

FY 2007 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) (Public Law 108-173) established a Medicare outpatient 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. According to the "2007 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds," during 2006, the first year of the benefit, expenditures totaled more than \$47 billion. According to the Centers for Medicare & Medicaid Services (CMS), as of January 2007, nearly 24 million beneficiaries were enrolled in Part D and an additional 7 million beneficiaries were enrolled in retiree drug coverage plans that receive the Retiree Drug Subsidy (RDS). 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 contain features that present significant management challenges. Part D coverage is provided by private entities, known as drug plan sponsors, that contract with CMS to provide Part D drug plans. Qualified employer-sponsored plans may also receive a subsidy, the RDS, to maintain drug coverage for the Medicare beneficiaries. Within the Department, CMS bears primary responsibility for implementing and administering Part D. However, administration of Medicare Part D depends upon extensive coordination and information sharing among Federal and State Government agencies, drug plan sponsors, contractors, health care providers, and third party payers.

Payments to drug plan sponsors based on bids, risk adjustments, and reconciliations add to the complexities and challenges of the benefit. Medicare pays plans prospectively based on sponsors' bids, which are submitted and approved prior to the plan year. Subsequently, Medicare reconciles payments to plans through a multi-stage process that begins 6 months after the conclusion of the plan year.

Based on our analysis of preliminary reconciliation amounts, OIG estimated that Part D sponsors owe Medicare a net total of \$4.4 billion for 2006. Eighty percent of sponsors owe money to Medicare, whereas 20 percent of sponsors will receive money from Medicare. The majority of the funds' that sponsors owe are profits that they must repay to Medicare as a result of risk-sharing requirements. CMS does not currently have mechanisms in place to collect these funds or to adjust prospective payments prior to reconciliation. As a result, sponsors have had the use of over \$4 billion owed to Medicare for a significant length of time. Additionally, sponsors' overestimates of their costs also resulted in higher beneficiary premiums; however, beneficiaries do not directly recoup any money paid in higher premiums.

During the coverage year, the relative financial responsibilities of Medicare, drug plan sponsors, and beneficiaries vary through four distinct phases (deductible, initial coverage period, coverage gap, and catastrophic coverage), depending on the beneficiaries' total drug costs and true out-of-pocket (TrOOP) spending at a given time. Drug plan sponsors are responsible for tracking enrollees' TrOOP, the out-of-pocket costs that count toward the catastrophic coverage threshold. Accurate tracking of TrOOP is essential to ensuring that each party pays the appropriate share of drug costs.

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. For example, neither CMS nor the one Medicare Drug Integrity Contractor (MEDIC) that was operating as of October 2006 had conducted any significant data analysis for fraud detection purposes. CMS relied largely on complaints to identify fraud and abuse, but OIG found that not all complaints were investigated timely. OIG also identified impediments to CMS's effective oversight of drug plan sponsors' financial reporting, Part D marketing, and utilization management.

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 few sponsors met all of CMS's requirements for compliance plans. Further, most sponsors' compliance plans did not address all of CMS's recommendations regarding fraud detection, correction, and prevention. In addition, sponsors' compliance plans contained only the broad outlines of a fraud and abuse plan and did not include details or describe specific processes. OIG is conducting follow-up work focused on sponsors' detection and reporting of fraud and abuse.

Several additional OIG reviews of Part D are under way. Some examples include reviews of plan bids and CMS's bid review process, point-of-sale drug prices, potential duplicate payments for drugs, States' contributions to the costs for coverage of dual eligibles, RDS payments for employer-sponsored coverage, tracking beneficiaries' TrOOP costs, and drug plan marketing materials. OIG is also involved in a number of investigations related to Medicare Part D. These cases involve potential wrongdoing committed by a variety of actors, including marketing agents, drug plan sponsors, and pharmacists.

Assessment of Progress in Addressing the Challenge:

CMS has demonstrated progress in protecting Medicare Part D from fraud and abuse, but further implementation of safeguards is needed. OIG identified six major types of Part D safeguard activities that CMS is planning or implementing, including (1) the complaint process, (2) data monitoring, (3) financial audits, (4) monitoring compliance of drug plan sponsors, (5) oversight of drug plan sponsors' efforts to reduce fraud and abuse, and (6) education and guidance. CMS is in various stages of implementation with respect to each of these safeguards. For example, the complaint process has been in place since November 2005, but the first financial audits are not expected to begin until January 2008. Data-monitoring efforts have been slow to materialize, but CMS has taken some promising steps. For example, 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 Medicare prescription drug data as well as data on inpatient care, physician services, and other services provided under Medicare Parts A and B and Medicaid. When developed, One PI is expected to offer powerful data analysis and fraud detection tools.

In its comments on OIG's report on CMS's implementation of safeguards during FY 2006, CMS reported several advances since the beginning of 2007. These include continued progress towards commencing the financial audits by the end of CY 2007, commencement of routine PDP compliance audits in February 2007, improvement in processing complaints timely, and release of four new chapters of the Prescription Drug Benefit Manual.

Although many of the Part D safeguard activities are to be conducted by MEDICs, for most of 2006, CMS had contracted with only one functioning MEDIC. In September 2006, three regional MEDICs and a data-focused MEDIC were awarded contracts, with operations scheduled to begin December 2006. The MEDICs have had challenges in obtaining complete Part D claims data to carry out these integrity activities. CMS reported to OIG that its top priority is to increase the MEDICs' access to Part D data and that additional funding will support the MEDICs' access to data and allow the MEDICs to provide additional analysis and thus sustain fraud, waste, and abuse prevention activities.

In response to OIG's report on reconciliation amounts owed, CMS stated that it believes that the variance between prospective and reconciled payments will markedly decrease over time as actual program data becomes available to CMS and drug plan sponsors. CMS also concurred with OIG's recommendation that the data collected from the 2006 and subsequent plan years be used in the review of future bid submissions.

Management Issue 2: Integrity of Medicare Payments

Management Challenge:

The size and scope of the Medicare program place it at high risk for payment errors. In fiscal year (FY) 2006, Medicare benefit payments totaled about \$382 billion for services provided to approximately 43 million beneficiaries. 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.

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 2006 financial report, CMS reported a gross paid claims error rate (overpayments plus underpayments) of 4.4 percent (\$10.8 billion) for the fiscal year. However, OIG's FY 2006 financial statement audit reported internal control weaknesses in managed care and the prescription drug benefit program and the lack of an integrated general ledger accounting system within CMS. Further, OIG audits continue to show that Medicare has serious internal control weaknesses in its financial systems and processes.

Targeted audits and evaluations by OIG also continue to identify significant 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, \$718 million in improper payments for Part B mental health services, an estimated \$402 million in improper payments for ambulance transports, and \$377.9 million in inaccurate hospital wage data that impact future Medicare payments. In additional reviews, OIG found \$72.4 million in improper payments to hospitals that incorrectly coded claims as discharges to home rather than transfers to post-acute care facilities. OIG also identified \$71.5 million in improper payments to independent diagnostic testing facilities for services that were not reasonable and necessary, were not sufficiently documented, or were performed without the knowledge of treating physicians.

OIG has also consistently found that the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) benefit is vulnerable to fraud and abuse. For example from 2002 to 2006, OIG excluded from the Medicare and Medicaid programs 121 DMEPOS companies and 457 individuals associated with DMEPOS. During this same period, OIG's investigations resulted in 289 successful criminal prosecutions of DMEPOS suppliers and 76 civil settlements or judgments were imposed. Together these criminal convictions and civil adjudications resulted in more than \$796 million in restitution, fines, and penalties.

In other work, OIG has identified weaknesses in the DMEPOS enrollment process and CMS's oversight of infusion claims that make Medicare vulnerable to fraudulent billing practices for these services. In a 2007 report, OIG found that 31 percent of DMEPOS suppliers in three South Florida counties (Miami-Dade, Broward, and Palm Beach) did not maintain physical facilities or were not open and staffed, contrary to Medicare participation guidelines. The guidelines are intended to ensure that only qualified suppliers are enrolled in the Medicare program. In a separate review, OIG determined that in the second half of 2006, the claims originating in the same three Florida counties constituted 50 percent of the submitted charges and 37 percent of the amount Medicare paid for services on behalf of beneficiaries with HIV/AIDS. These counties also accounted for 79 percent of the amount submitted to Medicare nationally for drug claims involving HIV/AIDS patients. However, only 10 percent of Medicare beneficiaries with HIV/AIDS lived in these three counties. Other metropolitan areas exhibited patterns of aberrant billing similar to those in South Florida, but to a lesser extent.

Additionally, in a 2007 report, OIG reviewed 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. For calendar years (CY) 1999-2002, before the Common Working File edits were fully operational, OIG found that Medicare Part B made \$100.8 million in potential overpayments to suppliers of DMEPOS on behalf of beneficiaries in Part A-covered skilled nursing facility stays. For CY 2003, after the edits were fully operational, OIG identified potential DMEPOS overpayments of \$15.4 million and estimated that durable medical equipment regional carriers had not recovered approximately 69 percent (\$11.2 million) of these overpayments.

To help combat DMEPOS fraud, 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 health care initiative designed to identify suspicious suppliers and review questionable financial activities. Since its inception in September 2006, the initiative has recovered more than \$10 million from nominee account holders who agreed to turn over the funds in the bank accounts when confronted by law enforcement officials. In most cases, the nominee account holders stated that they had no operational control of the businesses and had only lent their names in return for remuneration.

Assessment of Progress in Addressing the Challenge:

The FY 2006 gross paid claims error rate of 4.4 percent reported by CMS is 0.8 percentage points lower than the 5.2 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. 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 FY 2006 financial statements. However, the material weakness related to Medicare electronic data processing and the reportable conditions related to managed care and prescription drug payment cycles, taken together, represent substantial noncompliance with the Federal financial management system requirements. In addition, although the Healthcare Integrated General Ledger Accounting System (HIGLAS) is operational at numerous Medicare contractors, CMS has not yet completed its implementation and, as a result, is not compliant with the U.S. Government Standard General Ledger at the transaction level. Although CMS has also made improvements to its general and application controls (such as access controls, application software development controls, and program change controls), OIG's financial statement audit identified weaknesses 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.

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, CMS will implement 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. Those who fail to reapply within 30 days of receiving a letter from CMS; fail to report a change in ownership or address; or fail to report having owners, partners, or managing employees who have committed felonies within the past 10 years will have their billing privileges revoked. CMS has also recently announced a demonstration project in South Florida focusing on infusion therapy. Under this demonstration, currently enrolled infusion therapy clinics located in the targeted area will be required to submit new enrollment applications and will undergo mandatory site visits.

Additionally, CMS issued a proposed rule on August 1, 2007 (72 FR 42001) that would require all DMEPOS suppliers, except those that are Government operated, to obtain and retain surety bonds in the amount of \$65,000. Under this rule, Medicare can recover erroneous payments up to \$65,000 that result from fraudulent or abusive supplier billing practices. This requirement may also help to ensure that only legitimate DMEPOS suppliers are enrolled in the program.

Management Issue 3: Appropriateness of Medicaid and SCHIP Payments

Management Challenge:

Medicaid is a joint Federal and State program that provides medical assistance to an estimated 50 million low-income and disabled Americans. The Federal share of the Medicaid and State Children's Health Insurance Program (SCHIP) expenditures in FY 2006 was approximately \$185 billion. Because Medicaid and SCHIP are Federal/State matching programs, improper payments by States lead to corresponding improper Federal payments. Identifying payment errors and their causes in the Medicaid and SCHIP programs is

particularly difficult because of the diversity of State programs and the variation in their administrative and control systems.

Payment Error Rates

Until recently, little was known about payment error rates in the Medicaid and SCHIP programs. This lack of information represented a substantial vulnerability in preventing fraud, waste, and abuse. In July 2001, CMS invited States to participate in a demonstration project to develop a Payment Accuracy Measurement (PAM) methodology for Medicaid, i.e., a single methodology that can produce both State-specific and national-level payment error estimates. The PAM model was later modified to comply with the requirements of the Improper Payments Information Act of 2002 which requires heads of Federal agencies to estimate improper payments for the programs they oversee, report to Congress annually, and submit reports on actions the agencies are taking to reduce such payments.

The PAM project has since been renamed the Payment Error Rate Measurement (PERM) program and was published in late August 2006 as an interim final rule with comment. The final PERM rule was published on August 31, 2007 (72 FR 50490). The PERM 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 PERM also sets forth the State requirements for conducting reviews and estimating payment error rates due to errors in eligibility determinations.

To assist CMS with its development of PERM and at the request of the Office of Management and Budget (OMB), OIG conducted audits of Medicaid and SCHIP eligibility in three States: New York, California, and Florida. These reviews found significant eligibility errors in these programs. 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. For the majority of these Medicaid and SCHIP improper payments, beneficiaries were ineligible because household incomes exceeded the threshold on the dates of service, citizenship requirements were not being met, Social Security numbers were lacking, and spend-down requirements were not being complied with.

OIG also conducts targeted program reviews to identify vulnerabilities and inappropriate payments associated with specific types of services. For example, in a 2007 report, OIG assessed the appropriateness of Medicaid payments for pediatric dental services in five States and found that 31 percent of Medicaid pediatric dental services provided in those States during 2003 did not meet State and Federal requirements, resulting in improper payments of approximately \$155 million (Federal share \$96 million). OIG recommended that CMS increase efforts to ensure that States enforce existing policies relating to the proper documentation of pediatric dental services and provide assistance to States to promote provider compliance with documentation requirements.

In addition, ongoing and planned work includes various reviews to identify payment error vulnerabilities in the Medicaid managed care program, to determine whether children enrolled in separate SCHIPs should be enrolled in Medicaid, and identify potential inappropriate payments for durable medical equipment. OIG is also conducting reviews to oversee the Medicaid and SCHIP error rate determination process.

Medicaid Prescription Drugs

CMS estimates that Medicaid expenditures for prescription drugs in 2006 totaled more than \$28 billion. Although Medicaid drug expenditures declined significantly in 2006 because of the shift of the expenditures for dual eligibles to the new Medicare Part D program, drug spending continues to represent significant Medicaid expenditures.

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 (FUL) and many States have maximum allowable cost limits for multiple-source drugs (drugs with generic equivalents) that meet specific criteria.

Although States must reasonably reimburse pharmacies for prescription drugs provided to Medicaid beneficiaries, they often lack access to pharmacies' actual purchase prices. Because of 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 (AWP), or wholesale acquisition costs (WAC), which are published prices that States obtain through national drug pricing compendia. AWP's are not defined by law or regulation and are not necessarily based on actual sales transactions.

OIG has produced a body of work related to Medicaid's pharmacy reimbursement and has consistently recommended that Medicaid programs reimburse pharmacies for drugs based on prices that more accurately reflect pharmacies' acquisition costs. Earlier OIG reports demonstrated that the published AWP's used to determine Medicaid drug reimbursement amounts generally did not reflect the prices incurred by retail pharmacies.

The DRA impacts both Medicaid prescription drug reimbursement to pharmacies and the rebates that manufacturers are required to pay to State Medicaid programs. It changes the basis for establishing the FUL amounts from the lowest published price (e.g. the AWP or WAC) to the lowest average manufacturer price (AMP). The DRA also requires CMS to make AMP's available to State Medicaid programs on a monthly basis. With respect to Medicaid rebates, the DRA also addresses issues related to rebates on clarifying the AMP, including physician-administered drugs and the treatment of authorized generics.

OIG is continuing to address pricing of Medicaid drugs. In 2007, OIG issued a report comparing the FUL amounts based on the new formula to estimates of pharmacies' acquisition costs. OIG found that under the new calculation method established by the DRA, FUL amounts are likely to decrease substantially, as intended, but OIG has concerns that, at least initially, some of the new FUL amounts may be below pharmacy acquisition costs. OIG recommended that CMS take steps to identify when a new FUL amount may not be representative of a drug's acquisition cost to pharmacies.

In addition to identifying problems with pharmacy reimbursement, OIG is also concerned that State Medicaid programs may not be receiving the proper amount of drug rebates that 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 based on a formula that includes the reported AMP's. However, OIG has found that manufacturers may not always report AMP's in a timely manner or, in some cases, may not report them at all. Further, in a 2006 report mandated by the DRA, OIG found that manufacturers make inconsistent interpretations regarding how to calculate the reported AMP's. OIG has recommended that CMS work to ensure that manufacturers provide accurate and timely AMP data and provide additional clarification on how to determine reported AMP's.

OIG has also found instances in which pharmaceutical manufacturers have defrauded the Medicaid drug rebate program. For example, in 2005, the United States entered into a civil settlement with King Pharmaceuticals, Inc., for more than \$124 million to resolve allegations that King improperly calculated its Medicaid rebate pricing information and underpaid rebates due to the States' Medicaid programs. Several other major drug manufacturers have entered settlements with the United States in which Medicaid drug rebate violations were one of several issues resolved.

Additionally, OIG has investigated a number of cases involving retail pharmacy chains that allegedly billed Medicaid for prescription drugs that were not provided to beneficiaries. OIG and its law enforcement partners also have pursued cases in which pharmacies switched the drugs prescribed to patients to exploit Medicaid reimbursement rules. For instance, in November 2006, the Government entered into a \$49.5 million settlement with Omnicare, Inc., a nationwide institutional pharmacy that serves nursing home patients exclusively. The investigation found that Omnicare switched generic Zantac tablets with capsules to avoid a FUL set by CMS and the maximum allowable cost set by State Medicaid programs for the tablets. By these and other drug switches, Omnicare gained additional Federal and State dollars to which it was not otherwise entitled.

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 (DRA) are effectively implemented and monitored. Further, 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. Therefore it is essential that all manufacturers report timely and accurate data to CMS to ensure appropriate payments are made and correct rebates are collected.

Assessment of Progress in Addressing the Challenge:

Payment Error Rates

The FY 2006 CMS "Performance and Accountability Report" (PAR) included the results of the PERM pilot. The FY 2007 report will include 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 PAR, 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 requirements by FY 2008.

In response to OIG audits of Medicaid and SCHIP eligibility in New York, California, and Florida, the States generally agreed to improve their eligibility processes. The payments made on behalf of ineligible beneficiaries will be adjudicated by CMS as part of its audit clearance process. Additionally, in response to OIG's 2007 review of claims for Medicaid pediatric dental services, CMS indicated that its Medicaid Integrity Group plans to work with States to enforce existing policies related to the proper documentation for pediatric dental services as well as other Medicaid services.

Medicaid Prescription Drugs

CMS has been directed by section 6001(f) of the DRA 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 annually. CMS currently provides AMP data to State Medicaid agencies as mandated by the DRA.

On July 17, 2007, CMS published in the Federal Register 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, and (3) solicits public comments on the FUL outlier and AMP sections of the rule. In accordance with the DRA, the rule includes requirements related to State plans, Federal financial participation for drugs, and the payment for covered outpatient drugs under Medicaid.

In the final rule, CMS describes an outlier policy that precludes the lowest AMP from being used in the FUL calculation. In the notice of proposed rulemaking, CMS proposed excluding lowest AMPs that were 70 percent less than the second-lowest AMP. In the final rule, this threshold was decreased to 60 percent of the lowest AMP (the same threshold as in the OIG report). In those cases in which the lowest AMP is determined to be an outlier, the second lowest AMP will be used in the FUL calculations. CMS stated that this level will ensure that at least two drugs have AMPs at or below the FUL amount. Further, in response to the OIG draft report analyzing the impact of the new FULs, CMS strongly disagreed with the OIG's findings concerning the effect of the DRA-related changes to the FUL calculation. CMS stated that adequate reimbursement can be achieved with FULs based on AMP. In addition, CMS asserted that the analysis in the OIG is deficient in numerous ways and such deficiencies lead to flawed results and misleading conclusions. In the final report, the OIG responded that the data contained in the report are the best available for the timeframe, and any limitations have marginal impact and do not change the overall findings and conclusions.

Management Issue 4: Medicaid Administration

Management Challenge:

The Federal share of Medicaid outlays in FY 2006 exceeded \$180 billion. 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 by statute can range from 50 to 83 percent in the various State programs.

Over the past 6 years, OIG's work has identified significant problems in State Medicaid financing arrangements involving the use of intergovernmental transfers (IGT). Specifically, OIG found that six States inappropriately 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 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 facilities operated by units of government, OIG identified serious problems in Medicaid supplemental payments to public hospitals and long-term care facilities available under the upper payment limit (UPL) rules.

In addition, OIG has identified significant Federal overpayments involving school-based health services, disproportionate share hospital (DSH) payments, and targeted case management services. For example, OIG has consistently found that schools have not adequately supported the claims submitted to States for school-based health services. Particularly in New York, OIG identified significant overpayments involving speech therapy and transportation claims. From 2004 through 2006, OIG issued six reports questioning unallowable Federal funds to the New York Medicaid program totaling more than \$1 billion. 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, in a 2006 roll-up report, 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 another 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.

OIG is also working closely with DOJ to investigate and pursue False Claims Act cases concerning fraudulent billing of targeted case management and school-based health services. In a case settled 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 Corporate Integrity Agreement (CIA) with OIG that contained several unprecedented provisions. Under the CIA, OIG will review Maximus's contracts and require dissemination of the review findings to Maximus's clients.

As a result of another investigation by OIG and DOJ, the Medford School District in Oregon agreed to pay the United States \$830,000 to settle claims that, from January 1998 until December 2001, the school district improperly billed the Medicaid program for school based health services and transportation expenses that were not properly documented, were for services that did not qualify for school-based health services Medicaid reimbursement, or were for services that students did not actually receive.

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 limit (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 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 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.

CMS also has been working with States to stop the inappropriate use of IGTs. CMS should continue to work to ensure that all States eliminate the use of inappropriate IGTs involving supplemental payments made pursuant to UPL regulations, or any other type of Medicaid payment to a provider operated by a unit of government.

In addition, in May 2007, CMS placed 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) on display at the Federal Register (May 29, 2007; 72 Fed.Reg. 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

Medicaid beneficiaries. However, Public Law 110-28 prohibits implementation of the regulation for 1 year following the date of enactment, May 25, 2007.

CMS also is working to finalize regulations to clarify policies regarding reimbursement for school-based transportation services and administrative costs, DSH payments, and targeted case management services.

Management Issue 5: 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. OIG has produced a large body of work related to quality-of-care issues in a variety of settings, such as hospitals, nursing homes, and clinical trials. OIG has also examined a variety of factors that may affect the provision of care, including the impact of reimbursement systems on the provision of care, the effectiveness of oversight and enforcement systems, and the adequacy of mechanisms used to screen potential health care employees. Additionally, OIG partners with DOJ, Medicaid Fraud Control Units, and other State law enforcement offices to investigate and prosecute instances of substandard care that led to patient harm.

To supplement or, when appropriate, substitute for CMS or State enforcement actions, OIG pursues administrative remedies, often in conjunction with civil actions brought by DOJ. The False Claims Act, the Federal Government's primary civil enforcement tool for fraud, has been used successfully to address poor quality of care. These cases often involve allegations of widespread or systemic problems that result in harm to residents of nursing facilities, such as staffing shortages, failure to implement medical orders or services identified on the care plan, failure to ensure that residents are protected from harm, medication errors, and the unnecessary development of facility-acquired medical complications such as infected pressure ulcers. OIG is also developing exclusion actions against individuals and entities whose conduct results in poor care, with particular emphasis on higher level officials of nursing facilities and chains.

To illustrate, Federal prosecutors in Missouri charged American Healthcare Management (AHM), a long-term care facility management company, its Chief Executive Officer, and three nursing homes with criminal conspiracy and health care fraud based on their imposition of budgetary constraints that prevented the facilities from providing adequate care to residents. The investigation found that numerous residents suffered from dehydration and malnutrition, went for extended periods of time without cleaning or bathing, and contracted preventable pressure sores. The corporate defendants were convicted and fined, entered into a False Claims Act settlement requiring them to pay \$1.25 million, and agreed to be excluded from participation in Federal health care programs. The primary owner was convicted of a false statement misdemeanor offense, was sentenced to 2 months' incarceration, and agreed to be excluded for 20 years. Finally, in February 2007, AHM's former CEO was sentenced to 18 months of incarceration and fined \$29,000.

OIG also negotiates quality-of-care CIAs as part of the settlement of such False Claims Act cases. In cases involving poor quality of care, the CIA requires an outside quality-of-care monitor selected by the OIG and includes effective enforcement remedies for breach of the CIA, such as specific performance requirements, stipulated penalties, and exclusion. Over the last 7 years, many major nursing home chains, mid-size corporations, and individual health care facilities have operated under CIAs with independent quality monitors. OIG currently has 10 CIAs with nursing homes and psychiatric facilities (or chains) with independent quality monitor requirements. These 10 active quality-of-care CIAs cover operations in about 400 long-term care and psychiatric facilities across the country. In addition to conducting these ongoing monitoring efforts, OIG is examining the performance of nursing home chains operating under CIAs over the past several years to evaluate the effect of those CIAs on compliance and the quality of care provided by those chains.

OIG continues to have concerns about shortcomings in program oversight and enforcement systems that may result in insufficient identification or prevention of the delivery of substandard care in a variety of health care settings. For example, a 2007 OIG study assessed services provided to beneficiaries with consecutive Medicare stays involving hospitals 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 this study, OIG defined fragmentation as a pattern of unnecessary discharges or transfers across multiple stay sequences

when the same levels and types of services could have been consolidated into fewer stays. Medicare paid an estimated \$4.5 billion for these fragmented or poor quality services. Quality-of-care problems that reviewers found included medical errors, accidents, failure to treat patients in a timely manner, inadequate monitoring and treatment of patients, inadequate care planning, and inappropriate discharges. OIG recommended that CMS direct Quality Improvement Organizations (QIO) to monitor fragmentation and quality of care across consecutive stay sequences and the quality of care provided during the individual stays within those sequences, and encourage both QIOs and fiscal intermediaries to monitor the medical necessity and appropriateness of services provided within these consecutive stay sequences.

In another 2007 report, OIG assessed CMS's oversight of the Medicare hospice program. Currently, hospices are assigned a lower priority for survey and certification inspections than other health care organizations. The report 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. OIG also 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 should seek legislation to establish additional enforcement remedies for poor hospice performance. At present, CMS's only enforcement remedy is termination of a hospice provider from the Medicare program.

In a 2006 report, OIG reviewed the requirements for, and State oversight of, Medicaid personal care service attendants. These attendants assist the elderly and persons with disabilities or temporary or chronic conditions with daily activities (e.g., bathing, dressing, meal preparation). This review found substantial variation, both across States and within States, in the requirements for these attendants and found that oversight and administration of personal care programs were fragmented among different State agencies. OIG concluded that more consistent attendant requirements, less fragmentation in program administration, or some level of standardization within States may make monitoring attendant requirements less cumbersome and enhance quality assurance.

OIG is continuing to evaluate systemic issues that directly affect patient care. For example, studies are currently under way to examine the cyclical noncompliance of home health agencies with conditions of participation, to determine the nature and extent of hospice services provided to beneficiaries residing in nursing homes, to review the oversight of quality of care in Federal health centers, and to assess the impact of Part D on dual-eligible nursing home residents' receipt of prescription drugs. 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:

In response to OIG's recent report related to consecutive inpatient hospital and skilled nursing facility stays, CMS plans to increase monitoring of quality-of-care problems associated with consecutive stays. CMS is also working with the providers to improve care for Medicare beneficiaries regardless of where care is provided. Additionally, CMS is requiring the QIOs to categorize complaints to provide better data on lapses in care continuity with an emphasis on improved documentation.

CMS noted that it has included hospices in the annual State Performance Standards System that measures State performance in survey and certification activities. CMS is also exploring and implementing methods to become more efficient in targeting its resources toward providers most at risk of failing to meet quality of care requirements. Additionally, CMS plans to publish new Conditions of Participation (CoP) for hospices in 2008. The new CoPs will establish a framework for Quality Assessment and Performance Improvement and will amend the hospice section of the "State Operation Manual" to enable State surveyors to make more consistent decisions regarding compliance with Medicare regulations. CMS is also considering whether to pursue establishing new enforcement remedies for poor hospice performance. Finally, CMS indicated that greater inclusion of hospices in the validation surveys must await additional resources.

CMS is also taking steps to improve its enforcement of nursing home quality requirements. Recognizing the need to focus more attention on homes that historically provided poor care to residents, in January 1999, CMS implemented a Special Focus Facility program that involved enhanced monitoring of two nursing homes in each State. In December 2004, CMS revised its Special Focus Facility program to expand the scope of the program from about 100 homes nationwide to about 135 homes. CMS also revised the method for selecting nursing homes by reviewing 3 years' rather than 1 year's worth of deficiency data to better target homes with a history of noncompliance. Additionally, CMS strengthened its enforcement for Special Focus Facilities by requiring immediate sanctions for homes that failed to significantly improve their performance from one survey to the next, and by requiring termination for homes with no significant improvement after three surveys over an 18-month period. In 2004, CMS also established a voluntary program 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 18 States to help them redesign their clinical practices.

Management Issue 6: Public Health Emergency Preparedness and Response

Management Challenge:

Recent events, such as the terrorist attacks of September 11, 2001; the 2005 Gulf Coast hurricanes; and the potential for future public health emergencies, such as the threat of pandemic influenza, continue to underscore the importance of having a comprehensive national public health infrastructure that is prepared to rapidly respond to public health emergencies. OIG work in this area has focused on assessing 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. Recent OIG work has shown that, although some progress had been made, the States and localities are still generally under prepared.

Bioterrorism Preparedness

The security of internal HHS and Department-funded laboratories, including those using select agents, and the security of assets and materials to be used to respond to emergencies continue to be concerns of OIG. In 2002 and 2003, OIG reviewed Departmental and external (non-Federal) laboratories for compliance with laws and regulations governing select agents and found that many laboratories did not adequately safeguard the agents against theft or loss. Soon afterward, when legal requirements for the possession and use of select agents became more strict, OIG initiated audits of non-Federal entities with select agents from November 2003 to November 2004 and found that, contrary to the revised regulations, laboratories had problems with maintaining accurate inventory and access records, controlling access, security planning, and other areas.

In 2006, OIG also completed a number of physical security and environmental control audits of the Strategic National Stockpile managed by the Centers for Disease Control and Prevention (CDC) to provide ready access to drugs and medical supplies during medical emergencies. OIG identified methods to increase the sites' protection against theft, tampering, destruction, or other loss. Additionally, OIG has recently commenced work at Federal laboratories with select agents and begun two related reviews: an audit of select agent transfers and a follow-up audit on CDC's management of the select agent program.

As follow up to earlier work, in December 2006, OIG issued a report that determined that at the close of the CDC Bioterrorism Program in August 2005, about \$996 million, or 15.8 percent, of the program funds awarded to States and major health departments remained unobligated. Many awardees did not fully execute their expenditure plans or submit timely financial status reports, so CDC did not always receive the information needed to encourage the expenditure of funds and minimize unobligated balances. Under its new Public Health Emergency Preparedness Program, which began in August 2005, CDC strengthened its guidance and established additional oversight controls. OIG is currently performing additional reviews of CDC's oversight of Preparedness and Response for Bioterrorism and Public Emergency Program Funds.

Disaster Response

Since 2005, OIG has worked with the President's Council on Integrity and Efficiency (PCIE) Homeland Security Roundtable and Disaster Relief Working Group, as well as with other Federal, State, and local partners, to assess the overall effectiveness of the Department's deployment and recovery activities in

response to Hurricanes Katrina and Rita. As part of a coordinated oversight effort, OIG assessed Departmental procurements and associated management controls, beneficiary protections, and the delivery of critical health care services. In a 2006 report, OIG reviewed the emergency preparedness and response of a selection of nursing homes in five Gulf Coast 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. At the same time, OIG reviewed the U.S. Public Health Service Commissioned Corps response to Hurricanes Katrina and Rita. In this 2007 report, OIG found that although the Corps provided valuable support to the States, more officers were needed. Many of the officers lacked the necessary experience and effective training, and many experienced logistical difficulties in deployment. OIG recommended improved training for officers, a streamlined travel system, and staggered deployments for continuity of operations.

OIG also evaluated the use of Government purchase cards in support of the Department's response operations for the Gulf Coast hurricanes. Based on the findings of this 2007 report, OIG recommended that the Assistant Secretary for Administration and Management (ASAM) provide additional written guidance when cards are issued to employees to reduce the probability of misuse, deliberate or otherwise, and conduct annual training using mock scenarios to improve purchasing approvals. To enhance controls, OIG also recommended that ASAM develop a tracking system to monitor Government card purchases during emergency situations.

Additionally, OIG recently issued several reports on its review of the procurement process for pharmaceuticals and other relief-related products and services associated with the HHS response to the Gulf Coast hurricanes. OIG audited 51 contracting actions and procurements with a total value of \$79.6 million and found that procurement officials generally complied with the Federal Acquisition Regulations in awarding the contracts. OIG is reviewing CDC's Bioterrorism Preparedness Program and the Office of the Assistant Secretary for Preparedness and Response's (ASPR) Hospital Preparedness Program (formerly administered by HRSA) in the Gulf Coast States and will determine whether grantees are spending the funds on costs that are reasonable and allowable under the terms of the grant.

OIG will continue to identify and monitor areas of critical importance to ensure that the Department is ready to respond to future public health emergencies. For example, OIG is working in collaboration with ASPR to develop a cross-disciplinary initiative to build upon OIG's array of emergency preparedness and response work.

Assessment of Progress in Addressing the Challenge:

States and localities are making progress in strengthening their public health emergency preparedness programs. However, OIG findings still demonstrate the need for significant improvements for local health departments to be fully prepared to detect and respond to bioterrorism and, by extension, naturally occurring disasters. Federal, State, and local health departments are striving to work cooperatively to ensure that potential bioterrorist attacks are detected early and responded to appropriately. 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. Both CDC and ASPR have updated their Public Health and Hospital Preparedness Cooperative Agreements to incorporate stronger performance measures and clearer guidance for grant recipients. For example, recent CDC guidance now requires States to establish electronic systems that can effectively detect and report disease outbreaks and other public health emergencies. CDC also plans to implement automated data entry in laboratories, establish 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.

In the aftermath of Hurricanes Katrina and Rita in 2005, the Department placed new emphasis on preparedness outside the realm of terrorism and adopted an "all-hazards" approach to State and local emergency preparedness. This approach incorporates comprehensive preparedness plans that include more definitive and accurate performance measures to prepare stakeholders for a wide array of natural or terrorist threats on multiple scales. The Department will focus more efforts toward monitoring preparedness at the local level, including the testing of local preparedness plans to evaluate how governments perform when plans are put into action. The 2006 Pandemic and All-Hazards Preparedness Act (PAHPA) provides the

Department with additional authority and responsibility to carry out its mission, including the creation of the Office of the Assistant Secretary for Preparedness and Response. The PAHPA, among other things, authorizes the creation of a Biomedical Advanced Research and Development Authority, the transfer of the National Disaster Medical System from the Department of Homeland Security to HHS, and the expansion of the Medical Reserve Corps and other volunteer health professional registries.

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. In response to our 2006 nursing home emergency response and preparedness report, CMS 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. The Office of the Surgeon General, Office of Public Health and Science, is implementing many of OIG's recommendations related to the Commissioned Corps, including identifying, rostering, training, and equipping designated response teams of Commissioned Corps officers. And, in response to OIG's report on the use of purchase cards in responding to the 2005 hurricanes, ASAM has issued revised guidelines to improve the Department's purchase card program.

Management Issue 7: Oversight of Food, Drug, and Medical Device Safety

Management Challenge:

Through the work of FDA, the Department is responsible for ensuring the safety, efficacy, and security of human and veterinary drugs, 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 trials conducted for the products it regulates. Through the work of NIH, the Department is responsible for acquiring knowledge that can help prevent, diagnose, and treat disease and disability. Given these critical public health mandates, NIH and FDA must have in place policies and programs that ensure the integrity of medical research endeavors, protect human research subjects, provide for preapproval and postapproval monitoring of regulated medical products and treatments, and ensure the safety of the nation's food supply.

Over the past decade, numerous OIG evaluations and audits have consistently documented weaknesses in the Department's oversight system for protecting human research subjects in clinical trials associated with NIH grants and those conducted by manufacturers seeking FDA approval for regulated products. In 2007, OIG examined FDA's oversight of clinical trials through its Bioresearch Monitoring (BiMo) program. This work identified vulnerabilities, such as data limitations, that inhibit FDA's ability to effectively manage the BiMo program. OIG also found that FDA inspected only one 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. Looking forward, OIG will follow up on its previous work on protections for human research subjects and oversight of clinical trials. For example, in FY 2008, OIG will evaluate the review process for the Office of Human Research Protection (OHRP), which is charged with oversight of all research involving human subjects that is conducted or funded by the Department. OIG will also evaluate the use of data safety monitoring boards for clinical trials sponsored by NIH.

Recent OIG work has also identified weaknesses in FDA's monitoring of drugs following their approval for marketing. In 2006, OIG examined FDA's monitoring of drug sponsors' postmarketing study commitments and the timeliness with which these studies are 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 recommended that FDA instruct drug applicants to provide additional, 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. In the months following the OIG report, the Institute of Medicine issued a report that highlighted FDA's resource limitations and lack of regulatory authority to enforce required postmarketing studies. The challenge of monitoring a drug's safety after its initial approval has also been highlighted in media accounts and congressional inquiries. For example, Congress recently held

hearings on an approved diabetes drug, Avandia, that was associated with an elevated risk of heart attacks. In FY 2008, OIG will expand its review of FDA's postmarketing efforts to evaluate adverse events reports for medical devices.

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 is currently evaluating FDA's review process for generic drugs.

Since the terrorist attacks of 2001, and emphasized by the recent cases of microbial pathogens found in spinach, tomatoes, and peanut butter and a toxic chemical found in pet food, the security of the Nation's food supply has also been a great concern for the Department, as well as for public health and homeland security experts. OIG is assessing whether food can be traced through the distribution chain and whether food facilities are complying with the new requirements. In FY 2008, OIG also plans to review FDA's food safety operations related to its oversight of imported food products. As part of this study, OIG will review FDA's food facility inspection process, FDA's oversight of imported food, and FDA's procedures and activities related to 2007 recall of tainted pet food.

Assessment of Progress in Addressing the Challenge:

HHS has implemented many changes to protect human research subjects and to strengthen FDA and NIH oversight of scientific research. Within the Office of the Secretary, OHRP coordinates closely with both NIH and FDA in carrying out its responsibility to ensure human subject protections. In June of 2006, FDA announced a Human Subject Protection/Bioresearch Monitoring (HSP/BIMO) initiative and formed a HSP/BIMO permanent council that is responsible for central coordination and human subject protection. FDA also published a proposed rule in July 2004 for the creation of an institutional review board registry. Additionally, in 2006 and 2007, FDA released several draft guidances that addressed various bioresearch-monitoring topics. Finally, 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 electronically manage FDA's regulated product information.

FDA has also contracted with Booz Allen Hamilton to assess the decisionmaking, tracking, and review process behind requests for postmarketing study commitments (PMCs) for human drugs and biologics to develop recommendations for improving the quality of the PMC processes. On September 27, 2007, the Food and Drug Administration 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 post-market 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 post-market safety checks, and 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.

Recent events have demonstrated the critical need to protect the Nation's food supply and have drawn specific attention to the safety and security of imported food. FDA is now implementing provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which requires, among other things, all parties within the food distribution chain to establish and maintain records that identify sources and recipients of food products, allows for the detention of food under certain circumstances, requires food facility registration, and requires that the FDA receive prior notice of food imported into the United States. In 2007, FDA announced the creation of a new position, Assistant Commissioner for Food Protection.

Management Issue 8: Grants Management

Management Challenge:

The Department's 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 2008, the Department expects to issue grants totaling \$270 billion (\$38 billion discretionary and \$232 billion mandatory). Medicaid, which constitutes the largest portion of mandatory grants (\$204 billion in grants expected in FY 2008), is discussed under Issues 3, 4, and 5, where its program vulnerabilities are identified.

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 in 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 DOJ and several major universities.

To ensure the integrity of HHS's 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 continues to direct particular attention to vulnerabilities associated with expanded grant programs, newly funded initiatives, and first-time Federal grantees.

Discretionary Grants

Inadequate grant oversight and monitoring continues to be a concern of OIG. In 2007, OIG issued two reports on HRSA's distribution and use of Ryan White Comprehensive AIDS Resources Emergency (CARE) Act funding to grantees. Contrary to the CARE Act, HRSA did not recoup certain unobligated funds from States and reallocate them. HRSA also authorized States to carry over unobligated funds beyond one budget period and did not use its offset authority as provided by the Act. OIG has initiated a nationwide review of CARE Act AIDS Drugs Assistance Program funds. The review will examine compliance with the payer of last resort provision which requires that grant funds be used for payment only after reimbursement has been obtained from other Federal, State, or private sources.

In 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 Status 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.

HHS agencies have historically had 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 2005 and 2006, OIG completed two related reviews examining HRSA's 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. As of FY 2007, the HHS Office of Grants suspended the use of Department Alert List, pending a major redesign to increase internal control over its usage and to better support post-award monitoring and oversight.

Even when grantees are providing the intended services, they may not comply with all programmatic or financial requirements. 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 that certain aspects of grantee or subrecipient 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.

At NIH and university grantee sites, OIG has several additional ongoing initiatives aimed at evaluating the allowability of costs charged to NIH grants, focusing primarily on administrative and clerical costs charged to NIH grants. OIG also plans to evaluate the extent to which the National Cancer Institute (NCI) monitors its research project grants. This work will focus primarily on the extent to which NCI evaluates required reports, initiates actions in response to these evaluations, and ensures grantee responsiveness to action requests to comply with regulatory requirements and grant terms and conditions.

Mandatory Grants

Since 2002, OIG has performed reviews in 13 States that have focused on the appropriateness of Federal reimbursement related to Foster Care and Adoption Assistance training and administrative costs and maintenance claims. These reviews identified approximately \$58 million in unallowable, improperly allocated, and unsupported costs. During FY 2007, OIG performed reviews in three States to identify erroneous payments in the Administration for Children and Families (ACF) Temporary Assistance for Needy Families (TANF) program, which had a FY 2006 funding level of \$17.2 billion. Preliminary results in these three States have identified substantial improper payments. In addition, during FY 2008, OIG will perform an eight-State review to develop a nationwide improper payment rate for the TANF program.

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 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 subgrantees' program performance and require fiscal accountability through the life of the grants. A critical part of this streamlining process involves the consistent use of departmentwide grants management policies. Over the next fiscal year, OIG will continue to address departmentwide 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, in FY 2007 the Office of Grants suspended the alert listing it maintained pending a major redesign to increase internal control over its usage. This management decision was based in large part on critical concerns documented by OIG. AHRQ indicated that the recommendations in OIG's 2006 review of patient safety grants reinforce ongoing improvements begun subsequent to the years that we reviewed or support ongoing improvement activities. And, in response to recent OIG reviews of the TANF program, ACF indicated that it plans to use the findings and recommendations from OIG's review to provide technical assistance to the State grantees.

Management Issue 9: Integrity of Information Technology Systems and Infrastructure

Management Challenge:

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 (National Coordinator) and outlined incentives for the use of health information technology

(health IT). According to the order, “[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 health information technology in both the public and private health care sectors that will reduce medical errors, improve quality, and produce greater value for health care expenditures.” The Secretary established for the National Coordinator the Office of the National Coordinator for Health Information Technology (ONC).

In a 2007 report on State Medicaid agencies’ initiatives on health IT and health information exchange (HIE), OIG found that almost a quarter of State Medicaid agencies have implemented health IT initiatives, and over three quarters of States are developing similar health IT initiatives. Additionally, a number of Medicaid agencies are involved in the planning of statewide HIE networks and are incorporating the Medicaid Information Technology Architecture (MITA) into their health IT and HIE planning. Based on these findings, OIG recommended that CMS continue to support the goals of MITA to help facilitate future State Medicaid health IT and HIE initiatives. OIG also recommended that CMS, in collaboration with other Federal agencies and offices, assist State Medicaid agencies with developing privacy and security policies as well as continue to work with ONC to ensure that State Medicaid initiatives are consistent with national goals.

Additionally, there remains a need to ensure adherence to general controls. OIG’s work indicates that the Medicare payment errors are due more often to the input by people of incorrect information than due to computer system or programming errors. For example, 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. Clearly this represents a challenge to implement controls that ensure progressive improvement with respect to data integrity.

The recent expansion of HHS programs, such as the new Medicare Part D benefit, significantly increases the programmatic and system demands on the Department and creates new relationships or expands existing relationships with business partners. In turn, these new or expanded relationships create the potential for new system security exposures that have to be evaluated and, if need be, mitigated to ensure the confidentiality, integrity, and availability of critical assets. As part of the HHS responsibility to protect critical data assets and to protect the privacy of medical records, the Department oversees and endorses the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules, which identify privacy standards for certain individually identifiable health information and specify a series of administrative, technical, and physical security procedures for covered entities to use to ensure the confidentiality of electronic protected health information. The security standards are delineated into either required or addressable implementation specifications.

The development and expansion of Department IT systems 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 serious loss of data by Federal agencies. OMB has recently reemphasized Federal agency responsibilities under the law and policies to appropriately safeguard sensitive, personally identifiable information and train Federal employees regarding their responsibilities in this area. 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 already established process.

OIG has also identified that the human factor is a critical component of an effective security program and may be 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.

Therefore, 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 that store that information, and the physical or electronic transport of that 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 for numerous vital programs on which critical systems depend for the accurate payment of billions of dollars through the Department’s many programs. OIG will also review CMS’s activities related to the enforcement of the HIPAA Security

Rule. The review will focus on an internal control assessment at CMS headquarters as well as include vulnerability assessments at a sample of covered entities.

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.

Additionally, as part of its efforts to encourage the development and use of health IT, on August 8, 2006, the Department issued final regulations that establish new exceptions (71 FR 45140) under the physician self-referral law and new safe harbors (71 FR 45110) 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 electronic 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 records (EHR) software, IT, and training services necessary and used predominantly for EHRs.

Management Issue 10: Ethics Program Oversight and Enforcement

Management Challenge:

OIG has historically been involved in oversight and enforcement 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. In the past, OIG oversight has primarily focused on ethical issues related to scientific research and grants management. OIG's efforts related to ethics issues have steadily increased as a result of congressional hearings, Government Accountability Office (GAO) reviews, press reports, and investigative activity. Since 2005, ethics program oversight has been acknowledged within the Department's top management challenges in the context of both grants management and research and regulatory oversight management challenges.

Congress established OGE 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 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 (DECs) to serve as ethics advisers in the OPDIVs and Staff Divisions. 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 conflicts-of-interest statute, 18 U.S.C. § 208, prohibits employees from participating in official matters where they and certain others (such as spouses) have a financial interest.

Although the DAEO is responsible for administering the Department's ethics program, OIG is responsible for enforcement of the criminal ethics statutes. Within OIG, the Special Investigations Unit (SIU) 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 or supervisors to report nonfrivolous allegations of

“criminal offenses” (including conflict of interest) to OIG. Allegations of improper conduct with no criminal potential may be handled by agency management through administrative remedies.

Oversight

In late 2003, widespread press reports described apparent improprieties in the private consulting activities of some scientists at the National Institutes of Health (NIH). OIG undertook a study of the NIH outside activity process, culminating in a July 2005 report. This evaluation reviewed all outside activity requests for senior-level employees at NIH between January 1, 2001, and December 31, 2003. OIG identified several vulnerabilities that inhibited NIH’s ability to effectively review outside activities. For example, some approved outside activities were not disclosed on the annual financial disclosure forms as required of senior employees by regulation, and frequently the approved outside activities did not have complete documentation or supervisory signatures confirming approval of the requests. In addition, there were several problems with the review process itself, such as approvals after the start date, limited use of written recusals, and inadequate followup regarding ongoing outside activities. To address these vulnerabilities, OIG recommended that NIH improve the quality and extent of information it receives for outside activity requests and address inadequacies in the review process for outside activities.

OIG also undertook a study of possible conflict-of-interest actions by employees of the Food and Drug Administration (FDA). Released in February 2006, this report identified a variety of vulnerabilities in the FDA process for review and approval of outside activities between CYs 2000 and 2003. Most of these outside activities involved teaching, lecturing, speechwriting, and presenting. OIG found that FDA employees submitted limited information regarding outside activities. OIG also identified 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 extent of information it receives from its employees for outside activities and address inadequacies in the review process for outside activities.

In addition, in late 2006, OIG issued a memorandum to the HHS General Counsel outlining vulnerabilities in the Department’s issuance of conflict-of-interest waivers. These vulnerabilities were identified through an inquiry conducted by OIG regarding a conflict-of-interest waiver granted to a former Administrator of CMS. OIG identified four vulnerabilities. These included use of boilerplate language, insufficient oversight processes, absence of time limits on waivers, and lack of monitoring mechanisms. OIG provided four recommendations to eliminate the vulnerabilities. First, waivers should be improved by a more detailed discussion of the individual circumstances of the requester. Second, the Department should adopt additional safeguards for the issuance of waivers which might include a policy requiring consultation with OGE on the issuance of ethics waivers covering negotiations for future employment. Third, appropriate time limits should be incorporated into the waivers. And fourth, the Department should monitor the continued appropriateness of such waivers by requiring employees who have received waivers to report periodically on the status of their employment negotiations.

OIG’s ongoing work at selected OPDIVs reflects continued attention to ensuring effectiveness in the administration of the Department’s ethics program. In a review similar to the NIH and FDA outside activity reviews, OIG will examine the procedures used by CDC officials to review possible conflicts of interest related to certain categories of employees. Compliance with the ethics statutes and standards of ethical conduct is of particular concern with CDC employees because their research results and regulatory decisions affect the Nation’s public health security.

Additionally, in an April 2007 report, GAO concluded that the lack of clear recusal policies for senior employees at NIH is a vulnerability in NIH’s conflict-of-interest policies. GAO recommended that NIH expeditiously clarify its policies with regard to written recusals and supervisory notification related to senior employees’ use of recusal to resolve conflicts of interest. Despite changes in the operation of the NIH ethics program, the program remains decentralized and comprised of various offices. OIG is conducting a review of how these various NIH offices interact and manage allegations of employee conflicts of interest.

Although intramural research undertaken within the Department is vital and therefore the professional ethics of agency employees is of paramount concern, the bulk of the Department’s research funding goes to the private sector, primarily to research universities that undertake work pursuant to contracts and grants. As a

result, administration of the Department's ethics program also encompasses potential conflicts of interest relating to members of advisory panels and grantees. For this reason, OIG is reviewing NIH monitoring of extramural conflicts of interest. This review will identify the number and nature of financial conflicts of interest that are reported by grantee institutions to NIH and determine the extent to which NIH oversees grantee institutions' financial conflicts of interest. In addition, OIG will be initiating an assessment of the nature of financial interests disclosed by clinical investigators to FDA; the extent to which drug, biologic, and device applicants monitor their clinical investigators for conflicting financial interests; and the extent to which FDA monitors the financial interests disclosed by clinical investigators.

OIG's work also reflects congressional concern and related mandates associated with identification of conflicts of interest associated with experts and consultants at NIH and advisory committees and panels at FDA. Under the recent reauthorization of NIH (H.R. 6164, Public Law 109-482), the Director of NIH is required to submit annual reports to the Inspector General of HHS, the Secretary, and relevant congressional committees. The report must identify the number of experts and consultants whose services were obtained by NIH or its agencies and describe the qualifications of and the need for hiring such experts and consultants. The report will also include the income, gifts, assets and liabilities disclosed to NIH. Similar to the NIH reporting requirement, FDA is also required (H.R. 2744, section 795(c), Public Law 109-97) to submit a quarterly report to OIG and relevant congressional committees on the efforts made to identify qualified persons with minimal or no potential conflicts of interest for appointment to an advisory committee or panel of the FDA.

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. The caseload of the OIG SIU continues to increase, with the number of cases involving potential conflict of interest under investigation by this unit tripling between 2005 and 2006. As a recent example, an SIU investigation focused on the 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. He entered guilty pleas to two criminal charges for false writings and conflict of interest and was fined approximately \$90,000, received 3 years of supervised probation, and was ordered to perform 50 hours of community service. 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. A third example is the SIU review of NIH's handling of 103 cases that potentially revealed conflicts of interest by NIH employees identified in the files of the NIH Office of Management Assessment (OMA). The SIU and OIG ethics attorneys examined these 103 cases and have made determinations regarding those cases in which additional investigation is warranted. In order to improve the efficiency of the referral process, the SIU created a new, comprehensive form for the DAEO and the DEC's to use to refer conflict of interest cases to OIG for investigation.

In May 2007, OIG hosted a 1-day Conflict of Interest and Ethics Summit and invited HHS ethics officials as well as officials from all other Federal Departments and agencies. Attended by approximately 200 Federal officials, the goal of the Summit was to establish an ongoing dialogue between the oversight, enforcement, and ethics policy communities regarding ethics and conflict-of-interest issues. OGE plans to incorporate many of the themes raised at the Summit as it develops best practices as part of an ongoing Leadership Initiative.

Assessment of Progress in Addressing the Challenge:

Actions have been taken to address ethics issues identified by OIG. While the OIG study of outside activities at NIH was progressing, other reviews were being conducted by OGE and the Secretary's Office. NIH itself convened a Blue Ribbon Panel appointed by the NIH Director. The heightened focus on ethics in the Department brought about significant changes. The Department's Supplemental Standards of Ethical Conduct were revised in 2005, adding prohibitions on outside activities and financial holdings for certain employees at NIH. The revised Supplemental Standards also imposed a more detailed process for reviewing outside activity requests departmentwide.

Additionally, the staff of the DAEO, housed in the OGC Ethics Division, was expanded, nearly tripling its size. The Division has been organized into separate branches to reflect the specialized work performed. One branch handles ethics advisory services, with a specific attorney assigned to provide assistance to each operating and staff division of the Department, and also has a separate section responsible for financial disclosure matters. Another branch is responsible for developing and providing ethics training, as well as conducting reviews of the ethics programs of the various operating and staff divisions of the Department.

In March 2007, FDA posted procedures on the FDA web site for the completion and review of outside activity forms (Form 520) at FDA. FDA prepared two documents: (1) a guide on how to complete the Form 520 (useful to employees), and (2) a guide on how to review the Form 520 (useful to ethics reviewers).

The DAEO is also taking steps to tighten up the waiver process. The DAEO recently issued guidance to all DEC's reminding them of their responsibility to (1) send copies of all 18 U.S.C. § 208(b)(1) and (b)(3) waivers granted to Department employees to the DAEO, 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 and when granting 18 U.S.C. § 208 (b)(3) waivers if there are unique fact patterns, special circumstances, or unusual situations.

In addition, ethics staff in the DAEO's office are reaching out on a monthly basis to ethics contacts for each OPDIV and Staff Division to inquire about the operation of the divisions' ethics programs, including the review of waivers. The DAEO is also planning to issue a package with waiver guidance and information regarding which officials in the Department have the delegated authority to issue waivers.