Appendix 5: Department Management Challenges and High-Risk Areas

The breadth of essential human services the Department delivers to fulfill the President's vision of a healthier, safer, and more hopeful America bring a number of management challenges. Management challenges identified by the Office of Inspector General (OIG) and its assessment of progress in addressing these challenges are described below. This information is from the OIG's Top Management Challenges, originally published on November 15, 2007 in Section III of the HHS FY 2007 Agency Financial Report, available online at www.hhs.gov/afr/information/challenges/index.html. To ensure good stewardship of taxpayer resources, the Department is committed to efforts to make improvements related to these challenges. In recent years, HHS has made significant strides in improving the lives of Americans. This has been accomplished through the efforts of every HHS component. While HHS has made great progress, it must continue its current efforts to sustain positive outcomes and augment them with new, innovative strategies to continue to improve the Nation's health and well-being.

Management Issue 1: Oversight of Medicare Part D
Management Challenge: The administration of Part D is dependent upon extensive coordination and information sharing among Federal and State Government agencies, drug plan sponsors, contractors, health care providers, and third party payers. CMS and drug plan sponsors share responsibility for protecting the Part D program from fraud, waste, and abuse. Payments to drug plan sponsors based on bids, risk adjustments, and reconciliations add to the complexities and challenges of the benefit. Preliminary estimates indicated that Part D sponsors owed Medicare more than $4 billion for plan year 2006, with 80 percent of sponsors owing money to Medicare. OIG also determined that CMS's safeguard activities needed further development and application.

Assessment of Progress: CMS has demonstrated progress in protecting Medicare Part D from fraud and abuse, but further implementation of safeguards is needed. CMS has noted several advances made in 2007 including progress towards commencing financial audits, commencement of routine Prescription Drug Plan (PDP) compliance audits, improvement in processing complaints timely, and updates to the Prescription Drug Benefit manual. CMS is also planning or implementing additional safeguard activities, including data monitoring, monitoring of compliance of drug plan sponsors, and education and guidance. Finally, CMS indicated that it anticipates that the variance between prospective and reconciled payments will decrease over time as program data becomes available to CMS and drug plan sponsors.

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. To ensure both the solvency of the Trust Fund and beneficiaries' continued access to quality services, correct and appropriate payments must be made for properly rendered services. OIG audits continue to show that Medicare has serious internal control weaknesses in its financial systems and processes. Further audits and evaluations by OIG also continue to identify significant improper payments and problems in specific parts of the program, such as durable medical equipment.

Assessment of Progress: The FY 2006 gross paid claims error rate of 4.4 percent reported by CMS is 0.8 percentage points lower than the FY 2005 error rate. CMS has demonstrated continued vigilance in monitoring the error rate and is developing appropriate corrective action plans. CMS has made some progress in its general and application controls, such as access controls, application software development controls, and program change controls and has begun implementing the Healthcare Integrated General Ledger Accounting System (HIGLAS), but the 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 potential improper payment exposure for durable medical equipment, HHS announced a 2-year effort aimed at stopping fraudulent billing to the Medicare program and protecting beneficiaries and taxpayers.

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. 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. 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 addition, OIG has identified vulnerabilities in particular program areas such as prescription drugs. CMS estimates that Medicaid expenditures for prescription drugs in 2006 totaled more than $28 billion. OIG has consistently recommended that Medicaid programs reimburse pharmacies for drugs based on prices that more accurately reflect pharmacies' acquisition costs. OIG has also raised concerns that State Medicaid programs may not be receiving the proper amount of drug rebates that they are entitled to receive from drug manufacturers.

Assessment of Progress: *Payment Error Rates*: HHS' FY 2007 Performance and Accountability Report includes 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.

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. 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 Federal upper limits outlier and average manufacturer price sections of the rule.

Management Issue 4: Medicaid Administration

Management Challenge: Over the past 6 years, OIG's work has identified significant problems in State Medicaid financing arrangements involving the use of intergovernmental transfers (IGT). Once payments are returned to State governments through IGTs, 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. OIG has identified serious problems with IGTs in Medicaid supplemental payments to public hospitals and long term care facilities available under the upper payment limit (UPL) rules. Additionally, OIG has identified significant Federal overpayments involving school-based health services, disproportionate share hospital payments (DSH), and targeted case management services.

Assessment of Progress: To curb abuses in State Medicaid financing arrangements, CMS promulgated final regulations (effective March 13 and November 5, 2001, and May 14, 2002) that modified UPL regulations pursuant to the Benefits Improvement and Protection Act of 2000. CMS also has been working with States to stop the inappropriate use of IGTs. In addition, on May 29, 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. CMS also is developing 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 is a high priority of OIG. OIG has raised a number of concerns about shortcomings in program oversight and enforcement systems that may result in inadequate prevention or insufficient identification of the delivery of substandard care in a variety of health care settings. Some of these concerns include vulnerabilities associated with fragmentation of care, Quality Improvement Organization (QIO) monitoring, and hospice oversight.

Assessment of Progress: CMS plans to increase monitoring of quality-of-care problems associated with consecutive stays and is working with providers to improve care for Medicare beneficiaries regardless of where care is provided. CMS is also requiring the QIO to categorize complaints to better provided data on lapses in care continuity with emphasis on improved documentation. Additionally, CMS has included hospices in the annual State Performance Standards System that measures State performance in survey and certification activities.

Management Issue 6: Public Health Emergency Preparedness and Response
Management Challenge: 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. Recent OIG work has shown that, although some progress had been made, the States and localities are still generally under prepared.

Assessment of Progress: States and localities are making progress in strengthening their bioterrorism preparedness programs. Federal, State, and local health departments are striving to work cooperatively to ensure that potential bioterrorist attacks are detected early and responded to appropriately. 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. 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. 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. Additionally, 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.

Management Issue 7: Oversight of Food, Drug, and Medical Device Safety
Management Challenge: Given their critical public health oversight 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 pre-approval and post-approval monitoring of regulated medical products and treatments, and ensure the safety of the nation's food supply. OIG audits and evaluations 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. Recent work has also identified weaknesses in FDA's monitoring of drugs following their approval for marketing. Recent food contamination incidents have highlighted the importance ensuring the safety of our nation's food supply.

Assessment of Progress: HHS has implemented many changes to protect human research subjects and to strengthen FDA and NIH oversight of scientific research. In June of 2006, FDA announced a Human Subject Protection/Bioresearch Monitoring initiative, published a proposed rule for the creation of an institutional review board registry, released several draft guidance documents that addressed various bioresearch monitoring topics, and is developing an internal listing of all ongoing clinical trials. FDA has

also contracted a study to assess and provide recommendations concerning quality improvements to the post-marketing study commitments process. Additionally, FDA is implementing provisions of the Public Health Security and Bioterrorism Response Act of 2002, related to the processing and distribution of food products.

Management Issue 8: Grants Management
Management Challenge: In FY 2008, the Department expects to issue grants totaling $270 billion ($38 billion discretionary and $232 billion mandatory). 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. Inadequate grant oversight and monitoring continues to be a concern of OIG.

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

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. 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. 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.

Assessment of Progress: 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.

Management Issue 10: Ethics Program Oversight and Enforcement
Management Challenge: In recent years, OIG has devoted considerable efforts to ensuring the effectiveness in the administration of the Department's ethics program and to investigations related to violations of the criminal ethics statute. Pursuant to regulations issued by the Office of Government Ethics, the Secretary has delegated responsibility for the day-to-day administration of the ethics program to the Designated Ethics Official (DAEO). OIG has identified vulnerabilities in NIH and FDA's processes for review and approval of outside activities and in the Department's issuance of conflict-of-interest waivers, and continues to be concerned about potential conflicts of interest relating to members of scientific advisory panels and grantees of research funding.

Assessment of Progress: The heightened focus on ethics in the Department has brought about significant changes. NIH convened a Blue Ribbon Panel appointed by the NIH Director. 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 standards also imposed a more detailed process for reviewing outside activity requests department-wide. The staff of the DAEO, housed in the OGC Ethics Division, was expanded and ethics staff are reaching out on a monthly basis to ethics contacts for each OPDIV and Staff Division. The DAEO is also taking steps to tighten up the waiver process.