Section IV: Other Accompanying Information

This section contains the HHS Inspector General's summary of the most significant management and performance challenges facing the Department, the Department's response to the Inspector General's assessment, HHS' detailed Improper Payments Information Act of 2002 Report, and Other Financial Information.

FY 2006 Top Management and Performance Challenges Identified by the Office of Inspector General

Challenge 1: Oversight of Medicare Part D

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173) established the new Medicare prescription drug benefit, known as Medicare Part D, which took effect on January 1, 2006. This voluntary benefit is available to all 43 million Medicare beneficiaries and, according to Congressional Budget Office estimates, will cost more than $30 billion in 2006 and approximately $746 billion over the next 10 years. The magnitude of expenditures and impact of this benefit on beneficiaries, from both health and financial perspectives, make it critical that Medicare Part D operates efficiently and effectively and is protected from fraud and abuse.

The structure and operation of the Part D benefit contains features that present significant management challenges. Within the Department, the Centers for Medicare & Medicaid Services (CMS) bear primary responsibility for implementing and administering Part D. However, administration of the Medicare Part D benefit depends upon extensive coordination and information sharing among a number of diverse entities, including Federal and state government agencies, private drug plan sponsors, contractors, and healthcare providers. For example, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 required the transfer of more than 6 million dual eligibles (beneficiaries of both Medicare and Medicaid) from Medicaid to Medicare Part D drug coverage on the first day that the program became effective. Also, payments to drug plan sponsors based on bids, risk-adjustments, and reconciliations add to the complexities of the benefit. In addition, the relative financial responsibilities of Medicare, drug plan sponsors, and beneficiaries vary through three distinct phases (the initial coverage period, coverage gap, and catastrophic coverage) depending on the beneficiary's total drug costs at a given time. Finally, the complexities of this benefit also create challenges for educating beneficiaries in selecting a Part D plan as beneficiaries face a wide variety of drug plans with varying costs, formularies, and pharmacy networks.

The Office of Inspector General (OIG) plans a wide array of activities to identify and prevent fraud, waste, and abuse in the Medicare Part D program and to protect the health and welfare of beneficiaries enrolled in Part D. OIG's completed, ongoing, and planned work on Medicare Part D addresses the following areas: enforcement and compliance, payment accuracy and controls, beneficiary protections, informa-

tion technology and systems, drug pricing and reimbursement, and oversight. OIG is executing this plan through a combination of audits, evaluations, investigations, and legal guidance and assistance.

Prior to the implementation of Medicare Part D, OIG worked to identify potential vulnerabilities in the new benefit; train OIG staff, Federal law enforcement partners, CMS staff, and contractors; provide guidance to CMS and to industry; and build the infrastructure for Part D enforcement. In addition, OIG evaluated beneficiary enrollment and educational resources and assessed sponsors' materials associated with the temporary Prescription Drug Discount Card program to identify potential vulnerabilities that might impact individuals enrolling in Medicare Part D. OIG also assessed drug plan formularies' coverage of drugs commonly used by dual eligibles under Medicaid and found that drug plan formularies varied in their inclusion of commonly used drugs.

OIG is conducting a number of investigations of possible fraud and abuse related to Medicare Part D. Several OIG audits and evaluations of Part D are also underway. Some examples include assessing reimbursement to states for drug coverage and assistance provided to dual eligibles during the transition, reviewing the operations of prescription drug plans and retiree drug subsidy payments to employers, tracking beneficiaries' true out-of-pocket costs, and evaluating payments and access to contracted pharmacies in rural areas. This work will provide further insight into potential vulnerabilities and management challenges for Medicare Part D, as well as offer recommendations to help address such challenges.

OIG Assessment of Progress in Addressing the Challenge:

As of June 11, 2006, CMS reported that more than 22 million Medicare beneficiaries were enrolled in either a Part D standalone prescription drug plan or a Medicare Advantage drug plan. Additionally, almost 7 million beneficiaries have coverage through retiree drug subsidy plans.

CMS met the short timeframe for implementing the Part D program and has taken actions to respond to issues that arose during the enrollment and transition period. For example, CMS issued multiple letters to drug plan sponsors regarding their responsibilities for enrollment, appropriate drug access, and communication. Additionally, CMS reported that it reviewed prescription drug plan formularies and benefit structures to verify that plans comply with Part D formulary requirements. CMS has also developed a Part D oversight strategy. This strategy outlines activities in the areas of contractor management, auditing, compliance and enforcement, and program integrity. Most of the program integrity activities are designated as responsibilities of the four Medicare Drug Integrity Contractors (MEDIC). OIG is currently reviewing CMS' implementation of Medicare Part D program safeguards, including, but not limited to, the activities outlined in CMS' strategic plan.

Challenge 2: Integrity of Medicare Payments

The size and complexity of the Medicare program place it at high risk for payment errors. In FY 2005, Medicare benefit payments totaled about $330 billion for services provided to approximately 42 million beneficiaries. Ensuring that beneficiaries have continued access to appropriate and high-quality Medicare services and protecting the financial integrity of the program and the solvency of the Trust Fund require that correct and appropriate payments be made for properly rendered services. From FY 1996 through FY 2002, OIG developed and reported on the annual Medicare fee-for-service paid claims error rate. In FY 2003, CMS assumed responsibility for developing the error rate. In its 2005 financial report, CMS reported a gross paid claims error rate (overpayments plus underpayments) of 5.2 percent ($12.1 billion) for the fiscal year.

Targeted audits and evaluations by OIG and CMS continue to identify improper payments and problems in specific parts of the program. These reviews have revealed payments for unallowable services, improper coding, and other types of improper payments. For example, OIG identified $1.1 billion in improper payments for services billed as consultations, an estimated $402 million in improper payments for ambulance transports, and $285 million allowed for chiropractic services that did not meet Medicare coverage criteria or were miscoded and undocumented. OIG also found $72.4 million in improper payments to hospitals that incorrectly coded claims as discharges to home rather than transfers to postacute care facilities. In another example, OIG identified $71.5 million in improper payments to independent diagnostic testing facilities for services that were not reasonable and necessary, not sufficiently documented, or were performed without the knowledge of treating physicians. Finally, OIG

identified $16.8 million in improper payments to hospitals that inappropriately included dental residents in their position counts when computing Medicare graduate medical education payments.

The OIG's FY 2005 financial statement audit reported internal control weaknesses in managed care and the lack of an integrated general ledger accounting system. OIG audits continue to show that Medicare has serious internal control weaknesses in its financial systems and processes for producing financial statements. For example, the reporting mechanism that Medicare contractors use to reconcile and report funds expended depends heavily on inefficient, labor-intensive, manual processes that increase the risk of submitting inconsistent, incomplete, or inaccurate information to CMS.

OIG Assessment of Progress in Addressing the Challenge:

The FY 2005 gross paid claims error rate of 5.2 percent reported by CMS is 4.9 percentage points lower than the 10.1 percent error rate reported last year. CMS has demonstrated continued vigilance in monitoring the error rate and developing appropriate corrective action plans. For example, CMS has worked with the 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. These steps include increasing and refining one-on-one educational contacts with providers and working with contractors to assist providers in submitting sufficient documentation to support billed services.

CMS received an unqualified opinion on its 2005 financial statements. However, the lack of a fully integrated financial management system and insufficient oversight of Medicare contractors continued to impair CMS's reporting of accurate financial information. Although CMS has made improvements, the audit identified weaknesses in general and in application controls at Medicare contractors, at data centers where Medicare claims are processed, at sites that maintain the "shared" application system software used in claims processing, and at the CMS central office. In addition, although CMS had improved its oversight of Medicare contractors, continuing weaknesses affected its ability to analyze and accurately report financial information on a timely basis.

To address these problems, CMS has initiated steps to implement the Healthcare Integrated General Ledger Accounting System, expected to be fully operational at the end of FY 2009. In the interim, corrective action is needed to address persistent weaknesses in internal controls throughout the Medicare system.

Challenge 3: Medicaid Administration

Medicaid is a joint Federal and state program that provides medical assistance to an estimated 52 million low-income and disabled Americans. The Federal share of Medicaid outlays in FY 2005 exceeded $182 billion and is estimated to exceed $200 billion in FY 2007. The Federal share, known as the Federal Medicaid Assistance Percentage, is determined annually by a statutory formula based on state average per capita income and generally ranges from 50 to 83 percent in the various state programs. Over the past 6 years, OIG's body of work has identified significant problems in state Medicaid financing arrangements involving the use of intergovernmental transfers. Specifically, OIG found that six states inappropriately inflated the Federal share of Medicaid by more than $3 billion by requiring public providers to return Medicaid payments to state governments through intergovernmental transfers. Once the payments are returned, funds cannot be tracked, and they 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 public facilities, OIG identified serious problems in Medicaid supplemental payments available upper payment limits, disproportionate share hospital payments, and payments for school-based services.

OIG Assessment of Progress in Addressing the Challenge:

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 upper payment limits regulations pursuant to the Benefits Improvement and Protection

Act of 2000. The rules created three aggregate upper payment limits: one each for private, state, and non-state government-operated facilities. The new regulations will be gradually phased in and become fully effective on October 1, 2008. CMS projects that these revisions will save a total of $79.3 billion in Federal Medicaid funds over the 10-year period from 2002–2011. However, when fully implemented, these regulatory changes will limit, but not eliminate, the risks 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.

CMS also has been working with states to stop the inappropriate use of intergovernmental transfers. CMS identified 33 states that were using inappropriate intergovernmental transfers.

CMS should continue to work to ensure that all states eliminate the use of inappropriate intergovernmental transfers involving supplemental payments made pursuant to upper payment limits regulations, disproportionate share hospital payments, payments for school-based services, or any other type of Medicaid payment to a public provider.

In addition, CMS is drafting a "Notice of Proposed Rulemaking" that establishes a new regulatory provision explicitly requiring that providers retain the total computable amount of their Medicaid payments. OIG concurs with CMS' issuance of a regulation that requires that providers retain the total Medicaid payments received and considers this regulation to be a positive step in eliminating the inappropriate use of financing mechanisms. This change, in addition to the upper payment limits regulatory changes, will help ensure that Medicaid funds are used to provide necessary services to Medicaid beneficiaries.

Challenge 4: Integrity of Medicaid Payments

The Federal share of Medicaid outlays in FY 2005 exceeded $182 billion and is estimated to exceed $200 billion in FY 2007. Because Medicaid is a matching program, improper payments by states always cause corresponding improper Federal payments. However, because the Federal Government does not routinely examine individual provider claims, inappropriate state claims for a Federal share are not always easily identified.

Payment Error Rates

Payment accuracy in the Medicaid program helps to ensure the efficient use of Federal and state healthcare dollars. Until recently, little was known about payment error rates in the Medicaid program. This lack of information represented a substantial vulnerability in preventing fraud, waste, and abuse. Identifying errors and their causes is particularly difficult because of the diversity of state programs and their varying administrative and control systems.

To assist CMS with its development of Payment Error Rate Measurement, and at the request of the Office of Management and Budget, OIG conducted audits of Medicaid and the state Children's Health Insurance Program (SCHIP) eligibility in three of the four states with the largest Medicaid programs: New York, Florida, and California. Results of the three reviews indicated that Medicaid and SCHIP payments were made on behalf of beneficiaries who did not meet Federal and state eligibility requirements. The majority of the Medicaid and SCHIP improper payments were due to household incomes exceeding the threshold on the dates of service, citizenship requirements not being met, lack of Social Security numbers, beneficiaries improperly enrolled in SCHIP but eligible for Medicaid, and spend-down requirements not being met.

In addition to the eligibility issues discussed above, OIG has identified improper payments involving school-based health services, disproportionate share hospital payments, and targeted case management services. For example, OIG has consistently noted problems with schools adequately supporting the claims submitted to states for these services. Particularly in New York, OIG identified significant overpayments involving speech therapy and transportation claims. To date, OIG has issued four reports to the New York state Medicaid agency questioning unallowable Federal funds totaling $721 million. Major findings included payments for services that were not sufficiently documented, services not authorized, and services rendered by providers who did not have required qualifications. In another example, OIG identified states that made disproportionate share hospital payments that exceeded the hospital specific limits by approximately $1.6 billion ($902 million Federal share). Of the $902 million, $679 million resulted from using historical costs rather than actual costs, and $223 million resulted from including unal-

lowable costs in the calculations. OIG has 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. Signed into law February 8, 2006, the Deficit Reduction Act of 2005 provides additional funds to OIG to increase Medicaid program integrity efforts. OIG will receive $25 million for each of the fiscal years 2006 through 2010. With these additional resources, OIG has enhanced its efforts in addressing fraud, waste, and abuse. The Deficit Reduction Act mandated some activities for OIG, such as a report on issues to consider in developing the average manufacturers' prices used in the Medicaid reimbursement for prescription drugs.

OIG is planning reviews to oversee the Medicaid and SCHIP error rate process. In addition, ongoing and planned work includes various reviews to identify payment error vulnerabilities in the Medicaid managed care program, pediatric dental services, and durable medical equipment.

OIG Assessment of Progress in Addressing the Challenge:

Payment Error Rates

In July 2001, CMS invited states to participate in a demonstration project to develop a Payment Accuracy Measurement methodology for Medicaid, i.e., a single methodology that can produce both state-specific and national-level payment error estimates. The Payment Accuracy Measurement model was later modified to comply with the requirements of the Improper Payments Information Act of 2002.

The Improper Payments Information Act requires heads of Federal agencies to make estimates of improper payments for the programs they oversee, report to Congress annually, and submit a report on actions the agency is taking to reduce such payments.

FY 2004 was the final year for reporting the results of the Payment Accuracy Measurement pilots. The project has since been renamed the Payment Error Rate Measurement program and was published in late August 2006 as an interim final rule with comment. The Payment Error Rate Measurement includes the error rate processes for Medicaid and SCHIP—fee-for-service, managed care, and eligibility. CMS is using a national contracting strategy to produce Medicaid and SCHIP managed care and fee-for-service error rates. The Payment Error Rate Measurement also sets forth the state requirements for conducting reviews and estimating payment error rates due to errors in eligibility determinations. The FY 2006 Performance and Accountability Report will include the results of the Payment Error Rate Measurement pilot. The FY 2007 report will include a national Medicaid fee-for-service error rate for FY 2006 based on a statistically valid sample of states and claims within those states. CMS expects to be fully compliant with the Improper Payments Information Act requirements by FY 2008.

The Deficit Reduction Act provides additional funds to CMS to increase its Medicaid program integrity activities. The Act requires CMS to create a new Medicaid Integrity Program. In Section 6035 (d) of the Act, Congress mandated CMS to enter into contracts with "eligible entities" to review the actions of those seeking payment from Medicaid, conduct audits, identify overpayments, and educate providers and others on program integrity and quality of care. The Deficit Reduction Act also mandates that the agency devote at least 100 additional positions to support the Medicaid program integrity activities; to meet this mandate, in FY 2006, CMS created a new Medicaid Integrity Group. The hiring process is currently underway and CMS expects to complete the hiring of all 100 positions by September 2008. Additionally, the Act seeks to increase the effectiveness and efficiency of both Medicare and Medicaid through cost avoidance, savings, and recoupments of fraudulent, wasteful, or abusive expenditures through the Medicare-Medicaid match programs.

CMS was required by Deficit Reduction Act section 6035 to consult with OIG in the development of its Medicaid Integrity Program. In July 2006, CMS issued a 5-year comprehensive Medicaid Integrity Plan for implementing the program. CMS has created a new organization, the Medicaid Integrity Group, which will have three main divisions: the Division of Medicaid Integrity Contracting, the Division of Field Operations, and the Division of Fraud Research and Detection. CMS worked on designing the

infrastructure for the Medicaid Integrity Program in FY 2006 and plans to begin implementation and procurement of staff and other resources in FY 2007.

Challenge 5: Payment for Medicaid Prescription Drugs

OIG and the Government Accountability Office have consistently found that the Medicaid program pays too much for prescription drugs compared to prices available in the marketplace, impacting both Federal and state expenditures.

CMS estimates that Medicaid expenditures for prescription drugs in 2005 totaled more than $40 billion, a substantial increase over the $9 billion spent in 1994. While drug expenditures slowed significantly in 2005 due to states' efforts to contain drug costs, drug spending continued to represent significant Medicaid expenditures. Overall, Medicaid drug spending rose from 11.2 percent of all Medicaid spending in 2000 to 14 percent in 2005.

As of January 1, 2006, the new Medicare prescription drug benefit provides drug coverage for 6.5 million "dual eligibles" formerly covered by Medicaid. This shift is significant given the high drug utilization of the dual eligibles. Despite the transfer of dual eligibles, Medicaid will continue to provide prescription drugs to approximately 45 million Medicaid beneficiaries.

Under Federal law, states have substantial discretion in setting reimbursement rates for drugs covered under Medicaid. In general, Federal regulations require that each state's reimbursement for a drug not exceed the lower of the estimated acquisition cost plus a reasonable dispensing fee or the provider's usual and customary charge for the drug. In addition, CMS sets Federal upper limits and many states implement maximum allowable costs for multiple-source drugs (drugs with generic equivalents) that meet specific criteria.

While states must reasonably reimburse pharmacies for prescription drugs provided to Medicaid beneficiaries, they often lack access to pharmacies' actual purchase prices. Due to this lack of pricing data, states rely on estimates to determine Medicaid reimbursement. Most states base their calculations of estimated acquisition costs on average wholesale prices, which are published prices that states obtain through national drug pricing compendia. Average wholesale prices are not defined by law or regulation and are not necessarily based on actual sales transactions.

OIG has produced a body of work and consistently recommended that Medicaid programs reimburse pharmacies for drugs based on prices that more accurately reflect pharmacies' acquisition costs. OIG reports demonstrate that the published average wholesale prices used to determine Medicaid drug reimbursement amounts generally do not reflect the prices incurred by retail pharmacies. Most recently, OIG released two reports comparing the published prices that most states use to set Medicaid reimbursement, i.e., average wholesale prices and wholesale acquisition costs, to statutorily defined prices based on actual sales transactions, i.e., the average manufacturer price and average sales price. OIG found that average manufacturer prices and average sales prices were significantly lower than the published prices states use to set reimbursement, and these discrepancies were largest for generic drugs. Another report showed that Federal upper limit amounts were five times higher than the average manufacturer prices for generic drug products and that CMS could save from $650 million to $1.2 billion per year by basing Federal upper limit amounts on reported average manufacturer prices.

OIG is continuing to address pricing of Medicaid drugs. In its oversight role, OIG is comparing Federal upper limit amounts based on the new formula to the prices at which drugs are available from wholesalers, manufacturers, and other suppliers. OIG is also reviewing state reimbursement methodologies to determine whether states are planning to use reported average manufacturer prices as the basis for their reimbursements.

In addition to reimbursing pharmacies at prices that exceed drug acquisition costs, state Medicaid programs may not be receiving the proper amount of drug rebates they are entitled to receive from drug manufacturers. The statutory drug rebate program, which became effective in January 1991, requires drug manufacturers to pay rebates to state Medicaid programs. Medicaid rebates are partially based on the reported average manufacturer prices. OIG has found that manufacturers may not always report reported average manufacturer prices in a timely manner, or in some cases, may not report them at all. Further, both OIG and Government Accountability Office reviews have shown that manufacturers make inconsistent interpretations regarding how

to calculate the reported average manufacturer prices. OIG has recommended that CMS work to ensure that manufacturers provide accurate and timely reported average manufacturer price data and provide additional clarification on how to determine reported average manufacturer prices.

Most recently, as required by the Deficit Reduction Act, section 6001, OIG was required to "review the requirements for and manner in which average manufacturer prices are determined under section 1927 of the Social Security Act as amended," and provide recommendations to the Department for changes in the way the average manufacturer price is currently determined. OIG issued its recommendations to CMS on May 30, 2006.

OIG Assessment of Progress in Addressing the Challenge:

The Deficit Reduction Act impacts both Medicaid prescription drug reimbursement and rebates. It changes the basis for establishing the Federal upper limit amounts from the average wholesale price to the average manufacturer price. The Act also requires CMS to make average manufacturer prices available to state Medicaid programs on a monthly basis, as well as to post average manufacturer price data on its website quarterly. CMS has been directed to conduct a monthly survey of retail prices for prescription drugs. This information is to be provided to the states monthly and compared to state payment rates on an annual basis. With respect to Medicaid rebates, the Deficit Reduction Act clarifies issues related to rebates on physician-administered drugs and authorized generics. Finally, the statute made some changes to the way the average manufacturer price is calculated and requires CMS to promulgate a regulation no later than July 1, 2007, clarifying the manner in which the average manufacturer price is determined.

Although changes mandated by the Deficit Reduction Act are positive steps toward improving Medicaid reimbursement for prescription drugs and the collection of rebates, the remaining challenge is to ensure that the cost-saving provisions in the law are implemented in ways that assist Medicaid in appropriately paying for prescription drugs. For example, section 6001(b) of the Act requires CMS to make average manufacturer prices available to state Medicaid programs monthly and to the public quarterly on its website beginning July 1, 2006. While CMS has sent average manufacturer price data to state Medicaid agencies as mandated by the Act, CMS has stated that it would not publicly release the current average manufacturer price figures on its website because changes in the confidentiality provisions are not effective until January 1, 2007. CMS indicated that, instead, it would focus on developing a revised definition of average manufacturer price as well as data based on the new definition, for public disclosure.

Given the high Federal and state expenditures and the potential for significant savings, CMS should continue to be attentive in its oversight of Medicaid reimbursement for prescription drugs and the Medicaid drug rebate program. In particular, CMS should work to ensure that the cost-saving provisions in the Deficit Reduction Act are effectively implemented. States need accurate data that reliably reflect the actual costs of drugs paid by pharmacies and are based on pricing data that can be validated. Given that the Act allows states access to average manufacturer prices to assist in estimating prescription drug costs, it is also essential that all manufacturers report timely and accurate data. Currently, this is important for the rebate process to work as intended. If states begin to use the average manufacturer prices as the basis for Medicaid reimbursement, the timeliness and validity of the average manufacturer price will be crucial to ensuring accurate reimbursements as well.

Challenge 6: Quality of Care in Long-Term Care Services

With the expected growth in the long-term care population, ensuring quality of care provided to long- term care beneficiaries warrants significant attention to ensure that Federal dollars are spent on appropriate and quality long-term care. While there will always be a need for nursing home services, care will likely continue to shift to more community-based services. This shift may increase utilization of alternatives to institutional-based care such as home health, hospice care, and other community-based services. Thus, it is imperative that HHS continue to monitor quality of care provided to beneficiaries in all long-term care settings.

Through a body of work, OIG identified concerns regarding payment and quality issues in nursing facilities. Prior OIG work found an increase in the number of deficiencies and that a large number of nursing homes had been cited for substandard care. OIG continues to be concerned that enforcement mechanisms may neither be effectively bringing nursing homes with serious deficiencies back to compliance nor preventing nursing homes with egregious practices from continuing to provide substandard care to Medicare beneficiaries.

In three recent studies, OIG reported a number of concerns regarding enforcement of quality of care standards. In one study, OIG found that states appropriately referred most nursing home cases that warranted enforcement; but 8 percent of the cases were either not referred or were referred but the referral was not recognized as such by the CMS regional office. In another recent report, OIG found that for the majority of cases requiring mandatory termination, CMS did not apply the remedy due to both late case referrals by states and CMS' staff reluctance to impose this severe remedy. Finally, in a third report, OIG found that CMS did not investigate some of the most serious nursing home complaints within the required timeframe and that CMS oversight of nursing home complaint investigations is limited.

OIG is also concerned about whether payments to nursing homes are correct and whether the funds are being used for patient care-related activities. OIG examined the adequacy of Medicaid payments to nursing facilities in states that have enhanced payment programs for public nursing facilities. As part of these studies, in 2004 and 2005, OIG found that nursing homes were required by their states or counties to return a majority of their enhanced funding. These nursing homes had received the most unfavorable survey ratings the states can issue. The homes might have provided higher quality services if they had been able to retain all the funding they initially received.

Some nursing home care problems are so serious that they constitute "failure of care" and thereby invoke the civil False Claims Act. These cases often involve allegations of widespread or systemic problems, such as excessive falls, medication errors, an undue number of residents with facility-acquired pressure ulcers, and chronic staff shortages. OIG continues to work with U.S. Attorneys and the Department of Justice on development and settlement of these egregious cases. OIG is also working on more joint cases with the Medicaid Fraud Control Units to help protect the health and safety of this especially vulnerable population. OIG has developed exclusion actions against individuals and entities whose conduct causes the furnishing of poor care, with particular emphasis on higher-level officials of nursing facilities and chains. OIG continues to negotiate quality-of-care Corporate Integrity Agreements as part of the settlement of such False Claims Act cases. All of these Corporate Integrity Agreements require an outside monitor and include effective enforcement remedies for breach of the Corporate Integrity Agreements, such as specific performance, stipulated penalties, and exclusion.

OIG is currently conducting a series of reviews to further address quality issues in long-term care. Examples of topics include the use of psychotherapy services in nursing homes, the impact of Medicare Part D on dual eligible residents in nursing homes, cyclical noncompliance with certification standards in home health agencies, oversight of quality of care in hospices, and appropriateness of payments and care for hospice beneficiaries residing in nursing homes.

OIG Assessment of Progress in Addressing the Challenge:

CMS has implemented several data systems to manage survey and enforcement actions and complaint and incident-related activities. For example, CMS indicated that its Automated Survey Processing Environment enforcement management system, which contains information on both enforcement and survey results, has improved its ability to manage enforcement cases and has resulted in more timely application of mandatory denial of payment remedies. Additionally, a specific field in the system allows regional office staff to identify cases that have been referred by states and anticipate their arrival. However, increased dependence on these systems to manage and track survey, enforcement, and complaint actions, as well as increased national reporting capabilities of the two systems, is dependent upon timely, complete, and accurate data entry. Further, the data need to be routinely monitored and utilized to lead to improvement.

CMS has also made changes to state performance standards and its Special Focus Facility program to strengthen its oversight of quality of care in nursing homes. Further, CMS plans to begin an internal triage review geared to assess cases at specific intervals to identify any additional actions that might help bring a facility back into compliance in a timely manner. Recently, CMS has worked to make improvements in the complaint investigation process, including stronger protocols for handling complaints and strengthened oversight of the requirement to investigate complaints alleging actual harm (high) within 10 days.

Challenge 7: Public Health Emergency Preparedness and Response

The events of September 11, 2001, the 2005 Gulf Coast hurricanes, and the potential for future public health emergencies, such as the threat of pandemic influenza, have underscored the importance of having a comprehensive national public health infrastructure that is prepared to rapidly respond to public health emergencies. Because HHS manages most of the Nation's Federal health resources through surveillance, coordination, research, and delivery of healthcare service programs, OIG work has focused on vulnerabilities in those numerous programs. OIG assesses how well HHS programs and their grantees plan for, recognize, and respond to outside health threats; the security of HHS and grantee laboratory facilities; the management of these grant programs and funds by the Department and grantees; and the readiness and capacity of responders at all levels of government to protect the public's health.

Since 2001, OIG has completed numerous audits and evaluations of the Department's programs for bioterrorism preparedness and response. In earlier work, OIG evaluated the effectiveness of the Centers for Disease Control and Prevention (CDC) bioterrorism preparedness efforts, assessing the ability of state and local health departments to detect and respond to bioterrorist events and their ability to receive and deploy the Strategic National Stockpile (previously the National Pharmaceutical Stockpile). OIG has since conducted follow-up evaluations and found that, while some progress had been made, the states and localities were still under-prepared in general and their planning documents continued to overstate preparedness. OIG will continue to assess the Centers for Disease Control and Prevention's preparedness assistance to state and local health departments, paying particular attention to levels of preparedness for impending public health threats such as pandemic flu.

Ensuring the security of internal HHS and Department-funded laboratories, including those where select agents are used, and security over assets and materials to be used in responding to an emergency remains an OIG concern. In the past, OIG reviewed Departmental and external (non-Federal) laboratories' compliance with laws and regulations relating to the use of select agents and found that many of them did not adequately safeguard against the theft or loss of select agents. As legal requirements for the possession of select agents have become more stringent and detailed in the last several years, OIG initiated additional audits of entities with select agents to assess their compliance with select agent regulations. OIG plans in the near future to reassess Centers for Disease Control and Prevention's management of the select agent program. In a related effort, OIG will also evaluate physical security and environmental controls over the Strategic National Stockpile.

OIG has followed up on work performed in 2004 assessing grantees' efforts to comply with the financial accounting and reporting requirements of CDC's and the Health Resources and Services Administration's bioterrorism grant programs. OIG is drafting reports that will be issued in Fall 2006 reporting specifically on the timeliness with which all grantees obligated grant funds. In 2005 and 2006, as part of an interagency review in collaboration with the Inspectors General at the U.S. Environmental Protection Agency and the Department of Homeland Security, OIG reviewed CDC's role in the BioWatch program, which conducts surveillance for environmental indicators of bioterror agents. OIG's recommendations addressed overall management concerns, including inaccuracies in data reporting; background investigation levels for laboratory staff that were inconsistent with the level of program sensitivity; a need for more information sharing among laboratories; and CDC's limited guidance to health departments about response to positive test results. At the same time, OIG examined CDC's CHEMPACK program, a program designed to pre-deploy packages of medical countermeasures in anticipation of a chemical disaster. Similarly, OIG recommended that the CHEMPACK program should assist in deployment by providing testing guidelines and test containers to program participants, and utilize existing Centers for Disease Control and Prevention's medical expertise to answer participants' medical questions.

In addition to the significant investment in examining the Department's activities related to bioterrorism and public health preparedness, OIG has made it a priority to examine HHS' response to the public health challenges resulting from Hurricanes Katrina and Rita. In response to the 2005 Gulf Coast hurricanes, OIG continues to work with the President's Council on Integrity and Efficiency to assess the overall effectiveness of the Department's deployment and recovery activities, including Departmental procurements and associated management controls, beneficiary protections, and the delivery of critical healthcare services. OIG reviewed the emergency preparedness and response of nursing homes during recent hurricanes among a selection of nursing homes in five Gulf states and found that all experienced problems during the 2004 and 2005 hurricanes, whether evacuating or sheltering in place. OIG recommended that CMS consider strengthening Federal certification standards for nursing home emergency plans.

OIG recently issued several reports on its review of the procurement process for pharmaceuticals and other relief-related products and services associated with HHS' response to the Gulf Coast Hurricanes. OIG found that procurement officials complied with Federal Acquisition Regulation in awarding the contracts. A number of evaluations and audits are currently underway to examine the Department's overall response and recovery efforts, beneficiary protections, and Departmental procurements. OIG anticipates issuing a final report to be published before the end of 2006 that reviews the U.S. Public Health Service Commissioned Corps response to the hurricanes. For 2007, OIG plans to continue to evaluate the Department's approach to all-hazards disaster response and mitigation, including examining food facility security concerns, pandemic influenza preparedness, and early event detection efforts.

OIG Assessment of Progress in Addressing the Challenge:

HHS agencies continue to seek additional resources and work on corrective action plans that respond to OIG-reported concerns. 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 Centers for Disease Control and Prevention 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. Both the CDC and the Health Resources and Services Administration have updated their Public Health and Hospital Preparedness Cooperative Agreements to incorporate stronger performance measures and clearer guidance for grantees. In response to an OIG recommendation, the Centers for Disease Control and Prevention also now require states to address mental health needs in their Cooperative Agreement guidance. The Assistant Secretary for Public Health and Emergency Preparedness utilized earlier OIG reports to work with both components to standardize performance measures and required reporting for grantees.

Recent guidance for the CDC's Cooperative Agreement on Public Health Preparedness and Response now requires states to establish electronic systems that can effectively detect and report disease outbreaks and other public health emergencies. OIG will examine the extent to which states have made use of early event detection technology in fulfilling this requirement. In response to OIG's review of the Biowatch program, the Centers for Disease Control and Prevention stated that it has already begun addressing some of OIG's concerns and plans to implement automated data entry in laboratories and a forum for information sharing, as well as identify additional technical resources to increase state and local capacity to respond to a potential terrorist threat.

States and localities are currently strengthening their bioterrorism preparedness programs, and recent increases in HHS funding address some of OIG's concerns. However, based on OIG findings, significant improvements are still needed for local health departments to be fully prepared to detect and respond to bioterrorism and, by extension, naturally occurring disasters. The 2005 hurricanes underscored the need for a comprehensive Federal plan to respond quickly and effectively to a mass public health emergency event that also requires a seamless integration with responses at the state and local levels. CMS concurred with the findings in the nursing home emergency response and preparedness report. It is exploring ways to strengthen Federal certification standards for nursing home emergency preparedness and to promote better coordination among Federal, state, and local emergency management entities. As a result of a briefing on an early draft of the report reviewing the Commissioned Corps' response to the hurricanes, along with findings of the White House Katrina After-Action Report, the Office of the Surgeon

General, Office of Public Health and Science, is implementing many of the recommendations OIG identified, including the pre-identification, rostering, training, and equipping of designated response teams of Commissioned officers.

Challenge 8: Research and Regulatory Oversight

Through the work of the National Institutes of Health, the Department is responsible for acquiring knowledge that can help prevent, diagnose, and treat disease and disability. Additionally, through the work of the Food and Drug Administration, the Department is responsible for assuring the safety, efficacy, and security of human and veterinary drugs, medical devices, the Nation's food supply, cosmetics, and products that emit radiation. Given these critical public health mandates, it is necessary that NIH and FDA have in place policies and programs that ensure the integrity of medical research endeavors, including the protection of human research subjects and accountability over grant funds; pre-and post-approval of regulated medical products and treatments; ensuring the safety of the Nation's food supply; and the professional ethics of agency employees, members of advisory panels, and grantees.

Over the past decade, OIG has conducted numerous evaluations and audits that have consistently documented weaknesses in the oversight system for protecting human research subjects in clinical trials associated with NIH grants, those conducted by manufacturers seeking FDA approval for regulated products, and HHS oversight of clinical trials generally. FDA's bioresearch monitoring program conducts inspections of clinical investigators involved in clinical research to ensure the quality and integrity of data submitted to the agency and to protect the rights and welfare of human subjects. HHS agencies and grantees must effectively use appropriate tools to ensure both the safety of clinical trial participants and the validity and integrity of scientific data.

Research on approved drugs and devices often continues after products are approved for marketing. This research can help manufacturers and FDA identify important information about additional risks and benefits facing patients using these products. In 2006, OIG examined FDA's monitoring of these postmarketing study commitments and the timeliness with which these studies are being completed. This work identified several vulnerabilities that limit FDA's ability to readily identify whether or how timely these commitments are progressing toward completion. As a result, OIG made several recommendations to improve FDA's ability to oversee and monitor these commitments.

Vigilance in the area of medical research is especially crucial because when researchers fail to disclose and mitigate their financial conflicts of interest, their research findings may be or appear to be compromised. These concerns are magnified when Federal dollars are funding medical research. Federal concerns about conflict of interest extend to both intramural research performed by Federal employees in the Federal laboratories and extramural research, for which Federal research grants are provided to non-Federal research institutions. To address issues of conflicts of interest among HHS employees, in 2005, OIG evaluated the outside activity approval process for employees of both NIH and FDA. OIG identified several problems with the agencies' overall review process itself and recommended that both agencies improve the quality and extent of information they receive and address inadequacies in their review processes.

While intramural research undertaken within the Department is vital, the bulk of HHS' research funding goes to the private sector, primarily to research universities that undertake work pursuant to contracts and grants. HHS regulations require grantee institutions to utilize procedures to identify and deal with potential conflicts of interests of their researchers who are funded by the Department. In 2007, OIG will review NIH's oversight of these requirements. Furthermore, on November 29, 2005, OIG issued draft compliance program guidance for recipients of extramural research awards from NIH and other U.S. Public Health Service agencies. While focused on grant compliance and administration, the proposed compliance elements were intended to be helpful in connection with other areas, including conflicts of interest. On June 7, 2006, with the OIG's concurrence and support, the National Science and Technology Council's Committee on Science decided to expand the OIG draft guidance and establish an interagency initiative to develop voluntary compliance guidance for recipients of Federal research funding from all agencies across the Federal Government. These efforts will provide assistance to research institutions on guarding against conflicts of interest in Federally funded research.

OIG Assessment of Progress in Addressing the Challenge:

HHS has implemented many changes examining protections for human research subjects and NIH and FDA oversight of activities to protect the integrity and validity of scientific research. Notably, in June 2000, HHS created the Office for Human Research Protections within the Office of the Secretary, which is charged with oversight of all research involving human subjects that is conducted or funded by HHS. The Office for Human Research Protections closely coordinates with both NIH and FDA. However, recent reports of incidents concerning clinical drug trials have raised serious questions about potential vulnerabilities surrounding the protection of human research subjects and validity and integrity of scientific data from clinical trials. For example, in November 2005, a series of news articles highlighted problems with clinical trials at a for-profit Institutional Review Board. These articles raised concerns consistent with issues OIG had raised between 1998-2000[1] in reviewing oversight activities of Institutional Review Boards. The news series blamed lax oversight by FDA and Institutional Review Boards for deaths and injuries of several participants in clinical trials. The series identified specific problems with the oversight systems, including insufficient informed consent procedures, inadequate training and certification requirements for Institutional Review Boards, limited Federal regulations, and FDA's lack of enforcement of existing regulations.[2] To follow up on this previous work, in FY 2007 OIG will evaluate the oversight of clinical trials and human subject protections.

Federal law required HHS to issue regulations for the protection of human research subjects and to implement and update its programs of instruction and guidance in ethical issues associated with such research. The first harmonized regulations pertaining to informed consent and human subject protection were issued jointly by FDA and HHS in 1981. These regulations were revised and further harmonized in 1991 as the Federal Policy for the Protection of Human Subjects or the "Common Rule (45 Code of Federal Regulations Part 46)." The 16 Federal agencies that conduct, support, or otherwise regulate Federal human subject research agreed to abide by the requirements of the Common Rule. FDA adopted certain of the Common Rule's provisions. Revised regulations were issued on June 23, 2005, and amend the 1991 regulations. Pursuant to these regulations, all institutions that receive funds or seek approval of new drugs, devices, biologics, or other regulated products from HHS to conduct or support research with human subjects are subject to specific requirements and, as appropriate, to oversight by the Office for Human Research Protections and either NIH or FDA.

With respect to the vulnerabilities in oversight of postmarketing study commitments, FDA is currently undertaking a review of the decision-making process behind requests for postmarketing commitments for human drugs and biologics. The study is intended to assist FDA in determining if improved guidance is needed for industry. At the same time, FDA has undertaken activities to improve the response on postmarketing and postapproval studies for human drugs, biologics, and devices.

In the intramural arena, the Department has, in recent years, focused on devising new approaches and mechanisms for helping to ensure that HHS employees, particularly those involved in research and regulatory oversight at NIH and FDA, conduct their work free of conflicts of interest, so that the public can be assured that the Department's programs and responsibilities are not affected by financial concerns on the part of the Federal employees involved in this work. The Department's Designated Agency Ethics Official led an effort to strengthen the HHS Supplemental Standards of Ethical Conduct, culminating in the promulgation of a new final regulation on July 31, 2005. The new, expanded Supplemental Standards focus on the financial holdings and outside activities of FDA and NIH employees. A more thorough system of examining the outside activities of all HHS employees was also instituted, whereby the HHS Form 520, "Request for Approval of Outside Activities," was expanded from a 4-page to a 16-page detailed questionnaire and the requirement to annually report on outside activities was instituted.

Management Challenge 9: Grants Management

HHS' public health and human service agencies rely on grants and cooperative agreements to meet mission objectives, such as providing health and social services safety nets, preventing the spread of communicable diseases, and researching causes and treatments of diseases. In FY 2006, the Department expects to issue grants totaling $240 billion ($37 billion discretionary and $203 billion mandatory). Medicaid, which constitutes the largest portion of mandatory grants ($193 billion), is discussed under Issues three, four, and five, where program vulnerabilities are identified.

[1] OEI-01-97-00197: Protecting Human Research Subjects: Status of Recommendations; final report signed April 2000; report summarizes Department, NIH, and FDA responses to recommendations contained in OEI-01-97-00190-00196.

[2] Bloomberg.com, November 2, 2005.

Grants management remains a challenge because of the very nature of a grant. A grant is financial assistance for an approved activity with performance responsibility resting primarily on the grantee, with little or no government involvement in the funded activity. This expectation of minimal government involvement is compounded by the fact that many HHS grantees have limited experience managing Federal funds. New, inexperienced grantees are particularly likely to receive funding when new grant programs are created or existing programs are expanded. In addition, even experienced grantees sometimes allegedly use grant funds for nonapproved purposes, as evidenced by recent grant fraud related settlements between the Department of Justice and several major universities.

To ensure the integrity of HHS' grant programs, OIG will continue to examine grants management, including the agencies' grant selection and oversight processes, program performance and results, implementation of information technology efforts to increase program access and operational efficiency, and accountability for Federal funds. OIG plans to pay particular attention to vulnerabilities associated with expanded grant programs, newly funded initiatives, and first-time Federal grantees.

Discretionary Grants

The risk of inefficient use or misuse of grant funds is high when the grant-making or oversight process is flawed. In a September 2005 review of the Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome (HIV/AIDS) prevention grant-making process operated by CDC, OIG identified numerous deficiencies throughout the preaward, award, and postaward phases of the agency's grant management operations. OIG concluded that CDC could not be assured that its grant management operations provided appropriate direction and oversight for the activities of grantees under the HIV/AIDS prevention program.

HHS agencies have several grants management tools at their disposal, including the Department Alert List. Failure to use these tools increases the risk that grant funds will be used for purposes other than those intended. In September 2005 and May 2006, OIG completed two related reviews examining the Health Resources and Services Administration's (HRSA) and CDC's adherence to Departmental policies governing placement on and use of the Alert List. The Alert List contains the names of high-risk grantees and is used by the Department to ensure that such grantees are known to the HHS grant-making agencies and to safeguard Department funds. OIG found that HRSA and CDC did not consistently follow Alert List policies for placing grantees on the list and monitoring their status. OIG also found that HRSA grants officers did not use the information on the list to make grant decisions. OIG recommended that both HRSA and CDC develop methods to ensure that grants officers follow Alert List policies.

Even when grantees are providing the intended service, they often do not observe all of the programmatic or financial requirements to which such grantees are subject. A series of reviews of HRSA's Ryan White HIV/AIDS service providers completed in 2004 and 2005 indicated that the intended services were generally being provided, but certain aspects of grantee or sub-recipient operations, such as service delivery and fiscal management, could be improved. For example, a provider of emergency housing served some clients beyond the time period established in agency guidelines, while other potential clients were on waiting lists. OIG also identified a number of grantees that claimed costs at budgeted levels, rather than actual costs as required by Federal cost principles.

Grant oversight and monitoring continues to be a concern of OIG. In June 2006, OIG completed a review of the Agency for Healthcare Research and Quality's (AHRQ) monitoring of its Patient Safety Grants, which totaled $128 million in FYs 2001 through 2003. OIG found that although grantee performance reports generally complied with Federal requirements, most financial reports were not received or were late, and Federal requirements for closeout were not met. OIG recommended that AHRQ require submission of interim financial information, establish a tracking system for Financial Status Reports, require grantees with no-cost extensions to submit Financial Status Reports in compliance with Federal requirements, and ensure that grants awaiting closeout are closed promptly.

At NIH and university grantee sites, OIG has several initiatives aimed at evaluating the allowability of costs charged to NIH grants. Ongoing work is focused primarily on costs transferred to NIH grants and administrative and clerical costs charged to

NIH grants. OIG is also conducting a congressionally requested review of graduate student researcher compensation charged to NIH grants.

Mandatory Grants

OIG has reviewed the Administration for Children and Families' (ACF) monitoring and oversight of the Title IV-E Foster Care Programs, because these programs serve children who comprise a vulnerable population. OIG has examined states' standards and capacities to track frequency and content of caseworker visits with children in the Foster Care program. OIG found that although most states surveyed had written standards calling for a minimum of monthly caseworker visits, fewer than half demonstrated the ability to produce statewide visitation reports, and several states indicated that, on average, caseworkers visited fewer than half of foster children monthly. OIG recommended that ACF promote the use of automated systems for recording and reporting caseworker visitation data and work with states to ensure that these data are recorded in their systems. OIG also assessed states' methods of monitoring foster care sub-grantees and found that some states' systems were inadequate, according to study criteria that OIG developed based on Federal grants management requirements; some states did not communicate required information to sub-grantees; and ACF paid minimal attention to oversight of states' sub-grantee monitoring systems. OIG recommended that ACF hold states accountable for adhering to grant management requirements relating to sub-grantees.

Since 2002, OIG has performed reviews in 10 states that have focused on the appropriateness of Federal reimbursement related to Foster Care and Adoption Assistance training and administrative costs and maintenance claims. OIG has monitored ACF's plan to identify erroneous payments for Foster Care, Head Start, and Child Care as mandated by the Improper Payments Information Act and Office of Management and Budget Memorandum M-03-13. In addition, during FY 2007 OIG will perform reviews in three states to identify erroneous payments in its Temporary Assistance for Needy Families program, which has a FY 2006 funding level of $17.2 billion.

OIG Assessment of Progress in Addressing the Challenge:

Through the government-wide 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 entities responsible for delivering services. The initiative requires grant officials to examine the way they do business, focusing not only on streamlining the grant process, but also on ensuring that results are achieved and that Federal funds are used appropriately for the maximum benefit of program recipients. It is crucial that HHS agencies adequately manage and monitor their grantees' and, to the extent possible, their sub-grantees' program performance and require fiscal accountability through the life of the grant. A critical part of this streamlining process involves the consistent use of Department-wide grants management policies. Over the next fiscal year, OIG will continue to address Department-wide efforts to improve the streamlining of Federal assistance programs, grants management, and program oversight and monitoring.

In response to OIG's report on the Alert List, CDC has begun regular reviews of the list to ensure appropriateness of content and requires all grants management officers to review grants to determine the need for placement on the list due to special conditions and facilitate timely removal. It has also worked closely with the HHS Office of Grants for guidance and training and developed a written policy on Alert List procedures to complete its planned corrective actions. In its response to OIG's report, HRSA indicated that it expects that the recently concluded consolidation of its grants management operations into a single operating unit, with standardized operating procedures and uniform guidance, will prevent a recurrence of the types of adverse findings identified by OIG. Additionally, the HHS Office of Grants has conducted Department-wide training on Alert List policies and procedures.

AHRQ has committed to improving its grant monitoring overall and agreed in general to the recommendations in OIG's review of patient safety grants. In response to OIG's report, AHRQ intends to initiate several actions that are intended to improve the

availability of needed financial information for use in making funding decisions, developing an electronic tracking system for Financial Status Reports, and closing out grants timely.

ACF concurred with OIG recommendations concerning the frequency and content of state foster care caseworker visits and in response to the OIG report said that it plans to use the findings and recommendations from OIG's review to provide technical assistance to the state grantees.

Management Challenge 10: Integrity of IT Systems and Infrastructure

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, insurance companies and, most recently, the serious loss of data by Federal agencies. The Office of Management and Budget has recently reemphasized Federal agency responsibilities under the law and policies to appropriately safeguard sensitive, personally identifiable information and train employees regarding their responsibilities in this area. HHS has personal information in its internal systems and the systems that serve Medicare and Medicaid and other programs. HHS needs to ensure that all necessary technical and policy measures are being taken to protect sensitive information, the systems that store that information, and the physical or electronic transport of that information.

HHS continues to make progress in securing its most critical assets, both cyber-based and physical, such as computer systems, data communication networks, and Department laboratories. However, the widely distributed and complex network of systems, applications, and facilities makes this a daunting task. Recent expansion of HHS programs, such as the new Medicare Part D benefit, significantly increases the programmatic and system demands on the Department, creating new relationships or expanding existing relationships with business partners. These new or expanded relationships will create new system exposures that have to be evaluated and, if need be, strengthened to ensure the confidentiality, integrity, and availability of critical assets.

The human factor is a critical component of an effective security program. It is typically overlooked in the development of technical solutions to address weaknesses in entity-wide security, access controls, service continuity, application controls and development, and segregation of duties. As the Department focuses more on data integrity and application controls, the need to ensure adherence to general controls becomes paramount. For example, OIG's body of work indicates that the Medicare payment error rate is more often a function of the input of incorrect information than data processing. For the 7 years during which OIG produced the Medicare fee-for-service error rate, the overwhelming majority (more than 95 percent) of the improper payments identified were detected through medical reviews. When these claims were submitted for payment to Medicare contractors, they contained no visible errors. The OIG Federal Information Security Management Act assessments also found that many identified security weaknesses are attributed to either an absence of a process to protect resources or a failure to comply with an established process.

Through planned work, OIG will place new emphasis on controls designed to ensure the protection of personal data and will continue to place emphasis on controls that are designed to guarantee the integrity of data for numerous vital programs on which critical systems depend for the accurate payment of billions of dollars through the Department's many programs.

Health Information Technology

In 2001, the President identified the development and implementation of an "interoperable health information technology infrastructure" as a key initiative. To facilitate this, in April 2004, the President issued Executive Order 13335, which established the position of the National Health Information Technology Coordinator and outlined incentives for the use of health information technology (IT). According to the President's executive order, "The 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 health information technology in both the public and private healthcare sectors that will reduce medical errors, improve quality, and produce greater value for healthcare expenditures."

Because the majority of key health IT initiatives are in their formative stages, OIG will assess HHS' progress in implementing key health IT initiatives in the public health agencies and at CMS and identify barriers to their implementation. OIG's work related to the health IT initiative will focus on use of electronic health records, e-prescribing, state initiatives to utilize health IT, and the use of health IT to respond to public health emergencies.

OIG 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. Core requirements for security controls have been established and distributed, and system architecture documents are being developed.

The "Secure One HHS" project, which is supported through a multiyear contract, is the Department's effort to improve IT security from the top down by providing security policy, procedures, and guidance. The project began in earnest in March 2003. Its goal is to improve the Department's overall IT security posture, ensure adequate enterprise-wide security standards, support integration of IT security into lines of business, and promote an environment in which employee actions reflect the importance of IT security. However, insufficient resources have been allocated for the day-to-day oversight function for this project. Despite resource deficiencies, during FY 2005 the Department made significant progress in addressing deficiencies noted in prior Federal Information Security Management Act reviews.

Although the adoption of health IT is in its early stages throughout the Department, there are several areas where health IT is currently in use or development is being funded. AHRQ awards $166 million in grants and contracts to programs across the country to support and stimulate investment in health IT, especially in rural and underserved areas. For three decades, the Indian Health Service has used its Resource and Patient Management System to capture clinical and public health data and manages patient care and followup using electronic health records NIH, through the National Library of Medicine, hosts an online medical database that provides up-to-date information to consumers and healthcare professionals. Called Medline Plus, the database is free to use; provides extensive information about drugs; and offers an illustrated medical encyclopedia, interactive patient tutorials, and the latest health news.

On August 8, 2006, the Department issued final regulations that establish new exceptions under the physician self-referral law and new safe harbors under the anti-kickback statute involving the donation of certain electronic health IT and services. The final rules seek to lower perceived barriers to the adoption of health IT 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 Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the first exception and safe harbor establish the conditions under which hospitals and certain other 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 records software, IT, and training services.