and localities through various programs to enhance their emergency preparedness activities and to better enable them to respond to large-scale public health emergencies, such as bioterrorism, natural disasters, or outbreaks of infectious disease.

The threat of future public health emergencies, whether caused by terrorism, natural disasters, or pandemic diseases, continues to underscore the need for leadership by HHS in developing a comprehensive national public health infrastructure that can rapidly and capably respond to public health emergencies of all kinds. This expanding challenge of preventing and preparing for major emergencies necessitates "all hazards" planning to prepare governments at all levels to respond to a wide range of unpredictable threats and dangers.

Like HHS as a whole, OIG's oversight has expanded to address both specific emergency situations and a broader all-hazards approach. Although targeted reviews of the Department's response to past hurricanes and pandemic influenza preparedness efforts are event- and scenario-specific, the findings from this work form a basis for ongoing and future OIG work that can assist our Nation's public health system to be better prepared to respond to a broad range of emergencies. OIG work has focused on assessing: how well HHS programs and their grantees plan for, recognize, and respond to health threats; the capabilities and security of HHS and grantee laboratory facilities; the management of these grant programs and use of funds by the Department and grantees; and the readiness and capacity of responders at all levels of Government to protect the public's health.

Hurricane Response

As Congress considers options to assist in restoring the health care infrastructure in and around New Orleans, OIG continues to examine the Department's disaster response work in this area. Previously, OIG examined procurements, beneficiary protections, and the delivery of critical health care services. OIG issued several reports related to the procurement process for pharmaceuticals and other relief-related products and services associated with the HHS response to the Gulf Coast hurricanes, including audits of 51 contracting actions with a total value of \$79.6 million. OIG found that procurement officials generally complied with the Federal Acquisition Regulation and associated HHS contract requirements in awarding the contracts.

Additionally, OIG reviewed the emergency preparedness and response activities of a selection of nursing homes in five Gulf Coast States and found that all experienced problems during the hurricanes, whether evacuating or sheltering in place. At the same time, OIG reviewed the U.S. Public Health Service (PHS) Commissioned Corps' response to Hurricanes Katrina and Rita and found that although the Corps provided valuable support to the States, it could improve its response to public health emergencies. For example, although most deployed officers met Corps readiness standards, many lacked experience, effective training, and familiarity with response plans. OIG also evaluated the use of Government purchase cards in support of the Department's response operations for the Gulf Coast hurricanes and found that there was insufficient written guidance regarding emergency purchasing procedures and that purchase data contained inaccuracies.

In the aftermath of Hurricanes Katrina and Rita, OIG's Office of Investigations (OI) provided protection for PHS officials and vital records and assisted with evidence recovery for a number of hospitals in the affected area. OI also served as a liaison with State and local law enforcement officials, as part of the DOJ Fraud Task Force in Baton Rouge. That task force is investigating allegations of fraud related to Federal outlays in connection with Hurricane Katrina.

Our continuing work on the disaster response to the Gulf Coast hurricanes focuses on uncompensated care for evacuees and Federal assistance for area hospitals. OIG examined whether certain State Medicaid agencies appropriately claimed special Federal reimbursement available to them for care provided to Hurricane Katrina evacuees. Specifically, we performed reviews of the hurricane-related uncompensated care pools at four hospitals in Mississippi and Louisiana. For two hospitals in Mississippi, we found that the State agency generally claimed reimbursement for services provided by the hospitals in accordance with the approved uncompensated care pool plans. For two hospitals in Louisiana, we found that the State agency did not always do so and claimed over \$19 million unallowable costs for the two hospitals. In a separate assessment of five different States that provided care under their Medicaid programs for evacuees, we found that the State agencies did not always claim reimbursement for services provided and claimed over \$1 million unallowable costs for Hurricane Katrina evacuees.

In an August 2007 congressional hearing, five hospital groups testified that their hospitals experienced significant post-Katrina operating losses, largely because of the increased costs of providing hospital care in the hurricane-affected areas. The hospitals requested additional Federal financial assistance to use for recovery of the health care delivery system in the New Orleans area. OIG conducted a series of audits and found that the revenue and expenses reported by these five hospitals were generally accurate but that the

data omitted some revenue. Audits of the testifying hospitals' Medicare wage data showed they generally overstated the data used to calculate Medicare reimbursement rates.

We also issued two reports regarding profitability of the testifying hospitals. We found that for FYs 2002-2007, each of the testifying hospitals had a significantly different profitability trend. Specifically, the hospitals experienced negative margins during both the FYs before the hurricane and in the FY in which the hurricane occurred. Additionally, OIG recently issued a report concerning the distribution of grant funds to hospital facilities to improve access to health care. This review determined that the State agency followed the approved methodology for computing grant payments to facilities that were eligible to receive payments; however, data entry errors (incorrectly recorded contract labor expenses and the number of hours contractors worked) resulted in most of the hospitals receiving an incorrect grant payment amount. The overpayments and underpayments did not affect the total amount awarded under the grant. OIG is conducting an additional review to examine the distribution of grant money used to retain and recruit health care providers in the hurricane-affected areas.

Pandemic Influenza Preparedness

Over the past 2 years, HHS has provided States and localities with \$600 million in supplemental funding to be used to strengthen responses to bioterrorism, infectious diseases, and natural disasters. HHS has distributed these funds annually under two programs—the Centers for Disease Control and Prevention (CDC) Public Health Emergency Preparedness Program and the Assistant Secretary for Preparedness and Response (ASPR) Hospital Preparedness Program. A major focus for the funds is preparedness for pandemic influenza. HHS estimates that a pandemic similar to the severe 1918–19 pandemics would sicken 90 million people in the United States (30 percent of the population). Estimates of the impact of the next pandemic vary widely, depending on the kind of flu, the seasonal timing of the outbreak, and other factors. Although scientists cannot predict the severity or timing of a pandemic influenza, many believe it is only a matter of time until the next one occurs.

The Office of the Secretary also allocated \$1 million in FY 2008 to OIG to conduct pandemic influenza preparedness evaluations and audits. This initiative, referred to as “Operation Protect,” was developed in coordination with CDC and ASPR, and applies a cross-disciplinary approach to assess levels of emergency preparedness in State, local, and tribal entities. The initiative focuses on two coordinated efforts: (1) financial audits of State and local government expenditures of pandemic flu preparedness funding from CDC and (2) evaluations of selected State and locality preparedness for an influenza pandemic.

Our financial audits will be focused on: (1) determining whether expenditures comply with Federal cost principles, cooperative agreements, and supplemental guidance; and (2) determining the extent to which recipients have expended funds, and why any funds remained unexpended. Audit results will help to identify and explain any delays in spending and show whether claimed costs are reasonable, allocable, and allowable. We are currently performing audits in five States and will be adding States as part of Operation Protect.

As part of OIG's evaluations of preparedness, we will review the extent to which selected States and localities have met preparedness goals outlined in CDC's Pandemic Influenza Guidance Supplement to the 2006 Public Health Emergency Preparedness Cooperative Agreement, Phase II. This review will focus on two areas: preparedness to dispense medical countermeasures—specifically, vaccines and antivirals—during an influenza pandemic and medical surge preparedness for an influenza pandemic. OIG will assess the comprehensiveness of State and local plans and determine the extent to which States and localities can execute and have exercised their plans.

Additionally, CDC has determined that an understanding of legal requirements by those involved in emergency preparedness and response, as well as the lawyers advising these individuals and organizations, plays a critical role in protecting Americans from public health emergencies like pandemic flu. CDC has established a Community Legal Preparedness Initiative, with a goal of fostering coordination between public health care agencies and health care organizations. Building on the importance of legal

preparedness, in May 2008, OIG cosponsored, with the American Health Lawyers Association (AHLA) and CDC, a public-interest dialogue session focused on pandemic influenza. This session brought together senior officials from the private and public health care sectors, along with representatives of Federal, State, and local governments; trade associations; and academic sectors. Attendees discussed a variety of legal issues related to pandemic preparedness and the AHLA publication entitled "Community Pan-Flu Preparedness: A Checklist of Key Legal Issues for Healthcare Providers."

Laboratory Capacity and Security

Early and accurate detection and reporting of biological agents is a critical component of a national response to biological threats. These include agents of bioterrorism, influenza, and food-borne agents that cause outbreaks such as E. coli and Salmonella. The Nation's laboratory system is made up of State public health laboratories and private clinical laboratories. Clinical laboratories perform diagnostic tests ordered by physicians and may be the first to identify the causes of illness in communities. As an essential first line of detection, the Nation's laboratories must be secure and capable of providing swift and accurate results. However, not all clinical laboratories have the capacity to conduct initial screenings and refer suspicious specimens to a State laboratory which could confirm the presence of public health threats.

In 2007, OIG reported that although States had made progress toward completing eight CDC-required pandemic influenza laboratory critical tasks, opportunities exist to improve coordination between State public health and private clinical laboratories, specifically to decrease the time to detect and report pandemic influenza. All State-level public health laboratories reported the capability to conduct year-round influenza testing and to detect and subtype influenza viruses, such as H5 influenza, an avian influenza virus that has been documented among humans. However, local private clinical laboratories reported that they do not have this subtyping capability, a fact that could present a critical testing capability shortfall in the event of a pandemic. In 2008, OIG issued a similar report on public health laboratory capacity to detect and report biological threats. We found that all States reported meeting at least three of the nine CDC testing and reporting requirements we reviewed, but no State met all nine. Further, for two of these nine requirements, less than 10 percent of States met all required elements. States must meet all nine requirements by 2010.

The security of HHS and Department-funded laboratories continues to be a concern of OIG. Federal law charges the Secretary of HHS with the responsibility for regulating toxic materials that pose a severe threat to public health and safety. The Secretary does so, in part, using regulations governing the possession, use, and transfer of "select agents" i.e., pathogens or biological toxins that pose a severe threat to public health and safety.

In previous years, OIG reviewed departmental and external laboratories for compliance with the regulations governing select agents and found that many laboratories did not adequately safeguard the agents against theft or loss. OIG has also conducted audits at numerous universities, as well as public and private laboratories, to assess their compliance with the security and safety requirements of the select agent regulations. We subsequently found that laboratories had problems maintaining accurate inventory and access records, controlling access, security planning, and other areas. OIG has underway audits of HHS laboratories with select agents and an audit of select agent transfers.

OIG has the authority to impose civil monetary penalties against entities that violate select agent regulations. In recent years, OIG has sanctioned entities for various violations of the select agent regulations, including conducting unauthorized research with select agents, taking inadequate precautions in shipping select agents, storing toxins in an unsecured area prior to transfer, neglecting to train employees, and allowing unauthorized individuals access to select agents. One recent case involved a Texas University that paid \$1 million to resolve its liability for numerous violations of the select agent regulations. OIG's investigation revealed, among other violations, that the university failed to obtain CDC approval to conduct restricted experiments with a select agent; allowed researchers, on multiple occasions, to have access to select agents without prior CDC approval and without having the appropriate education, training, and/or experience to handle or use select agents; failed to ensure that appropriate biosafety and

security plans were implemented; failed to implement an accurate recordkeeping system for its select agent inventory; and failed to report occupational exposures to select agents.

Bioterrorism and Chemical Emergencies

To enhance the ability of hospitals and health care systems to prepare for and respond to bioterrorism and other public health emergencies, the Hospital Preparedness Program was established. Available funding for FYs 2007 through 2009 is almost \$1.3 billion. Current program priority areas include interoperable communication systems, bed tracking, personnel management, fatality management planning, and hospital evacuation planning. OIG completed an audit of one New England State where we determined that the State did not comply with Federal requirements governing employee compensation and recommended a disallowance of \$9.2 million of grant funds. OIG will also continue to audit grants awarded in two Gulf Coast States to determine whether these funds were used in accordance with the grant award.

In addition, OIG is currently evaluating the storage of drugs to treat nerve agent exposure. The CDC CHEMPAK project provides funds to cities and States to place nerve agent antidotes in monitored storage containers for immediate use in the event of a chemical emergency. OIG will determine whether CHEMPAK drugs are stored according to Federal requirements, and the extent to which CDC ensures that these drugs meet the requirements of the Shelf Life Extension Program (SLEP). In SLEP, the Food and Drug Administration may extend the expiration date of drugs that pass efficacy testing standards.

Critical Infrastructure and Continuity of Operations

In the event of a disaster, it is essential that the Department continue to function smoothly to provide critical health and human services to the public. To do so, the Department must have a strong critical infrastructure that protects and connects regions and an established plan in place to ensure the continuity of operations (COOP). Pursuant to National Security Presidential Directive-51/Homeland Security, Presidential Directive-20, and Federal Continuity Directives 1 and 2, Federal agencies are responsible for developing COOP programs. OIG is currently reviewing HHS compliance with these Directives including assessing regional office and Staff and Operating Division continuity program plans to determine if they contain the required continuity elements and supporting tasks.

Additionally, we are conducting a broad risk assessment of nine HHS agencies that includes an assessment of information and communication systems to determine whether they capture and store data in a sufficiently timely and reliable manner to facilitate identification and assessment of and response to risks. We will also assess whether the agencies have developed communication systems that provide information to appropriate personnel to enable them to carry out strategic, operating, compliance, and reporting responsibilities.

ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

On October 18, 2007, President Bush signed Homeland Security Presidential Directive (HSPD)-21, establishing a new national strategy for "Public Health and Medical Preparedness" (the Strategy). The Strategy aims to improve the Nation's ability to plan for, respond to, and recover from public health and medical emergencies at the Federal, State, tribal, and local levels. It calls for the development of a national health security strategy, as well as a robust infrastructure — including healthcare facilities, responders and providers — which can be drawn upon in the event of an emergency. The Strategy also seeks to ensure the adequate flow of information before, during, and after an event, including critical biosurveillance data and risk analysis. Finally, the Strategy calls for the development of resources at the community level to ensure that individuals and families are empowered to protect themselves during an emergency.

HSPD-21 mandates the development of an implementation plan for the Strategy that contains detailed information regarding how the Federal agencies will execute these actions. Six workgroups have been established to oversee implementation of HSPD-21, four of which are chaired by HHS: (1) Medical Countermeasure Stockpiling and Distribution, (2) Biosurveillance, (3) Mass Casualty Care, and

(4) Community Resilience. A fifth workgroup on Education and Training is cochaired by HHS and the Department of Defense, and a sixth workgroup on Risk Awareness is being led by the Department of Homeland Security.

In addition, HSPD-21 directed the establishment of two advisory committees. The National BioSurveillance Advisory Committee has been established as a subcommittee to the CDC Advisory Committee to the Director. A Disaster Mental Health Advisory Committee is being established as a subcommittee under the National Biodefense Science Board, which advises the Secretary. HHS has also recently established the Emergency Care Coordination Center. This center is a collaborative effort involving the Departments of Defense, Homeland Security, Transportation, and Veterans Affairs that will serve as the coordinating focal point for an Emergency Care Enterprise, coordinating with the Federal Interagency Committee on Emergency Medical Services.

Consistent with requirements contained in 2802(b) of the Public Health Service Act, as amended by the Pandemic and All-Hazards Preparedness Act (PAHPA) (P.L. 109-417), HHS has updated the performance measures used for its related grant programs (existing Public Health Emergency Preparedness, Hospital Preparedness Program, Centers for Public Health Preparedness grants; and implementing new authorities for Real-Time Disease Detection, Health Care Facility Partnerships, Situational Awareness, and Loan Repayment grants). HHS sought to provide greater clarity in language, the use of definitions, and the addition of targets. HHS strongly supported the new accountability provisions included in PAHPA and is implementing these provisions.

HHS is also improving its operational capabilities to respond to emergencies. The National Disaster Medical System, transferred from the Department of Homeland Security to HHS, remains the front line of the Federal disaster health care response capability, maintaining 6,200 medical and public health professionals and over 1,800 participating hospitals with approximately 32,000 beds. Over the past 5 years, the Hospital Preparedness Program has provided more than \$2.6 billion to fund the development of medical surge capacity and capability at the State and local levels.

With respect to pandemic preparedness, CMS disseminated through its provider communications network the American Health Lawyers Association publication entitled "Community Pan-Flu Preparedness: A Checklist of Key Legal Issues for Healthcare Providers." By doing this, CMS was able to reach approximately 600,000 subscribers, most national associations, and over 2,400 local provider associations. This checklist serves as a practical tool to assist providers in preparing for a pandemic.

States and localities continue to make progress in strengthening their public health emergency preparedness programs. Federal, State, and local health departments are striving to work cooperatively to ensure that potential bioterrorist attacks are detected early and responded to appropriately. For example, CDC has taken steps to improve its capacity to detect and respond to harmful agents and to expand the availability of pharmaceuticals needed in the event of chemical, biological, or radiological attacks.

Additionally, in response to our nursing home emergency response and preparedness report, CMS reported that it plans to implement a communication strategy that will disseminate information among State survey agencies, CMS regional offices, and health care facilities. It also reported participating in several departmental and interagency workgroups that are developing recommendations for improved collaboration and coordination among Federal, State, and local emergency entities. In response to a separate OIG report, the Commissioned Corps is initiating development of a more effective deployment-related training program for officers, improving contact and communication mechanisms for officer deployments, and revamping its travel systems in support of deployments.

In response to OIG's report on the use of purchase cards following the 2005 hurricanes, the Assistant Secretary for Administration and Management will add a separate appendix to existing purchase card guidance devoted to the use of purchase cards during emergencies and will develop a "quick reference" guide to aid cardholders during both emergency and nonemergency situations. It will also revise the HHS

University purchase card training course to include mock scenarios and define roles and responsibilities designed specifically for emergency situations.

However, OIG findings still demonstrate the need for significant improvements for Federal, State, and local health entities to be fully prepared to detect and respond to bioterrorism and natural disasters. OIG will continue to conduct emergency preparedness and response oversight activities to better protect the Nation's health and to optimize the use of funding.

Management Issue 6: Oversight of Food, Drugs, and Medical Devices

MANAGEMENT CHALLENGE:

The Food and Drug Administration (FDA) is responsible for protecting and promoting public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, the Nation's food supply, cosmetics, and products that emit radiation. FDA is also responsible for protecting the rights, safety, and well-being of human subjects who participate in clinical trials conducted for the products it regulates. The National Institutes of Health (NIH) is responsible for acquiring knowledge through medical science that can help prevent, diagnose, and treat disease and disability.

OIG recognizes the significant risks to public health and safety if these critical mandates are not properly met. Therefore, OIG continues to focus efforts on reviewing and monitoring the adequacy and effectiveness of FDA and NIH policies and programs designed to: protect the Nation's food supply, ensure the safety of drugs, biologics, and medical devices, and protect human research subjects. Given FDA's broader responsibilities in this area, OIG audits and evaluations have focused primarily on FDA activities. OIG's enforcement efforts have also addressed fraudulent marketing activities by drug and device manufacturers, including kickback activity and the promotion of drugs for uses not approved by FDA. Such fraudulent activities undermine the integrity of the products' labeling and medical decisionmaking, and may lead to the products' inappropriate use, putting patients at risk.

Oversight

OIG's work reflects growing concerns in the areas of the oversight of food, drug, and medical device safety, as well as the oversight of clinical trials. Over the past decade, numerous OIG evaluations and audits have consistently documented weaknesses in the Department's oversight systems for ensuring the safety of food, drugs, and medical devices and for protecting human research subjects in clinical trials associated with NIH grants.

Food Safety

Since the terrorist attacks of 2001, and emphasized by the recent cases of microbial pathogens found in spinach, peppers, and peanut butter and a toxic chemical found in pet food, the security and safety of the Nation's food supply has been a great concern for the Department, as well as for other public health and homeland security experts. FDA is responsible for ensuring the safety of about 80 percent of the Nation's food supply, including \$417 billion in domestic food and \$49 billion in imported food brought to market annually. Recent recalls of human and pet food raise questions about the protocols that FDA uses to prevent and respond to the contamination of our Nation's food and feed supply.

OIG is currently examining the extent to which FDA can trace food through the distribution chain during a food emergency. OIG is also reviewing the extent to which food facilities comply with FDA's registration requirements, as well as examining FDA's food facility inspection and complaint investigation processes. Additionally, in a series of audits, OIG is examining FDA's oversight and operations related to three broad areas: imported food, imported pet food and feed products, and recall procedures for human food and pet food. For each of the three areas, OIG is reviewing the extent of FDA's enforcement authorities, its

procedures to implement those authorities, how FDA is carrying out the activities called for in its procedures, and the sufficiency of FDA authorities.

Drug Safety

Recent OIG work has also identified weaknesses in FDA's monitoring of drugs following their approval for marketing. For example, in 2006, OIG examined FDA's monitoring of drug sponsors' postmarketing study commitments. OIG identified several vulnerabilities that limit FDA's ability to readily identify whether these commitments are progressing toward completion or the timeliness with which they are completed. As a result, OIG recommended that FDA instruct drug applicants to provide additional and meaningful information in their annual status reports about postmarketing studies. OIG also recommended that FDA improve its management system for monitoring postmarketing study commitments and ensure that these commitments are being monitored.

OIG has recently conducted other evaluations of FDA's preapproval and postapproval oversight of drugs. In 2006, OIG completed a review of FDA's National Drug Code (NDC) Directory, which is intended to be a complete and accurate listing of currently marketed prescription drug products. OIG found that the NDC Directory is neither complete nor accurate and recommended that FDA improve guidance for industry and streamline the NDC submission and verification processes. Further, because of concerns about a generic drug review backlog, OIG recently evaluated FDA's review process for generic drugs. Pharmaceutical companies must submit Abbreviated New Drug Applications (ANDA) to FDA's Office of Generic Drugs (OGD) and receive OGD's approval before marketing new generic drugs, and Federal law requires that FDA approve or disapprove original ANDAs within 180 days of receipt. In a 2008 report, OIG found that FDA disapproved 96 percent of original ANDAs under review in 2006 because they did not meet FDA review standards and that FDA prioritization practices negatively affect ANDA review times. OIG recommended that FDA identify common ANDA deficiencies and offer more guidance to the industry to decrease the percentage of disapproved original ANDAs, and that FDA implement new prioritization practices.

In future work, OIG will review the extent to which FDA conducts compliance inspections of domestic drug manufacturers and examine FDA's oversight of firms that collect and process human cells and tissue for transplantation.

Medical Device Safety

OIG has also increasingly focused attention on issues related to the safety of medical devices. About 100,000 types of medical devices are currently in use and range in complexity from bandages to replacement heart valves. FDA receives about 200,000 adverse event reports each year regarding medical devices. About half these reports involve serious injuries and a few involve deaths.

In ongoing work, OIG is reviewing FDA's adverse event reporting system for medical devices. In this review, OIG is evaluating the extent to which FDA ensures compliance with adverse event reporting requirements and examining how FDA uses medical device adverse event reports to identify and address safety concerns as well. In future work, OIG plans to review FDA's oversight of medical device postmarketing surveillance studies. Specifically, OIG plans to review the extent to which FDA has required postmarketing studies of medical devices, the level of compliance among sponsors that have been required to perform such studies, and FDA's oversight of sponsors' study commitments. OIG also plans to identify trends and challenges associated with postmarketing surveillance studies.

OIG testified before the Senate Special Committee on Aging in 2008 on how financial relationships between the medical device industry and physicians can create both benefits and risks to patients and health care programs. OIG noted that the risks associated with these practices and relationships can lead to increased health care costs and improperly influence physicians' medical judgment.

Clinical Trials

In addition to conducting reviews related to the safety of food, drugs, and medical devices, OIG is continuing its work concerning human subject protections in clinical trials. For example, in 2007, OIG evaluated FDA's Bioresearch Monitoring (BiMo) program. OIG found that the lack of a clinical trial registry and inconsistencies in inspection classifications inhibited FDA's ability to manage the BiMo program effectively. OIG also found that FDA inspected only about 1 percent of clinical trial sites during the FY 2000 - 2005 period. OIG recommended that FDA improve its information systems and processes, establish a mechanism to provide feedback to BiMo investigators on inspection findings, and seek legal authority to provide oversight that reflects current clinical trial practices.

OIG will continue to focus on the oversight of clinical trials. In FY 2009, for example, OIG plans to evaluate FDA's oversight of foreign clinical trials. Future OIG work will also examine NIH's use of Data Safety Monitoring Boards to ensure the safety of human subjects in clinical trials.

Enforcement

OIG, along with its Government partners, has participated in the investigation and/or resolution of pharmaceutical and medical device fraud cases that have resulted in more than \$5 billion in recoveries and fines since 1999. The Government is currently investigating numerous additional allegations of fraudulent marketing and promotional practices in the pharmaceutical industry and is reviewing over 100 sealed *qui tam* complaints involving pharmaceutical 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.

OIG has continued to work with its law enforcement partners to successfully pursue and resolve complex cases involving alleged wrongdoing by pharmaceutical manufacturers in connection with the marketing and promotion of drugs. For example, in May 2007, Purdue Frederick Company, Inc., and Purdue Pharma L.P. and three of its top executives entered a \$600 million global settlement relating to allegations that the companies engaged in fraudulent marketing of OxyContin. OxyContin is a Schedule II controlled substance used to control and relieve pain. It is a highly addictive drug with a history of abuse. The settlement resolved allegations that the Purdue companies marketed OxyContin as less subject to abuse, illicit use, and diversion, and as less addictive and less likely to cause tolerance and withdrawal than other pain drugs.

Also in 2007, Bristol-Myers Squibb Co. (BMS), and its wholly owned subsidiary, Apothecon, Inc., agreed to pay more than \$499 million as part of the resolution of a False Claims Act case associated with a variety of drug marketing and pricing practices, including the payment of kickbacks aimed at inducing providers to purchase and prescribe their drugs. In addition, BMS allegedly used fraudulent marketing tactics to promote the sale of the drug Abilify, an atypical antipsychotic drug, for uses not approved by FDA, including the treatment of dementia-related psychosis in the elderly. In fact, FDA has mandated that the package for Abilify carry a "black box" warning concerning its use in the treatment of dementia-related psychosis. A black box warning is a type of warning that appears on the package insert for prescription drugs that may cause serious adverse effects.

OIG administrative sanctions complement criminal and civil enforcement by providing an additional avenue for Government enforcement. OIG has the authority to exclude individuals and entities from the Federal health care programs and to impose civil monetary penalties (CMP) for a range of abusive practices, including kickbacks and false claims.

In recent years, OIG has increasingly used its CMP authority to sanction the payers and recipients of kickbacks. Many of the same schemes that OIG has encountered in the pharmaceutical sector are present in the medical device manufacturing sector. OIG's settlement in July 2007 with Advanced Neuromodulation Systems, Inc. (ANS), a device company specializing in spinal cord stimulation, is illustrative. In this matter, OIG alleged that ANS engaged in a marketing program in which it paid a number of physicians \$5,000 for every five new patients they tested with an ANS product. OIG alleged

that ANS's program did not have any significant clinical value but rather served as a marketing tool to increase ANS's sales. In addition, OIG alleged that ANS's sales and marketing personnel provided physicians with sports tickets, free trips, free dinners, grants, and other gifts. ANS paid \$2.9 million and entered into a 3-year CIA with OIG to resolve allegations that it paid kickbacks to physicians in violation of the CMP law.

Kickbacks were also the underlying issue in a recent set of settlements with four major medical device manufacturers. In September 2007, Zimmer, Inc., DePuy Orthopaedics, Inc., Biomet Inc., and Smith & Nephew, Inc., entered into civil settlement agreements with the Government collectively totaling \$311 million to resolve allegations under the False Claims Act. The Government alleged that the four companies provided financial incentives in the form of consulting agreements, lavish trips, and other perks to induce physicians to use a particular company's artificial hip and knee reconstruction and replacement products.

ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

HHS and Congress have made progress in addressing the challenges of food, drug, and medical device safety. For example, on September 27, 2007, the FDA Amendment Act of 2007 (the Act) was signed into law, providing FDA with increased resources for improving its postmarketing safety surveillance. Among other things, the Act reauthorized the prescription drug user fee program, with increased funding for postmarket safety surveillance and the review of direct-to-consumer advertising submitted by companies to FDA. The Act also reauthorized the medical device user fee program, which includes additional postmarket safety checks. Furthermore, it provided FDA with the authority to require label changes on drugs to reflect new safety information and to fine companies that do not comply with requests for additional trials after a drug reaches the market.

FDA has also implemented several organizational changes to address the challenges of food, drug, and medical device safety. For example, in 2007, FDA announced the creation of a new position, Assistant Commissioner for Food Protection, and unveiled its Food Protection Plan to keep the Nation's food supply safe from both unintentional and deliberate contamination. That plan incorporates strategies for prevention, intervention, and response. Additionally, in 2008, FDA established offices in China to facilitate inspections of Chinese food and drugs before they are imported to the United States.

To better manage the generic drug review process, FDA has provided guidance to assist the industry in submitting more easily reviewed applications and has revised the prioritization process based on a generic drug's potential market entry date. FDA also indicated that it continues to alter its review process with the goal of reducing review times and may consider additional revisions to the prioritization process. Moreover, in response to OIG's recent report on the oversight of clinical trials, FDA indicated that it is developing an internal listing of all ongoing clinical trials as part of a broader effort to manage FDA's regulated product information electronically.

FDA has also made progress in tracking postmarketing study commitments. Section 921 of the Act added a requirement for FDA to review the entire backlog of postmarketing study commitments on an annual basis to determine which commitments require revision or should be eliminated. FDA must report to Congress on its determinations. To develop recommendations for improving the quality of its postmarketing study commitment processes, FDA contracted with a consultant to assess the decisionmaking, tracking, and review processes behind requests for postmarketing study commitments for human drugs and biologics.

Management Issue 7: Grants Management

MANAGEMENT CHALLENGE:

HHS is the largest grant-awarding agency in the Federal Government. The Department's public health and human service agencies rely on grants and cooperative agreements to meet their mission objectives, such as providing health and social services safety nets, preventing the spread of communicable diseases, and researching causes and treatments of diseases. During FY 2007, the Department issued grants totaling \$273 billion (\$40 billion discretionary and \$233 billion mandatory). Medicaid constituted the largest portion of mandatory grants (\$188 billion) and is discussed under Management Issue 3: Medicaid and SCHIP Integrity. This management issue focuses on grant programs administered by NIH, the Administration for Children and Families (ACF), and the Health Resources and Services Administration (HRSA).

The size and scope of HHS grant expenditures, coupled with unique vulnerabilities associated with the very nature of a grant, have made grants management a significant area of focus for OIG. Unlike the management of other Government expenditures, performance responsibility and management of a grant rest primarily with the grantee, with little or no Government involvement in the funded activity. Vulnerabilities stemming from this limited oversight are compounded by the limited experience of many HHS grantees. For example, inexperienced grantees are particularly likely to receive funding when new grant programs are created or existing programs are expanded.

OIG, through its audits, evaluations, and investigations, has sought to ensure that grant monies are used for their intended purposes and are overseen in the most efficient and effective manner. However, OIG has continued to find misuse of grant funds and weaknesses in the oversight of these funds.

Discretionary Grants

Discretionary grants permit the Federal Government to exercise discretion in selecting grantees typically through a competitive grant process. NIH, ACF, and HRSA award about 84 percent of the \$40 billion in discretionary grants.

NIH is the primary agency for conducting and supporting medical research, awarding over \$21 billion in grants in FY 2007. In 2008, OIG assessed the management and oversight of the National Cancer Institute's (NCI) Research Project Grants and identified several areas in need of improvement. OIG found that NCI reviewed all progress reports to monitor grantee performance, but that 41 percent of progress reports were received after the required deadline. Additionally, not all grant closeouts were performed within departmental guidelines, and in some cases supporting documentation was insufficient. Also in 2008, OIG assessed NIH's oversight of grantee institutions' financial conflicts of interest as well as NIH's handling of allegations concerning conflicts of interest and ethics violations (discussed in more detail in Management Issue 9: Ethics Program Oversight and Enforcement). In upcoming years, OIG intends to review: (1) the process the National Center for Research Resources uses to oversee clinical and translational science award grantees, (2) the process the National Institute of Allergy and Infectious Diseases uses to monitor Project BioShield grantee compliance with Federal requirements, (3) the extent to which Data and Safety Monitoring Boards monitor data in clinical trials, and (4) grantee management of financial conflicts of interest in NIH-funded research.

During FY 2007, ACF administered \$7.6 billion in discretionary grant programs that promote the economic and social well-being of families, children, individuals, and communities. The Head Start program accounted for \$6.6 billion of ACF discretionary grants. OIG has identified vulnerabilities in the Head Start program including problems related to financial management, the health and safety of children, and underenrollment. To illustrate, during FYs 2007 and 2008, OIG investigated a fiscal manager who embezzled \$20,000 and a chief financial officer who embezzled over \$29,000 from separate Head Start grantees. Additionally, ACF suspended a Head Start agency when OIG discovered that its financial management systems did not meet Federal requirements to properly account for Federal funds and assets,

and found several instances in which the agency did not comply with applicable health and safety requirements. For example, four employees had been arrested and/or convicted for domestic violent assault or possession of drugs, and three employees should have been disqualified from employment because of a history of child abuse and neglect.

Further, in a 2007 review related to enrollment in the Head Start program, OIG found that 5 percent of Head Start slots were funded but not filled and identified barriers that grantees face in maintaining full enrollment. These problems may be compounded by ACF relying on inaccurate data to monitor enrollment levels. Finally, during FY 2008, OIG collaborated with ACF to launch a national review to determine compliance with licensing, health and safety standards at selected childcare facilities within eight States.

During FY 2007, HRSA awarded over \$4.7 billion to improve access to health care services for people who are uninsured, isolated, or medically vulnerable. Making Federal funds available for reimbursement of costly health care services continues to expose HRSA to a host of vulnerabilities. To illustrate, one of HRSA's major programs is administration of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act. The Act was reauthorized in 2006 as the Ryan White HIV/AIDS Treatment Modernization Act, with a 3-year authorization set to expire on September 30, 2009. Additionally, a new requirement established that at least 75 percent of grant funds awarded for metropolitan areas, States, and early intervention services must be spent on core medical services unless the grantee requests and receives a waiver from this requirement. From FYs 2004 through 2006, HRSA awarded over \$2.3 billion in grants to fund health care and support services for uninsured or underinsured people with HIV/AIDS. During 2008, OIG finished its pilot review of a single territory and determined that over \$24 million in services paid for with Ryan White grant funds should have been covered by other health insurance. OIG plans to extend this review to eight more States. OIG also plans to assess HRSA's oversight for ensuring that Ryan White grantees comply with the new 75-percent requirement and how this new requirement might affect grantee operations.

Mandatory Grants

Mandatory grants are those that a Federal agency is required by statute to award if the recipient, usually a State, submits an acceptable application and meets eligibility and compliance requirements. ACF awarded almost \$38 billion in mandatory grants during FY 2007, with the Temporary Assistance for Needy Families (TANF), Foster Care and Adoption Assistance, Child Support Enforcement, and Child Care and Development Fund programs accounting for about \$30 billion.

During FY 2007, OIG established error rates for improper TANF payments in a pilot review of three States to assist the Department in meeting the requirements of the Improper Payments Information Act of 2002. We estimated that the improper payment rates for the three States ranged from 12 to 40 percent of the Federal dollars expended for the 6-month audit period. Total erroneous payments amounted to an estimated \$95 million. These improper payments resulted in the States either not meeting eligibility requirements or not adequately documenting eligibility and payment determinations. We recommended that these States ensure compliance with Federal and State TANF requirements, determine the current eligibility of all recipients identified as improperly enrolled and deny further assistance to those who remain ineligible, and recalculate assistance budgets for all recipients identified in these reviews as having received improperly calculated payments. During FY 2008, OIG statistically selected eight States to develop a nationwide improper payment rate for the TANF program. OIG has completed work in seven States and plans to begin work in the eighth State in FY 2009. Error rates for the seven reviewed States range from 6 to 29 percent of the Federal dollars expended for the 1-year audit period, amounting to an estimated \$190 million in improper payments.

Foster care training and administrative costs have risen dramatically in relation to maintenance payments in recent years. Certain training costs qualify for an enhanced 75-percent Federal funding rate. In FY 2007, we identified two States that claimed \$22 million in foster care administrative costs that were either claimed as training costs, or were otherwise unallowable, improperly allocated or unsupported. Two

reviews of another State in FY 2008 questioned an additional \$4 million in foster care administrative costs that were claimed as training costs, or were otherwise unallowable, improperly allocated or unsupported. OIG recommended that these States refund the amounts improperly claimed, identify and resolve any unallowable claims made after the audit period, and discontinue claiming reimbursement for unlicensed facilities and ineligible children and services. Because of the apparent vulnerabilities created by enhanced reimbursement rates for training costs, we have started work in three additional States.

OIG has also identified specific vulnerabilities associated with State claims for foster care maintenance and administrative costs. For example, maintenance costs cover room and other costs for children who meet Title IV-E eligibility requirements and facilities that are appropriately licensed. Administrative costs cover staff activities, such as case management and supervision of children placed in foster care. Our work in one State during FY 2008 identified \$23 million in unallowable maintenance payments claimed for unlicensed facilities or ineligible children. Related administrative costs amounted to an unallowable \$38 million. Because of the significant amounts identified in this one State, we plan to conduct similar reviews in additional States in FY 2009. Because the adoption assistance program relies primarily on foster care eligibility criteria, OIG conducted pilot reviews in three States during FY 2007 to identify whether this program faced similar vulnerabilities to the foster care program. The pilot reviews revealed an average error rate of 27 percent and about \$14 million in improper adoption assistance payments. During FY 2009, OIG will continue its reviews of the foster care and adoption assistance programs in additional States.

OIG has also focused attention on federally funded child support enforcement and has identified concerns related to undistributed child support collections and obtaining payments from noncustodial parents with large child support debts. Historically, States have had difficulty in distributing sizable amounts of support payments because certain identifiers, such as custodial parents' addresses, were not current or the case numbers were omitted from collection receipts. Federal criteria require that undistributable child support payments be counted as program income and used to reduce Title IV-D program expenditures, which the Federal Government generally reimburses at a rate of 66 percent. During FYs 2007 and 2008, OIG found that nine States had not reported \$8.8 million in undistributed Title IV-D child support collections as program income to ACF. In 2007, OIG examined States' use of debt compromise to collect payments from noncustodial parents with large debt balances. OIG found that child support enforcement agencies in 20 States operate fully implemented or pilot debt compromise programs, and another 23 States settle arrearage debt on a case-by-case basis. Further, those States with debt compromise programs experienced average settlements of \$9,383 per case and subsequently closed 41 percent of the cases reviewed. However, four of five selected States did not routinely follow up when noncustodial parents paid irregularly following debt compromise.

During FY 2009, OIG will evaluate the effectiveness of tools for improving collections from independent contractors, making noncustodial parents accountable for court-ordered medical support by contributing toward their children's Medicaid costs, securing identifier information from financial institutions, and ensuring that Federal agencies accurately submit child support payments garnished from employee paychecks.

OIG also is authorized to investigate the interstate nonpayment of child support under 18 U.S.C. § 228. During FYs 2007 and 2008, based on OIG investigations, 96 deadbeat parents were successfully prosecuted and, as a result, \$4.9 million in outstanding child support payments were ordered to be paid.

ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

Through the Governmentwide Federal Grant Streamlining Program, the HHS grants management environment is continually undergoing significant changes. The program is intended to implement the Federal Financial Assistance Management Improvement Act of 1999 (Public Law 106-107), which requires agencies to improve the effectiveness and performance of their grant programs, simplify the grant application and reporting process, improve the delivery of services to the public, and increase

communication among the entities responsible for delivering services. HHS has worked to develop more consistent policies and practices throughout the Department and has undertaken a principal role in enhancing the transparency of Government funding through its leadership and implementation of the Federal Funding Accountability and Transparency Act (FFATA). To comply with FFATA requirements, HHS has modified its Tracking Accountability in Government Grants System and worked with the Office of Management and Budget (OMB) to help solve data collection issues. HHS also remains committed to ensuring the successful implementation of Grants.gov as the single Governmentwide portal for locating funding opportunities, obtaining application packages, and reporting annual results.

NIH reported a number of planned and ongoing activities to address the areas of improvement that OIG identified in our 2008 review of NCI's grants oversight. NIH stated that it will engage in education and outreach with grantee officials to address late submission of progress reports, Financial Status Reports, and closeout documents. Additionally, NIH expects to increase timeliness of grantee reporting through continued development and deployment of its electronic grants management system. NIH is also planning to conduct a pilot study to review the Federal Cash Transaction Report.

ACF has taken action to address several issues identified in OIG's 2007 report on enrollment levels in Head Start. To address transportation challenges that may hinder grantee efforts to achieve full enrollment, ACF recently developed a Web-based "transportation pathfinder" tool. ACF has also modified its Program Information Report system to ensure that the funded enrollment is accurately reported. Additionally, in December 2007, Public Law 110-134 reauthorized the Head Start program, making several significant changes to the Head Start Act that address OIG's findings. Specifically, subject to the specifics of the implementing regulations, grantees may now propose to serve up to 35 percent of their enrollment from children whose families' incomes are between 100 percent and 130 percent of the poverty line. Further, reviews of Head Start agencies will now include a review of grantee efforts to collaborate with other entities serving the Head Start population. Finally, the new legislation clarifies when funding withdrawals due to underenrollment are appropriate.

ACF also noted that efforts have been made by States to reduce net child support undistributed collections. Specifically, ACF reported that net undistributed collections decreased 36 percent over the past seven years, from \$738 million in FY 2001 to \$472 million in FY 2007.

In March 2008, HRSA reported that it had taken steps to implement several OIG recommendations made in 2004 to address oversight of Ryan White grantees. Specifically, HRSA reported that it has enhanced training for project officers, developed a site visit protocol for onsite monitoring, and increased the number of grantee site visits.

It is imperative that HHS agencies adequately manage and monitor their grantees' and, to the extent possible, their subgrantees' program performance and require fiscal accountability through the life of the grants. Over the next fiscal year, OIG will continue to oversee departmentwide efforts related to the streamlining of Federal assistance programs, grants management, and program oversight and monitoring.

Management Issue 8: Integrity of Information Systems and the Implementation of Health Information Technology

MANAGEMENT CHALLENGE:

The Department faces the related challenges of ensuring the integrity of its information systems and developing a strategy and framework for advancing the development and adoption of a new interoperable nationwide health information technology (HIT) infrastructure. To ensure the confidentiality, integrity, and reliability of critical data that support departmental operations, it is essential that the Department have adequate internal controls over its information systems. Similarly, as the Department moves forward in carrying out the President's Executive Order 13335, which requires the development and nationwide

implementation of an interoperable HIT, similar controls to ensure reliability, confidentiality, privacy, and security when exchanging, storing, and using electronic health information must also be established.

OIG, through mandated and other efforts, evaluates information systems controls and the oversight of Federal information security programs. This includes the oversight of HHS financial systems as well as systems used by HHS operating divisions, Medicare contractors and providers, and State Medicaid agencies. OIG also monitors the development and operation of a variety of departmental HIT systems.

Integrity of Systems

To accomplish its mission, the Department relies on a distributed network environment that includes Federal agencies, State and local governments, grantees, contractors, and colleges and universities. This distributed network environment, composed of autonomous entities, complicates the Department's efforts to establish a baseline of core security requirements and to design and implement an information security program to protect its critical infrastructure and assets. The expansion of HHS programs, such as the creation of the Medicare Part D benefit, significantly increases the programmatic and system demands on the Department. It creates new and expands existing relationships with business partners, such as Medicaid State agencies and contractors. In turn, these relationships create the potential for new system security exposures that must be evaluated and, if need be, mitigated to ensure the confidentiality, integrity, and availability of critical assets.

OIG is required to conduct specific information technology (IT) reviews including annual reviews required by the Federal Information Security Management Act (FISMA) and by section 912 of the MMA. The purpose of FISMA is to provide a comprehensive framework for ensuring the effectiveness of information security controls over information resources that support Federal operations and assets and to provide a mechanism for improved oversight of agency information security programs. Section 912 of the MMA requires each Medicare fiscal intermediary and carrier to have its information security program evaluated annually by an independent auditor.

In both types of reviews, OIG has continued to identify similar weaknesses in security controls. For example, recent OIG reviews have identified security vulnerabilities, including faulty firewalls protecting networks, antivirus and patch management procedures not being adhered to, password requirements not being followed, and untimely background checks that allowed individuals without the proper security clearances to access data. Such control weaknesses can compromise the integrity of sensitive program data and increase the risk that such data may be inappropriately used or disclosed.

The development and expansion of Department IT systems also brings new focus to additional areas of risk. For instance, over the past several years the importance of protecting personal data has become much more visible, as illustrated by media attention to personal data lost by accounting firms, credit bureaus, universities, and insurance companies, and, most recently, the loss of data by Federal agencies. OMB has recently reemphasized Federal agency responsibilities under the law to appropriately safeguard sensitive, personally identifiable information and to train Federal employees regarding their responsibilities in this area. The OIG FISMA assessments of the last several years have continued to find that many identified security weaknesses are attributable to either an absence of a process to protect resources or a failure to comply with an established process.

As part of HHS's responsibility to protect patient health information, the Department oversees and enforces HIPAA Privacy and Security Rules. HIPAA specifies a series of administrative, technical, and physical security procedures for covered entities, such as providers and data centers, to be utilized to ensure the confidentiality of electronic health information. However, OIG recently reported that, as of August 2007, CMS had taken limited actions to ensure that covered entities adequately implement the HIPAA Security Rule. These actions have not provided effective oversight or encouraged enforcement of the HIPAA Security Rule by covered entities. Although authorized to do so by Federal regulations, CMS had not conducted any HIPAA Security Rule compliance reviews of covered entities at the time of our review. To fulfill its oversight responsibilities, CMS relied on complaints to identify any noncompliant

covered entities that it might investigate. As a result, CMS had no effective mechanism to ensure that covered entities were complying with the HIPAA Security Rule or that electronic personal health information was being adequately protected. Currently, OIG is assessing the control environment at major hospitals to determine if personally identifiable information and electronic protected health information data are adequately protected.

OIG continues its efforts to monitor HHS oversight of its vital IT systems to ensure that all necessary technical and policy measures are being taken to protect sensitive information, the systems storing the information, and the physical or electronic transport of the information. Through planned work, OIG will place new emphasis on controls designed to ensure the protection of personal data. OIG will also continue to review the controls that are designed to ensure the integrity of data on which critical systems depend for the accurate payment of billions of dollars through the numerous vital programs administered by the Department. For example, in FY 2009, OIG will review CMS oversight of data security requirements that require State-produced Medicaid information to be adequately stored and processed to protect it against unauthorized disclosure.

Health Information Technology

In 2001, the President announced the development and implementation of an “interoperable health information technology infrastructure” as a key initiative for ensuring that health care programs administered or sponsored by the Federal Government continue to promote health care quality and efficiency. HIT is the electronic technology used to collect, store, retrieve, and transfer data related to the clinical, administrative, and financial information of patients receiving health care services. In April 2004, the President issued Executive Order 13335 to facilitate reaching this goal and, in doing so, he directed the Secretary of HHS to establish the position of National Health Information Technology Coordinator (National Coordinator). According to the Executive Order, under the direction of the Secretary of HHS, “[t]he National Coordinator shall, to the extent permitted by law, develop, maintain, and direct the implementation of a strategic plan to guide the nationwide implementation of interoperable HIT in both the public and private health care sectors that will reduce medical errors, improve quality, and produce greater value for health care expenditures.” A target date for the majority of Americans to have access to electronic health records by 2014 has also been set.

After being established in 2005, the Office of the National Coordinator for Health Information Technology (ONC) began addressing many of the considerations involved in developing and implementing a nationwide system of interoperable HIT. In particular, ONC participated in the establishment and facilitation of a Federal Advisory Committee, the American Health Information Community (AHIC), to assist in the development of specific recommendations on such topics as consumer empowerment, chronic care, bio-surveillance, and electronic health records. Additionally, AHIC is tasked with addressing issues of privacy and security, HIT systems certification, quality of care, and personalized care, among others. Much of this work will be transitioned to the AHIC successor organization when it is established in CY 2008.

In 2007, OIG conducted a survey of the implementation status of HIT and health information exchange (HIE) efforts in State Medicaid agencies. OIG found that almost a quarter of State Medicaid agencies have implemented HIT initiatives and that more than three quarters of States are developing similar HIT initiatives. Additionally, OIG reported that a number of Medicaid agencies were involved in the planning of statewide HIE networks, including incorporating the Medicaid Information Technology Architecture (MITA) into their HIT and HIE planning. Based on the survey findings, OIG recommended that CMS continue to support the goals of MITA to help facilitate future State Medicaid HIT and HIE initiatives, work in collaboration with other Federal agencies and offices to assist State Medicaid agencies in developing privacy and security policies, and continue to work with ONC to ensure that State Medicaid initiatives remain consistent with national goals.

In future HIT related work, OIG plans to examine the experiences of Part D plan sponsors related to e-prescribing, a prescription delivery practice that enables providers and pharmacists to electronically

transmit prescription orders and other prescription-related information for Part D beneficiaries. CMS rules require that Part D plans support an “electronic prescription program” for any providers and pharmacies that voluntarily choose to use e-prescribing, and OIG will examine how Part D sponsors have implemented e-prescribing programs and standards. Additionally, OIG will continue monitoring proposed changes to the Health Insurance Portability and Accountability Act of 1996 related to HIT and the impact that such changes would have on the permissible secondary uses of health information data for such activities as quality of care investigations and oversight.

To enable us to adapt to changing practices in health care and to continually update our oversight capabilities in this area, OIG is developing a specialized computer lab to train staff in new IT auditing technologies, tools, and approaches. This lab will enable OIG to improve the skills of its staff related to conducting assessments of HIT systems that contain clinical, administrative, and financial health information.

ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

HHS has made progress in the security of the Department’s most critical and essential assets, both physical and cyber-based, such as laboratories, computer systems, and data communication networks. The Secure One HHS project, begun in FY 2003 and supported through a multiyear contract, was initiated by the Department to improve IT security from the top down by providing security policy, procedures, and guidance to HHS agencies. The goals of this project are to improve the overall security of the Department’s IT operations, ensure adequate departmentwide security standards, support integration of IT security practices into all phases of HHS operations, and promote an environment in which employee actions reflect the importance of IT security.

Since our review, CMS has made some progress in its oversight of covered entities implementation of the HIPAA Security Rule. After we completed our fieldwork in 2007, CMS executed a contract to conduct compliance reviews at covered entities. A list of potential policies, procedures and documents that could be included in these reviews was posted to the CMS Web site in late 2007. In its response to our draft report, CMS also described outreach and education efforts it has undertaken to heighten the industry’s understanding of HIPAA security requirements and promote compliance.

In response to our review of HIT and HIE efforts in State Medicaid agencies, CMS stated that it is working with the Agency for Healthcare Research and Quality on selecting a vendor to work with State Medicaid and SCHIP agencies to expand their involvement with HIT and HIE in the areas of privacy and security. CMS also stated its intent to work closely with ONC to ensure that MITA and the State initiatives that CMS supports are consistent with national HIT goals and objectives.

As part of its efforts to encourage the development and use of HIT, on August 8, 2006, the Department issued final regulations that establish new exceptions (42 CFR 411.385 (v) and (w)) under the physician self-referral law and new safe harbors under the anti-kickback statute (42 CFR 1001.952(x) and (y)) involving the donation of certain HIT equipment and services. The final rules seek to lower perceived barriers to the adoption of HIT through exceptions and safe harbors that promote the adoption of e-prescribing technology and interoperable electronic health record systems while safeguarding the Federal programs and beneficiaries against undue risks of fraud and abuse. As required by the MMA, the first exception and safe harbor establish the conditions under which hospitals and certain other health care entities may donate to physicians and certain other recipients’ hardware, software, or IT and training services necessary and used solely for e-prescribing. The second exception and safe harbor establish conditions under which certain entities may donate to physicians and certain other recipients interoperable electronic health record (EHR) software, IT, and training services necessary and used predominantly for EHRs.

In June 2008, ONC issued the ONC-Coordinated Federal HIT Strategic Plan to meet the requirements of Executive Order 13335. The plan outlines two goals covering “patient-focused health care” and “population health,” and each goal shares four objectives focusing on privacy and security,

interoperability, adoption, and collaborative governance. Among the initiatives, programs and projects cited in the strategic plan as advancements that contribute to the President's vision, ONC highlights hosting or participating in numerous partnerships for developing interoperability, privacy, and security standards and definitions; creating frameworks for pilot testing select standards for future use; and launching HIT "use cases" through the Healthcare Information Technology Standards Panel.

ONC has also continued to lead the Interagency Health Information Technology Policy Council, which involves representation from across the Federal Government. Through this group, more than 20 Federal departments and agencies regularly interact and exchange information about Federal HIT activities and examine collaborative approaches to implementing HIT policy priorities, including those of privacy and security. Additionally, HHS plans to release by the end of 2008 a privacy and security framework to increase trust among consumers and users of electronic individual health information and to govern all privacy and security efforts related to electronic health information exchange.

Management Issue 9: Ethics Program Oversight and Enforcement

MANAGEMENT CHALLENGE:

OIG has historically been involved in oversight of the Department's ethics program. OIG's activities have ranged from evaluating agency ethics programs at selected Operating Divisions (OPDIV) to determine whether they comply with regulations issued by the Office of Government Ethics (OGE) and HHS, to investigating allegations of criminal ethics violations by current and former HHS employees. OIG's activities related to ethics issues have steadily increased as a result of congressional hearings, GAO reviews, press reports, and casework. Since 2005, ethics program oversight has been recognized as one of the Department's top management challenges in the context of both grants management and research and regulatory oversight management challenges.

OGE was established in 1978 to assist the executive branch in preventing and resolving conflicts of interest by Government employees. In partnership with executive branch agencies, OGE fosters adherence to high ethical standards to strengthen the public's confidence that the Government's business is conducted with impartiality and integrity. The Secretary of HHS has delegated responsibility for the day-to-day administration of the ethics program to the Designated Agency Ethics Official (DAEO). The DAEO appoints Deputy Ethics Counselors (DEC) to serve as ethics advisers in the OPDIVs and Staff Divisions (STAFFDIV). In addition, Congress has imposed prohibitions to help ensure that Federal employees are not compromised by conflicts of interest when performing their official duties. For example, the criminal conflict-of-interest statute, 18 U.S.C. § 208, prohibits employees from participating in official matters in which they and certain others (such as spouses) have a financial interest.

Although the DAEO is responsible for administering the Department's ethics program, OIG and DOJ are responsible for enforcement of the criminal ethics statutes. Within OIG, the Special Investigations Branch provides a central point for the DAEO and DECs to refer potential criminal violations and to discuss matters to determine whether referral is appropriate. Federal regulations and the Department's "General Administration Manual" require HHS employees and supervisors to report nonfrivolous allegations of "criminal offenses" (including conflicts of interest) to OIG. Allegations of improper conduct that do not implicate criminal laws may be handled by agency management through administrative remedies.

Although OIG continues to focus on the HHS ethics program covering the employees of the Department, we also are broadening our work to include conflict-of-interest issues related to non-Federal entities and non-Federal participants that play a role in HHS programs. As discussed below, we are looking at how NIH oversees financial conflicts of interest of grantees and how FDA oversees financial conflicts of interest of clinical investigators. Additionally, new emphasis is being placed on the role of Government contractors. 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, we created and posted on our Web site an OIG Hotline poster for use by HHS contractors. And, as OGE released guidance on conflict-of-interest considerations of contractor employees in the workplace in 2007, OIG developed internal training on this topic for all OIG employees as part of their required annual ethics training (released on October 21, 2008). In addition, training is in progress for OIG contractors to inform them of emerging issues.

Oversight

OIG's prior work on ethics issues within HHS has focused on the oversight of employees' potential conflicts of interest. In a July 2005 report, OIG studied NIH's outside activities processes. OIG identified several vulnerabilities that inhibited NIH's ability to effectively review outside activities, such as a lack of supervisory signatures confirming approval of the requests. There were also several problems with the review process itself, such as approvals after the start dates, limited use of written recusals, and inadequate followup regarding ongoing outside activities. To address these vulnerabilities, OIG recommended that NIH improve the quality and increase the extent of information it receives for outside activity requests and address inadequacies in the outside activity review process.

In February 2006, OIG issued a report on conflicts of interest at FDA in which we identified a variety of vulnerabilities in the FDA process for review and approval of requests to engage in outside activities. OIG found that FDA employees submitted limited information regarding outside activities and found several problems in the review process itself, such as approvals after the start date, multiple activities listed on a single activity request, and inadequate followup for ongoing outside activities. To address these vulnerabilities, OIG recommended that FDA improve the quality and increase the extent of information it receives in outside activity requests and address inadequacies in the review process for outside activities.

OIG work will continue to focus on the oversight of ethics issues involving departmental employees. For example, in a review similar to the NIH and FDA outside activity reviews, OIG will assess whether CDC identifies and resolves conflicts of interests among Federal Advisory Committee Special Government Employees (SGEs) in a timely and complete manner. Compliance with the ethics statutes and standards of ethical conduct is of particular importance for these CDC employees because their research results and regulatory decisions affect the Nation's public health security.

OIG has also reviewed specific allegations that NIH received about employee activities that might be criminal or improper. The evaluation determined the number and nature of the allegations that NIH received and examined how NIH handled and resolved these allegations. OIG found that the majority of the Institutes do not have Institute-specific policies or procedures for reviewing allegations, do not handle allegations uniformly, and do not uniformly confer with the appropriate outside parties when handling allegations. To address these vulnerabilities, OIG recommended that NIH develop a formal, written policy outlining how allegations of conflicts of interest and ethics violations are to be handled among the Institutes' ethics offices, the NIH Ethics Office, the OGC Ethics Division, and the Office of Management Assessment and to maintain documentation detailing how allegations are ultimately resolved.

Although it is vital that intramural research undertaken within the Department be free from potential biases stemming from employee conflicts of interest, 80 percent of NIH's research funding goes to extramural grantees, primarily to research universities that undertake work pursuant to contracts and grants. As a result, OIG work has also focused on potential conflicts of interest relating to extramural grantees and researchers.

In January 2008, OIG released a report on the conflict-of-interest reports external grantees submitted to NIH in FYs 2004 through 2006. OIG found that NIH's Institutes and the Office of Extramural Research (OER) were unable to provide all of 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 (1) increase oversight of grantee institutions to ensure their compliance with Federal financial conflict-of-interest regulations; (2) require grantee institutions to provide details

regarding the nature of financial conflicts of interest and how they are managed, reduced, or eliminated; and (3) require Institutes to forward to OER all financial conflict-of-interest reports that they receive from grantee institutions and ensure that OER's conflict-of-interest database contains information on all conflict-of-interest reports provided by grantee institutions.

OIG is continuing its efforts in this area. For example, OIG is conducting a study to determine the nature of financial conflicts of interest reported by grantee institutions to NIH. More specifically, OIG will examine how grantee institutions managed, reduced, or eliminated these conflicts. OIG will also review the conflict-of-interest policies established by these institutions.

Similarly, OIG is conducting a study on FDA's oversight of clinical investigators' financial interests. Clinical investigators lead clinical trials, recruit subjects, supervise, analyze, and report clinical trial results. The study will describe the extent and nature of clinical investigators' financial interest information submitted to FDA with all the marketing applications approved by FDA in 2007. It will also assess FDA's process for reviewing the information about clinical investigators' financial interests submitted with the marketing applications.

Enforcement

In addition to performing systemic reviews identifying vulnerabilities in the administration of the Department's ethics program, on the enforcement side, OIG has managed a significant caseload of conflict-of-interest matters. OIG has emphasized outreach within the Department, which has resulted in an increased number of conflict-of-interest referrals from across the various OPDIVs and STAFFDIVs. Additionally, OIG has partnered with Federal agencies outside HHS, such as the U.S. Securities and Exchange Commission, to investigate potential conflict-of-interest allegations.

OIG continues to investigate complaints involving potential conflicts of interest. For instance, an OIG investigation of a former FDA Commissioner's false reporting that he had sold stock in companies regulated by FDA, when in fact he continued to hold shares in those firms, resulted in guilty pleas to two criminal charges for false writings and conflict of interest, a fine of approximately \$90,000, 3 years of supervised probation, and 50 hours of community service. In 2008, the former FDA Commissioner was debarred from being involved in contracting, subcontracting, or any covered transaction with any agency of the U.S. Government for 2 years. In another example, OIG handled a case involving an NIH senior scientist. The Chief of the Geriatric Psychiatry Branch at NIH pled guilty in December 2006 to conflict-of-interest charges relating to his alleged acceptance of \$285,000 in consulting fees and additional travel expenses from a drug company without the required approval of and disclosure to NIH officials.

OIG's overall approach to conflict-of-interest enforcement has also emphasized outreach as a tool for improving the referral of conflict-of-interest matters within the Department. In 2006, in an effort to improve the efficiency of the referral process, OIG created a comprehensive form for the DAEO and DEC's to use when referring conflict-of-interest cases to OIG. At a quarterly DEC meeting in 2007, representatives from OIG and the OGC Ethics Division gave a joint presentation regarding OIG's involvement with the enforcement of conflict of interest matters. This presentation outlined the use of the OIG referral form and increased the OIG's visibility with the DEC's. Additionally, OIG's ongoing relationship with OGC, as well as regular OPDIV and STAFFDIV interaction by OIG staff, has yielded positive results with regard to conflict of interest matters. Specifically, OIG has noted an increase in the quality of the referrals, an increase in the number of referrals from various departmental divisions, and an increase in departmental contacts seeking input and guidance on conflict of interest matters.

ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

Actions have been taken to address ethics issues identified by OIG. In response to recommendations in OIG studies of outside activities, both NIH and FDA have strengthened their process for reviewing outside activities by posting new guidance on the completion and evaluation of HHS form 520, "Request for

Approval of Outside Activity.” In June 2008, NIH released new policy guidance on managing conflicts of interest and possible biases, including detailed procedures for ensuring that employees are appropriately recused from participating in official matters that might create an actual or apparent conflict of interest.

In response to recommendations pertaining to the conflicts of interest in extramural research, NIH has developed a Web-based financial conflict-of-interest tracking and monitoring system for its internal use. This system enables grantee institutes’ grants management and program staff to enter their own records and view financial conflict-of-interest reports across NIH. The database also reminds grants management personnel to send acknowledgments to institutions and to forward copies of conflict-of-interest reports to OER. Moreover, NIH updated its OER Web site to better address grantee institutions’ frequently asked questions on financial conflict requirements, and also launched a pilot Federal FCOI compliance program. This pilot program, which began in February 2008, will assess institutional implementation of and compliance with the regulatory requirements of the FCOI in research pertaining to NIH grants and cooperative agreements.

For its part, FDA is revising its conflict-of-interest procedures regarding advisory committee members to make the waiver of conflict-of-interest process more transparent and compliant with the Food and Drug Administration Amendments Act of 2007. In 2007, FDA posted on its Web site draft guidance for the public on procedures for identifying conflicts of interest and eligibility for participation in FDA Advisory Committees and on public availability of advisory committee members’ financial interest information and waivers.

The OGC Ethics Division, led by the DAEO, continues to expand its ethics program oversight, guidance, and training activities. The ethics program of each OPDIV and STAFFDIV in HHS has been reviewed (except for FDA, which was scheduled for review in July 2008) and the review staff has begun the next phase by revisiting components with newly appointed ethics officials or where specific issues have surfaced. The Ethics Division sponsors half-day quarterly meetings for DEC’s and an annual full-day DEC workshop and also issues a quarterly “Ethics Update” newsletter, which is distributed to all HHS ethics program officials and posted on the Division’s Intranet page.

The DAEO is also taking steps to tighten up the waiver process, issuing guidance to all DEC’s reminding them of their responsibility to (1) send to the DAEO copies of all waivers granted to Department employees along with data regarding the number of waivers issued; (2) establish a reliable tracking system for waivers; and (3) consult with an Ethics Division attorney prior to granting any 18 U.S.C. § 208 (b)(1) waiver (certifying that the individual’s financial interest is not so substantial as to be deemed likely to affect the integrity of his or her services) and when granting 18 U.S.C. § 208 (b)(3) waivers (certifying that the need for an SGE’s services on a Federal advisory committee outweigh the potential conflict of interest from the individual’s financial interest) if there are unique fact patterns, special circumstances, or unusual situations. The DAEO is planning to issue a package with waiver guidance and information regarding which Department officials have the delegated authority to issue waivers. In addition, the DAEO’s office is reaching out on a monthly basis to ethics coordinators for each OPDIV and STAFFDIV to inquire about the operation of the divisions’ ethics programs, including the review of waivers.

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

Date: November 17, 2008

To: Daniel R. Levinson, Inspector General

From: Charles E. Johnson, Chief Financial Officer

Subject: FY 2008 Top Management and Performance Challenges Identified by the Office of the Inspector General

This memorandum is in response to OIG's FY 2008 *Top Management and Performance Challenges*. The OIG's *Top Management and Performance Challenges* report summarized the top management and performance challenges that the Department has faced over recent years. Additionally, OIG provided an assessment of our progress in addressing those challenges. This assessment is primarily based on cost to taxpayer, visibility, management, and other pertinent factors.

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 2009.

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 2008 TOP MANAGEMENT AND PERFORMANCE CHALLENGES SUMMARY

Management Challenge Identified by the OIG	OIG Progress Assessment	Management Response	Future Plans to Address the Challenge
1. Oversight of Medicare Part D	CMS has demonstrated progress in: payment accuracy and internal controls; program safeguards; beneficiary protections.	CMS has made progress in its use of bid audits. MEDICs have not conducted data analysis to identify potential fraud. CMS has issued 9/18 chapters of the Prescription Drug Benefit Manual.	CMS will develop a centralized data repository to warehouse data on Medicare Parts A, B, D and Medicaid to provide a single source of information for CMS fraud, waste, and abuse activities.
2. Integrity of Medicare Payments	CMS has demonstrated vigilance in monitoring the gross paid claims error rate and is developing appropriate corrective action plans.	The CMS FY 2007 gross paid claims error rate of 3.9 percent is 6.2 percent lower than the FY 2004 error rate. CMS has made progress in its general and applicable controls and has begun implementing the Healthcare Integrated General Ledger Accounting System.	HHS will continue to address potential improper payment exposure for durable medical equipment under a 2-year effort aimed at stopping fraudulent billing to protect beneficiaries and taxpayers.
3. Appropriateness of Medicaid and SCHIP Payments	CMS has annually updated its 5-year Comprehensive Medicaid Integrity Plan to promote the proper expenditure of Medicaid fund, improve integrity performance, and foster collaboration with internal and external stakeholders.	The final Medicaid payment error rate is reported in the IPIA Report, included in the <i>FY 2008 Agency Financial Report</i> , Section III.	CMS plans to start educating providers on payment and billing integrity as well as quality-of-care issues related to personal care services beginning in FY 2009. CMS is working to address data limitations by creating a new database to store Medicaid data from all States.

Management Challenge Identified by the OIG	OIG Progress Assessment	Management Response	Future Plans to Address the Challenge
4. Quality of Care	Progress continues to strengthen oversight of the quality of care paid for by the Medicare and Medicaid programs. CMS has promoted quality by collecting and publishing quality-related data on nursing homes and hospitals.	Progress continues to strengthen oversight of the quality of care paid for by the Medicare and Medicaid programs.	CMS plans to improve hospice oversight by improving the survey process and proposes to amend the hospice section of the State Operations Manual to enable State surveyors to make more consistent decisions regarding compliance with Medicare regulations.
5. Public Health and Medical Emergency Preparedness	States and localities are making progress in strengthening their bioterrorism preparedness programs. Federal, State and local health departments are striving to work cooperatively to ensure that potential bioterrorist attacks are detected early and responded to appropriately. The Commissioned Corps are equipping designated response teams.	HHS issued an updated Purchase Card Guide and a 2-page Quick Reference Guide that highlights key information about emergency situations related to HHS purchase card policies and procedures.	CDC implemented stronger performance measures, which will continue to expand in future years, for the Public Health Emergency Preparedness cooperative agreement. Additionally, clearer guidance was developed for grantees to report on these measures.
6. Oversight of Food, Drug, and Medical Device Safety	HHS has implemented many changes to protect human research subjects and to strengthen FDA and NIH oversight of scientific research. During FY 2008, FDA established offices in China to facilitate inspections of Chinese food and drugs before they are imported to the United States.	As a major milestone in the globalization of efforts to enhance the safety of imported food and medical products, FDA announced plans to establish overseas offices in China, India, Europe and Latin American before the end of 2008, with a fifth office in the Middle East to follow in 2009.	FDA is developing an internal listing of all ongoing clinical trials as part of a broader effort to manage FDA's regulated product information electronically. FDA is also developing recommendations for improving the quality of its post-marketing study commitment processes for human drugs and biologics.

Management Challenge Identified by the OIG	OIG Progress Assessment	Management Response	Future Plans to Address the Challenge
7. Grants Management	HHS has worked to develop more consistent policies and practices, and has undertaken a leadership role in implementation of key legislation, along with the availability of grants funding opportunities via grants.gov.	AHRQ has established practices to ensure the integrity of grant data, timeliness of grantee reporting, and closeout procedures.	Emphasis is being placed on timely financial closeout of ended projects.
8. Integrity of Information Technology Systems and the Implementation of Health Information Technology	HHS has made progress in the security of its most critical and essential assets, such as laboratories, computer systems, and data communication networks. CMS has made progress in oversight of the HIPAA Security rules. ONC issued the ONC-coordinated Federal Health IT Strategic Plan, outlining two goals covering patient-focused health care and population health.	<p>ONC is actively involved in several activities including the drafting of a privacy and security framework for electronic health information exchange and other supplemental materials. Significant progress also continues with collaborative initiatives involving state leadership and other stakeholders to address issues that have direct benefit to U.S. citizens, and cannot be resolved at the Federal level alone.</p> <p>ONC awarded a contract in May 2008, to engage experts and the public to develop a knowledgebase and a roadmap for health IT and health information exchange actions to help prevent, detect, and remedy medical identity theft in the U.S.</p>	<p>HHS plans to release by the end of 2008, a privacy and security framework to increase trust among consumers and users of electronic individual health information and to govern all privacy and security efforts related to electronic health information exchange.</p> <p>In FY 2009, plans are to build on the momentum achieved in FY 2008, and continue to develop more detailed best practices, tools, training and outreach mechanisms that could be built into existing health information technology initiatives.</p>

Management Challenge Identified by the OIG	OIG Progress Assessment	Management Response	Future Plans to Address the Challenge
<p>9. Ethics Program Oversight and Enforcement</p>	<p>Both NIH and FDA have strengthened processes for reviewing outside activities. Additionally, the OGC Ethics Division continues to expand its ethics program oversight, guidance and training activities.</p>	<p>HHS continued program reviews at NIH and other components. The Program Review Section, uncovered significant vulnerabilities in a number of component ethics programs and has issued formal reports this year containing recommendations for improvement, including monitoring by OPDIVs and STAFFDIVs to achieve full compliance with applicable laws and regulations. The Program Review Section also devoted significant efforts in monitoring certification. The Ethics Division provided many ethics presentations for a variety of HHS personnel.</p>	<p>The OGC Ethics Division is planning to issue a package with waiver guidance and information regarding delegation of authority to issue waivers. In addition, the Ethics Division oversees component ethics program operations, including the review of waivers.</p>